National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Horizon scan of medical technologies

Technologies with an expected impact on the organisation and expenditure of healthcare

RIVM Letter report 2018-0064
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Synopsis

Horizon scan of medical technologies
Technologies with an expected impact on the organisation and expenditure of healthcare

Medical technology is developing rapidly. Promising new technologies could offer benefits for the quality and organisation of healthcare. However, in practice innovations do not always fully match with medical and societal needs. Healthcare professionals, patients, health insurers, industry and the authorities all agree it is important to improve this. To achieve this, it is important that relevant stakeholders start to join forces already in early stages of development. This is a message from a 'horizon scan' of medical technologies performed by the RIVM at the request of the Dutch Ministry of Health, Welfare and Sports.

The 'horizon scan' identifies technologies with a potentially major impact on the society. eHealth, robotics to support care for the elderly, and the 3D printing of for example implants or of organ models to be used for the preparation of surgery, may offer major potential benefits. These technologies are expected to affect the organisation and costs of care, either in a positive or negative sense. The precise impact of these technologies is difficult to predict.

Other technologies may also have major impact. Nanotechnology, for example, is considered a technology that enables other innovative developments, such as early diagnosis and treatment of cancer; personalised medicine (customized care) as a development that is enabled by promising medical technologies. In addition, non-medical technologies such as 'big data' and artificial intelligence can have major impact on healthcare.

Bringing together stakeholders is the first, important, step to better connect technological possibilities with medical and societal needs. This may provide direction to developers of technology. It can also help healthcare organisations to take full advantage of promising medical technology.

Keywords: medical technology, horizon scan, medical needs, societal needs, healthcare expenditure, organisation of healthcare

Publiekssamenvatting

Horizonscan van medische technologieën
Technologieën met verwachte impact op de organisatie en kosten van de zorg

Medische technologie ontwikkelt zich snel. Nieuwe, veelbelovende technologieën kunnen kansen bieden voor een betere kwaliteit en efficiëntere organisatie van zorg. Innovaties sluiten echter niet altijd volledig aan bij medische en maatschappelijke behoeften of worden nog niet optimaal benut. Professionals in de gezondheidszorg, patiënten, zorgverzekeraars, industrie en de overheid vinden het belangrijk dat dit verbetert. Om dit te realiseren is het van belang dat relevante stakeholders al in een vroeg stadium van ontwikkeling samen optrekken. Dit blijkt uit een 'horizonscan' van medische technologieën, die het RIVM uitvoerde in opdracht van het ministerie van VWS.

In de 'horizonscan' zijn technologieën beschreven die een grote impact op de samenleving kunnen hebben. e-Health, robots om de ouderenzorg te ondersteunen, en het 3D-printen van bijvoorbeeld implantaten of modellen van organen waarmee operaties kunnen worden voorbereid, bieden grote mogelijkheden. Naar verwachting kunnen deze technologieën de organisatie van de zorg en de kosten van de zorg beïnvloeden, zowel positief als negatief. De precieze impact van deze technologieën is moeilijk te voorspellen.
Ook andere technologieën hebben mogelijk grote impact. Zo wordt nanotechnologie beschouwd als een technologie die de mogelijkheden vergroot voor andere innovatieve ontwikkelingen, bijvoorbeeld voor vroege diagnose en behandeling van kanker; *personalised medicine* (zorg op maat) als een ontwikkeling die mede mogelijk wordt gemaakt door veelbelovende medische technologieën. Daarnaast zijn er niet-medische technologieën die grote impact kunnen hebben op de gezondheidszorg. Voorbeelden hiervan zijn 'big data' en kunstmatige intelligentie.
Het samenbrengen van stakeholders is de eerste, belangrijke stap om de technologische mogelijkheden en de medische en maatschappelijke behoeften beter op elkaar te laten aansluiten. Dit kan richting geven aan de ontwikkelaars van technologie. Ook kan het organisaties in de gezondheidszorg helpen om veelbelovende medische technologie optimaal te benutten.

Kernwoorden: medische technologie, horizonscan, medische behoeften, maatschappelijke behoeften, zorguitgaven, organisatie van de zorg

Contents

Summary

Introduction, aim and scope

People's medical needs and societal needs are continually changing. Apart from the changes in the future healthcare demand, the market for technological innovations in healthcare is evolving rapidly. In response to the aging population, population growth and increasing costs of medical treatment, healthcare expenditure will inevitably rise in the near future. The increased use of and developments in technology in healthcare could offer many potential benefits for patients, healthcare professionals and the technology industry. However, as well as potential benefits, there are potential downsides and challenges to the increasing use of technology in healthcare.

Based on the expected future healthcare demand, this study aimed to identify the medical technologies expected to emerge in the next 5 to 10 years that could best meet the medical or societal needs of the future. The investigation resulted in a horizon scan of the medical technologies with a potentially major impact on the organisation of healthcare, or on healthcare expenditure. The data collection consisted of a literature study of both international scientific and grey literature. In addition, opinion leaders and experts in the field of medical technology were interviewed, each viewing the issue from a different perspective, including those of academia, the healthcare sector, industry, health insurance and patients' organisations.

Results

The types of impact that were defined as relevant to the selection of medical technology for this horizon scan were the following:

- fulfilling (unmet) medical needs or societal needs;
- impact on the organisation of healthcare;
- budgetary impact;
- Potential for substitution of existing methods;
- impact for a large magnitude of the patient population;
- impact for individual patients.

An analysis of the mechanisms by which medical technologies in general may affect healthcare expenditure was carried out and included as a separate section in the report. From an initial list of emerging medical technologies, three technologies were selected for more elaborate analysis, based on discussions within the research team about their expected impact, fueled by literature and interviews: (1) eHealth, (2) robotics and (3) 3D printing. Other medical technologies with a potentially major impact are described in less detail. These include tissue engineering and regenerative medicine, focusing on the use of biodegradable materials and materials-driven regeneration in accordance with the intended scope of the study: to cover products covered by the medical devices regulations. New *in vitro* diagnostic (IVD) technologies identified in the investigation were liquid biopsy, next-generation sequencing, point-of-care diagnostics and synthetic biology. Nanotechnology was also described, as an enabling technology for many innovative devices, and personalised medicine as a development in healthcare being enabled by

emerging medical technologies. Finally, a number of technologies beyond the scope of the study were mentioned, on the basis that several opinion leaders believed these technologies to have an even greater potential impact on healthcare than those that are within the scope of the study: data-driven technology, big data, interoperability, artificial intelligence and blockchain.

Medical technology and healthcare expenditure
Technology is believed to be a major force behind increasing healthcare expenditure. A precise analysis of the effect of specific medical technology on healthcare expenditure is difficult because specific data on the use and costs of medical devices are lacking, especially with regard to medical equipment and devices used in hospitals. Moreover, in health economics the term 'technology' refers to a loose conglomerate comprised of medical devices, new diagnostic methods, treatment innovations and medicinal products. A number of factors contribute to the effect of medical technology on healthcare expenditure. First, new technology usually leads to a temporary rise in costs because it is usually more expensive than the old technology it is supposed to replace or complement. Second, new technology often creates new demand, resulting in rising healthcare expenditure – and the risk of excessive use of technology: 'technology creep'. Third, the benefits of new medical technology often end up outside the healthcare domain.

Similarly, the question whether or not technology can help to contain rising healthcare expenditure is difficult to answer for a number of reasons. Most new technologies enter the healthcare system as an addition to what is already available, which increases costs. Still, single technologies can also result in cost decreases. The highest potential for cost reduction through technology lies outside the field of medical devices. Technology that plays an important role in streamlining processes in healthcare, for example by increasing the efficiency and speed of information exchange between health professionals has a high potential for cost reduction. Furthermore, positive effects in other domains than healthcare, e.g. increased labour participation are usually not incorporated in evaluative studies.

Drivers that are deemed important in the assessment of the effect of a specific technology on healthcare expenditure include autonomous drivers (e.g. demography), technology-related drivers (e.g. implementation), and social and political drivers (e.g. technology creep).

eHealth
In essence, eHealth is the use of modern information and communication technologies – internet technology in particular – to support or improve health and healthcare. The generation, interchange and use of digital data are suggested to be the key elements of eHealth developments in the upcoming years. The pace of development and the implementation of new eHealth applications, however, differ per healthcare setting and disease area. Interviewees pointed at increased self-management as a major potential benefit of eHealth, but it was emphasised that the adoption of eHealth by healthcare professionals is slow. Risks mentioned by the interviewees include increased medicalisation, overtreatment, and the overestimation of eHealth

effects. The lack of compatibility and interoperability between the ICT systems needed to harvest the benefits of eHealth is also a well-known area of concern. From the interview results and information available in the literature, the impact of eHealth is expected to arise in three of the key areas identified:

- impact on organisation of healthcare;
- fulfilling (unmet) medical or societal needs;
- impact for individual patients.

eHealth has the potential to improve the quality and effectiveness of care and to reduce expenditure, but it is still difficult to assess the added value of eHealth in healthcare. The budgetary impact of eHealth applications will depend on the type of intervention (add-on or substitution), their costs in relation to the total healthcare expenditure for a disease, and their effectiveness compared with standard care. It is therefore difficult to predict any budgetary impact for this technology as a whole.

Robotics

For the purpose of this report a robot was defined as a device that has the following characteristics: (a) sensors to receive information about the environment and/or instructions from a human, and (b) algorithms to make decisions based on the information received from the sensors, and (c) motors/actuators to generate mechanical movement, and/or devices to make sounds and/or display images. On the basis of their function it is possible to categorize robots into four main groups: social robots, service robots, surgical robots and exoskeletons – each having different potential benefits, presenting different risks, being faced with different barriers to adoption, and having different levels of impact on healthcare effectiveness. Apart from increasing the quality of life of patients/clients, social robots may help to alleviate the shortage of caregivers (nurses) by saving time expended on peripheral duties, such as calming older patients.

The potential of the three other types of robot is less obvious. Service robots may be a tool to help patients with self-management at home. However, it will probably be a long time before robots capable of multiple physical activities become available. In the case of surgical robots, developments will continue, but breakthrough advances (compared with existing technology) are not expected in the near future. Exoskeletons are at too early a stage of development for their potential to be assessed. With regard to risks and barriers to adoption, a general risk with robots is related to cybersecurity, since many robots are connected to the internet. There may also be legal, financial and ethical issues that could hinder the deployment of robots in healthcare.

According to interviewees, the number of social and service robots that are currently used in healthcare is very small, but it may increase in the future. How this may affect the organisation of healthcare is, however, still difficult to say. This will depend on the future developments of such robots and on how they are implemented. In line with the trend in general surgery towards less invasive procedures, the use of and demand for surgical robots is increasing and new technologies are increasingly implemented to improve on existing systems.

The possible budgetary impact of robotics on healthcare is hard to assess, mainly due to the lack of data and economic studies. In the case of service robots and exoskeletons, this is likely due to the fact that many of these are as yet only prototypes. Their penetration in healthcare is still very limited. Small-scale studies on social robots have been carried out, but their potential added value is not yet clear; nor is their potential for cost saving. In the case of surgical robots, most studies conclude that the clinical outcomes of robot-assisted surgery are comparable to conventional procedures, but robots are considerably more expensive. With several companies currently developing robots, however, competition may reduce costs. Looking at the broader impact, only marginal benefits in terms of reducing the use of primary care and the number of hospital days have been reported, but it has been suggested that robots could have beneficial effects with regard to the wellbeing and efficiency of surgeons.

3D printing
3D printing is a manufacturing method that creates a three-dimensional object by building successive layers of raw material. Each new layer is attached to the previous one until the object is complete. Objects are produced from a digital file. Dentistry, orthopaedics, cardiology and cardiothoracic surgery are disciplines well known to use 3D-printing applications, but maxillofacial surgery, neurosurgery oncology and other disciplines are also using them.
According to the interviewees, and as confirmed in scientific reviews, the most important types of applications are:

- surgical planning by creating a 3D model that can be studied before a surgical procedure, e.g. in paediatric cardiology;
- surgical planning resulting in the design and 3D printing of surgical guides, e.g. in orthopaedic surgery;
- production of personalised implants in relatively large numbers, e.g. dental crowns/implants;
- production of personalised implants for individual patients, e.g. hip implants;
- production of personalised external support devices, e.g. braces for hands, feet, spine (scoliosis patients).

In general, interviewees expect that as the technology will be further developed, more application areas will make use of it, and costs will decrease. However, 3D printing is currently only feasible and/or affordable in certain specialised applications. Existing barriers to widespread application include the cost of materials, software and personnel; and the difficulty of gathering clinical evidence on the performance of 3D-printed devices due to the small amount of available data and the long follow-up needed for particular applications, such as joint implants. Potential risks of the use of 3D-printing applications are related to quality control of raw materials, the printer and the production process, including correct functioning of the various software applications. The potential impact of 3D printing on healthcare largely depends on how the technology develops and on how implementation takes place.

As is the case with eHealth and robotics, the impact of 3D printing on the healthcare budget is difficult to predict, but expectations are high.

3D printing is still a relatively expensive option for many applications, especially due to the cost of the software. It does, however, hold the promise of low-cost/low-volume production. If more application areas start using the technology, as expected, costs are likely to decrease. Furthermore, 3D printing may result in savings in the logistical processes in healthcare. It holds promise as a time-saving instrument by making preoperative planning easier or by providing tailor-made surgical guides or implants at the point of care.

Discussion and conclusion

This study should form one of the building blocks based on which the Dutch Ministry of Health, Welfare and Sports can develop a long-term policy agenda for medical technologies. With this in mind, input from different sources, including the literature and interviews with opinion leaders representing various stakeholders, was combined to identify technologies with a potentially major impact relevant to the ministry, as well as the Dutch society in general. The information provided in this report is therefore considered fit for purpose. It is noted that innovations in medical technologies are constantly emerging. In order to keep track of future developments and to be able to further evolve strategies and policies related to technology or healthcare, it could be considered to set up a more structural system of horizon scanning.

As a general observation, the various stakeholders agree that new technologies should primarily address current medical and societal needs. In order to stimulate the successful development and implementation of new medical technologies based on this principle, a coordinated effort with input from all relevant stakeholders would appear to be the best way forward. In order to successfully implement a new technology in a healthcare organisation, preparations by a multidisciplinary team will enable the identification of the necessary financial, infrastructural, logistical, and organisational provisions, so they can be managed in advance. It should also be realised that the implementation of new technologies may involve new competences and changes in the roles of healthcare professionals as well as of patients.

At national level, joining forces of stakeholders to optimally combine technological possibilities and medical or societal needs could be agenda setting. Such an effort should guide innovators in their research and development, as well as healthcare organisations and healthcare professionals in making optimal use of the opportunities provided by new and emerging medical technologies. It would also improve regulatory preparedness for future innovations and help the government to design strategies and policies aimed at the optimal development of the healthcare system.

1 Introduction

Care demands and technological innovations

People's medical and societal needs are continually changing. Important factors in these changes are the general aging of the population, the increased prevalence of age-related disorders, and the availability of technologies enabling more specific, accurate and successful diagnostics and treatments. These factors are expected to induce major changes in care demands over the coming decades (1). Healthcare will become more personalised and there will be a significant shift towards treating patients at home (2-4). Also, a growing number of patients have an increased desire for independence and self-management with regard to the healthcare they receive (5-8).

Apart from the anticipated changes in healthcare demand, the market for technological innovations in healthcare is evolving rapidly. In 2016, the market for medical technology in the Netherlands was valued at an estimated €4.7 billion (9). In 2017 the global market was estimated at €521 billion, and it will continue to grow in the coming years (10). In recent years, an increasingly diverse range of technological applications has become available for the treatment and support of patients in hospitals and nursing homes or living at home. Much-acclaimed emerging technologies include IT applications in healthcare (e.g. artificial intelligence and data-driven technology), innovative surgical tools (e.g. surgical robots) and personalised health technology (e.g. 3D-printed implants) (1, 9, 11, 12). Overall, the potential scope and extent of healthcare technology applications is vast, and expectations among healthcare professionals, governments, industry and society are high.

Innovation in (medical) technology can originate from either a demand or a supply perspective (13). In the latter case, the development of new technologies is primarily driven by industry rather than by the healthcare consumer, a phenomenon referred to as 'technology push'. However, technological innovations only have an impact when they are able to fulfil future medical or societal needs. Cooperation between healthcare providers, patients and industry may help to valorise developments to fit future demands from the healthcare perspective (14).

Innovation in healthcare

The Dutch government encourages innovation, including in the fields of healthcare and medical technology. The Dutch Ministry of Economic Affairs designated the Dutch Life Sciences & Health sector as one of nine 'top sectors' in the Netherlands. The scope of the Life Sciences & Health Sector is broad and includes healthcare infrastructure and medical technology (15). Devising a collective innovation agenda for the large-scale and smart deployment of technological innovations is considered one of the sector's priorities in the coming years, as addressed in the 'Agenda voor de zorg', which is composed by representatives of patients and clients, healthcare providers, public health services and health insurers. Other examples of governmental encouragement include the Dutch National Research Agenda and the new subsidy scheme for

promising care, with specific focus on innovations in medical technology (16-18).

Costs of medical technology
In response to the aging population, population growth and the increasing costs of medical treatment, healthcare expenditure will inevitably grow in the near future. Healthcare expenditure is expected to rise to €174 billion by 2040 (19). In order for a sustainable healthcare system to be maintained, expenses for prevention, cure, care and innovations such as new medical technology must be properly balanced.

The costs and benefits of emerging medical technology depend greatly on the specific application or innovation in question. The adoption of new medical technology may offer health benefits, but it can at the same time considerably increase healthcare costs. It should be noted that the costs of new medical technology are not limited to the purchase of specific devices. The bigger budgetary picture also includes the costs of the recruitment and training of staff, the adaptation of infrastructure, and increased healthcare use. On the other hand, when technology triggers an efficiency shift and improves the organisation of care, healthcare expenditure might drop (20). Moreover, where the implementation of a technological innovation substitutes regular treatment, this may result in savings (1). Section 3.4 will elaborate on the relationship between technology and healthcare expenditure.

Possible impact of increased technology use in healthcare
The increased use of and developments in technology in healthcare could offer many benefits to patients, healthcare professionals and the technology industry. For the patient, the increased use of specific products may lead to improved and faster healthcare, which may positively affect their quality of life. A positive impact may also be expected with regard to the quality and organisation of healthcare. For example, a major improvement in the availability and accessibility of patient data could lead to more refined and earlier diagnoses, as well as reduced numbers of treatment errors, thereby impacting both prevention and treatment of (chronic) disease (21). Technological solutions may also enhance interaction between the healthcare professional and the patient, and older people may be able to live at home for longer (22). Other applications may enable surgery to be performed more quickly and accurately, thereby potentially reducing complications and shortening hospitalisation.

As well as potential benefits, there are possible downsides and challenges to the use of emerging technology in healthcare (23). For example, new technologies are not always the best solution for everyone in all situations: people must be able and willing to use them (24). Furthermore, the Dutch healthcare system may not be ready for certain developments, e.g. with regard to the interoperability of ICT systems (25). Safety aspects must be weighed carefully against potential health benefits. The correct use of devices is paramount to ensure the safety of all parties involved and to reduce healthcare-related harm through the use of medical technology (26). Scientific research to assess the efficacy of specific applications often lags behind the speed of technology or fails to encompass the wider context of the healthcare system. As a result,

reliable data about efficacy and safety of newly developed technology is often lacking.

It is unknown whether the advantages and opportunities of increased medical technology outweigh the disadvantages and risks that are also involved. The long-term consequences of the use of medical technology on healthcare expenditure are also as yet unclear. Despite the availability of lists of promising developments in medical technology, it remains uncertain which developments will have a major impact in the coming years, taking into consideration unmet care needs and societal needs, but also risks, benefits and costs.

Formulating policy on medical technology

The changing healthcare demands of the future and the rapid developments in the market for medical technologies prompted the Dutch Ministry of Health, Welfare and Sports (VWS) to develop a long-term policy agenda on medical technology. In this context, VWS commissioned a market scan of the current field of medical technology in the Netherlands. This resulted in a report by KPMG, published in 2017 (9). Subsequently, VWS asked the RIVM to assess which types of new or emerging medical technology with a major impact on the organisation or the sustainability of healthcare can be expected in the next 5–10 years. The results of this study are contained in this report.

Aim and scope of the study

Aim

Based on the future healthcare demand, this study aimed to investigate which types of medical technologies that are expected to emerge in the next 5 to 10 years could fulfil the medical or societal needs of the future. This investigation resulted in a horizon scan of medical technologies with a potentially major impact on the organisation of healthcare – e.g. fostering a shift from secondary to primary care or home care – or on healthcare expenditure.

Scope

With regard to technology used in healthcare, a distinction must be made between *health technology* in general (which includes procedures and organisational systems used in healthcare) and the more limited category of *medical technology*. There is no universally accepted definition of medical technology. It generally comprises medical devices developed by a manufacturer for the diagnosis or treatment of patients. However, in a discipline like health economics it also includes treatment innovations and medicinal products. The scope of the study described in this report is delimited by two recent regulations for medical devices: the Medical Device Regulation(MDR) (27) and the *In vitro* Medical Device Regulation (IVDR) (28), both introducing stricter safety requirements for market authorisation. The full definitions of medical devices and medical devices for *in vitro* diagnostics as included in the MDR and the IVDR are shown in Text box 1.

Textbox 1: definitions of 'medical device' and '*in vitro* diagnostic medical device'

MDR definition Medical device
'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

IVDR definition In vitro diagnostic medical device
'*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

(a) concerning a physiological or pathological process or state;
(b) concerning congenital physical or mental impairments;
(c) concerning the predisposition to a medical condition or a disease;
(d) to determine the safety and compatibility with potential recipients;
(e) to predict treatment response or reactions;
(f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices;

2 Methods

2.1 Stepwise approach

A stepwise approach was used in this horizon scan of medical technologies. Data and knowledge obtained from a literature study (Section 2.2) and interviews (Section 2.3) were used. The following steps were taken:

1. The project team defined the types of impact to be taken into account for the selection of medical technologies. In doing so, the study aim and VWS's (future) policy on medical technology were taken into account. The types of impact were defined using knowledge from literature study, information from interviews with experts/opinion leaders in the broad field of innovative medical technology and discussions within the project team.
2. An analysis of mechanisms by which medical technologies in general may affect healthcare expenditure was carried out.
3. An initial list of emerging medical technologies was made using existing resources with regard to predictions of emerging medical technologies, including international literature and grey literature, such as the KPMG market scan (9), other relevant reports and websites.
4. From the initial list of emerging medical technologies, a selection of three technologies was made for more elaborate analysis. These were the technologies that were expected to have a major impact, based on literature study, interviews with experts/opinion leaders in the broad field of innovative medical technology and discussions within the project team linking the technologies to the defined types of impact.
5. The potential opportunities, barriers and risks, as well as the potential impact on the organisation of healthcare and budgetary impact, were elaborated upon for the three selected technologies, using knowledge from literature study and interviews with experts in the field of one of the specific technologies.

2.2 Literature study

The literature study took place between November 2017 and January 2018 and was conducted by two researchers working independently of each other.

One researcher scanned an existing corpus of technology foresight studies, trend analyses and the publications and websites of well known international horizon scanning organisations (Table 1). This corpus was scanned for relevant technologies. A selection was made, using two questions:

a. What is the stage of development (proof of concept, prototype or ready to be used)?
b. Does the technology match the definitions of the MDR and the IVDR?

Table 1: Foresight studies and horizon scanning organisations consulted

Foresight study / Trend analysis
Public Health Foresight Study 2018 (NL)
COGEM Trendanalyse biotechnologie (NL)
Peilstation Medische technologie (NL)
KPMG Marketscan
KPMG Medical Devices 2030
Horizon scanning organisation
Canadian Agency for Drugs and Technologies in Health
Cleveland Clinic Innovations (US)
The Medical Futurist (US)
International Network of Agencies for Health Technology Assessment
NIHR Innovation Observatory (UK)

The first question was used to make a distinction between technologies that are still at the stage of proof-of-concept or prototyping (usually *single technologies*) and technologies that are (ready to be) used in healthcare. While prototype technologies can represent major technological or scientific breakthroughs, their application in healthcare within the next 5 to 10 years is uncertain. Therefore, these kinds of technologies were not included. Since the definitions of medical technology used in this study were those of the MDR and the IVDR, the second question was also considered. This meant that, for example, medicinal products and innovations in the field of procedures (e.g. gamification) and organisational systems in healthcare were excluded or addressed as borderline technologies. Using these criteria, a list of 25 categories of emerging medical technology was yielded.

The second researcher searched the databases of PubMed and Google using a broad and pre-defined search strategy (Appendix 1). By scanning titles and/or abstracts on PubMed, the researcher identified 12 articles on technologies that address the above questons. Supplementing the PubMed search with a Google search resulted in a list of 41 emerging technologies.

Researchers 1 and 2 subsequently merged their lists, resulting in a list of emerging technologies.

2.3 Interviews

In order to obtain insight into which emerging medical technologies are expected to have a major impact, experts/opinion leaders in the broad field of innovative medical technology were selected from academic institutions and the (medical) technology industry, and interviewed, along with representatives of patient federations, medical specialist federations, hospital federations and health insurers. Experts in each of the three specific technologies were also selected for interview.

Interviewees were asked which medical technologies they expected to have a major impact in the light of the future healthcare demand, the potential benefits, risks and barriers of these technologies, their expected impact on the organisation of healthcare, and their potential

budgetary impact. Interviews with the experts from the three specific technologies addressed the impact of the specific technology in greater depth. The questions used for the interviews are included in Appendix 2.

An interview report was made for each interview that took place. Interviewees were sent the reports for approval. All interviewees approved the contents of the reports.

The experts that were interviewed are listed in Appendix 3.

3 Results

3.1 Healthcare demand of the future

Important future changes in the healthcare demand up to 2040 are addressed in the thematic report 'Future healthcare demand' of the Public Health Foresight Study 2018. This foresight study provides handles that were used in the selection of medical technologies for this report. The main developments are listed in Text box 2 (29).

Text box 2: Public Health Foresight Study 2018: Thematic report 'Future healthcare demand'

Main developments

- The number of people with age-related diseases will rise sharply due to the ageing of the population. This increases the pressure on the entire healthcare system, from informal care to primary care and from emergency care to nursing home care.
- As the population ages, the number of people with multiple diseases (i.e. multimorbidity) will increase. Some elderly people also experience social problems, such as loneliness. The number of people with complex care needs beyond the health sector will increase.
- Healthcare demands change as a consequence of sustained improvement in the treatment of some diseases. This also has consequences for the longer term, especially for the quality of life of patients and their possibilities to participate in society.
- Self-management among patients will further increase. This will require new and different skills from both patients and healthcare professionals, but also attention for those groups incapable of self-management.
- The mental pressure on youths and young adults seems to be increasing, with possible consequences for their mental health. Technologies such as social media and virtual reality play a role in this. These technologies bring new risks, but also offer opportunities for the treatment of mental illnesses.
- Both patients and healthcare providers have increased expectations with respect to the potential of healthcare, partly fueled by technological developments. This lowers the levels of acceptance in situations when a disease cannot be cured.
- Diagnoses and treatments are becoming more specific. This leads to a continuing personalization of healthcare. An increase in unique treatment paths might put pressure on the efficiency of the care system, which benefits from uniformity in treatments.
- Care is increasingly being provided to patients at home. This requires adjustments in the care system and the skills of healthcare professionals and patients.
- There will be a growth in certain groups of patients, such as single older men, elderly migrants, and LGBT-elderly. As a result, their specific needs and requirements will become more visible. The currently available information on these groups is quite scarce.

Considering the main developments addressed in Text box 2, medical technologies could contribute to a number of intersecting areas, such as older people and age-related diseases; the efficiency and organisation of the healthcare system; the enabling of self-management and personalised treatments/treatment in the home situation. Furthermore, medical technologies may be able to address gaps in care with regard to mental illness, social problems and specific patient groups, or different approaches to these. These developments were taken into account in defining the types of impact used for the selection of technologies for the current study.

3.2 Types of impact for the selection of medical technologies

Types of impact that were defined as relevant to the selection of a medical technology in the context of this horizon scan were the following:

- *Fulfilling (unmet) medical or societal needs*
  A technology should be in line with the future healthcare demand, and/or be able to fulfil (unmet) medical or societal needs of the future. This means it should be connected with the developments listed in Text box 2, including both medical needs, such as age-related diseases and personalised treatments, and societal needs, such as self-management and participation in society.
- *Impact on organisation of healthcare*
  Technology could facilitate shifts of treatment or monitoring from hospital care to primary care or home care. Such shifts have consequences for the patient as well as the healthcare provider and could also affect healthcare costs. Technology could also lead to changes in the types of healthcare professionals needed, education programmes, logistics, infrastructure, and facilities and/or IT systems.
- *Budgetary impact*
  Developing and implementing new technologies usually involves financial investment and may have a major budgetary impact. However, technologies may become better, more efficient and cheaper in time; they may even catch up with traditional treatment with regard to costs. Therefore, both direct and indirect future budgetary impacts should be considered.
- *Potential for substitution of existing methods*
  Many new technologies are just as effective as traditional treatments, and so may be substituted for the latter. Other technologies offer advantages for patients in addition to the treatment the patients already receive and can therefore function as add-ons. In this case, implementation of the technology will enhance costs per patient. A technology will have greater impact when it is (eventually) able to substitute a traditional treatment.
- *Impact for a large magnitude of the patient population*
  The implementation of a new medical technology can have a major impact when it is able to provide a better, quicker, cheaper or less invasive treatment to a large group of patients.
- *Impact for individual patients*
  Certain innovative treatments are suitable for only small groups of specific patients. However, in the overall picture, the impact

may be great when the benefit per patient is very large or the patient groups are relevant in relation to societal needs.

3.3 Medical technology and healthcare expenditure

How does medical technology affect healthcare expenditure?
Alongside demographic changes (i.e. population ageing) and income growth, technology is believed to be a major force behind increasing healthcare expenditure (30-32). A precise analysis of the effect of specific medical technology on healthcare expenditure is extremely difficult. There are two reasons for this. More importantly, specific data on the use and costs of medical technology (i.e. in hospitals) are sorely lacking, in contrast to, for example, data on medical devices used outside hospitals[1] and on medicinal products (1). Second, in health economics the term 'technology' refers to a loose conglomeration of medical devices, new diagnostic methods, treatment innovations and medicinal products (30-32). This makes it hard to single out medical devices in most economic studies dealing with technology in healthcare. This section will therefore deal with general aspects of the relationship between technology and healthcare expenditure, which will be illustrated using medical device examples where available.

As the thematic report on technology within the Public Health Foresight Report 2018 (VTV-2018) points out, technology can either increase or decrease costs (1). Three factors play an important role in this respect. Two factors are included in the simple formula: price x volume = healthcare spending. If either the price or the volume increases, healthcare expenditure will increase – and vice versa. A third factor, technology creep (see page 26), is more elusive because it affects volume indirectly. This section will elaborate on all three factors.

New technology usually leads to a temporary rise in prices
New technology is usually more expensive than the old technology it is supposed to replace or complement. For example, a recent (2016) analysis of more than 6,000 comparisons between innovations and incumbent technologies in healthcare (both medical devices *and* medicinal products) in both the United States of America and the European Union shows that in roughly two-thirds of cases the new technology is more expensive than the existing one. According to this study, innovations, on average, lead to an increase in the price of treatment of 8%. If health gains (€/QALY) are taken into account, prices rise by an average of 4% (33). Higher prices can be explained by the fact that innovations require research and development and/or new skills (and thus training). As technologies become widely used, implementation costs drop. If and when prices start to decline for a given medical device depends on the type of technology, the extent of competition and whether the new technology can replace a traditional treatment or technology. For example, the price of blood glucose monitoring devices has steadily dropped over time, shifting the focus

[1] The GIP-databank (Zorginstituut Nederland) does hold data on medical devices paid for by standard health insurance (basisverzekering) and distributed by, amongst others, community pharmacies: e.g. wound dressing materials, blood glucose meters or hearing aids. However, the GIP-databank does *not* hold information on medical technology paid for by additional health insurance (aanvullende verzekering) or technology used in hospital settings (mostly due to the DBC/DOT financing mechanism).

from the device itself to the reagent strips as the main source of income for manufacturers (34). If competition is lacking, prices usually remain high. For example, since the acquisition of its only competitor (Computer Motion) in 2003, Intuitive Surgical – the manufacturer of the da Vinci® surgical robot – has virtually controlled the market for robotic surgery (35, 36). As a result, the price of initial acquisition, maintenance, training, and the consumables needed to keep the da Vinci® robot in operation have not fallen over time (35-38).

New technology creates new demand, resulting in rising healthcare expenditure

While high prices usually have a temporary effect on healthcare expenditure, the increased demand often created by new technology has a more permanent effect. Falling prices will therefore not always lead to a decrease in healthcare expenditure. Studies by Thorpe (39, 40) and others based on US Medicare data have shown that the costs per treatment for new technologies (both medical devices and medicinal products) is usually comparable to older technologies over time. Yet, total healthcare expenditure rises anyway due to increased demand. This can be explained by the fact that new technologies often enable the treatment of groups of patients that could not be treated by the older technology or traditional treatment. For example, new and less invasive surgical techniques make it possible to treat more and more fragile patients – as with laparoscopic surgery, which is now widely used to reach various parts of the body with minimal invasive damage. Yet, laparoscopy is not always the most (cost-)effective treatment option available (41, 42).

The risks of new technology in healthcare: technology creep and other social dynamics

The term ‘technology creep’ is used in healthcare to refer to the excessive use of technology. The mechanisms behind excessive use are simple. A technology is approved for a certain (high-risk) population in which there is a proven benefit. But once the technology is approved and acquired by, for example, a hospital, it will almost automatically be used also to treat patients for whom the health gains are not proven (36, 43-45). This may mean that an increase in the use of a specific technology, leading to increased costs related to this technology, does not always result in better health outcomes for patients.

The use of technology in healthcare is influenced by other social dynamics as well. For some health professionals (so called ‘early adopters’), the use of *cutting-edge* technology is important in itself; and for hospitals, having the latest surgical robot or imaging device can have great marketing potential (45-47).

In 2014, the Dutch Health Council used the example of Positron-emission tomography scanners (PET scanners) to illustrate these phenomena. Based on clinical guidelines, it was estimated in 2007 that around 8 or 9 PET scanners would suffice to meet the total (guideline-based) demand for PET scans in the Netherlands. Yet, between 2006 and 2009 the number of PET scanners grew from 24 to 44, none of which were *not* used (45).

It should be noted that technology creep is not limited to new technologies. Older technologies are also used in patient groups in which there is no proven benefit. These costs are, however, already incorporated in the current healthcare budget (36, 43, 44).

Monitoring the use of technology with real world data
Technology creep emphasises the importance of monitoring the cost-effectiveness of the use of new technology in healthcare. Skinner and Staiger (2015) developed three categories of technologies according to their health benefit per dollar of spending. The first category consists of technologies that are highly cost-effective[2], such as blood glucose meters or casts for simple fractures (43). Not all technologies in this category are, however, inexpensive: e.g. biventricular pacemakers (48). The second category consists of technologies having substantial benefits for some patients, but not for all (or there is no scientific evidence that they benefit all patients). An example of such a technology is the metal stent used in combination with angioplasty. During angioplasty, a balloon catheter is used to prop open blocked blood vessels in the heart and subsequently a stent is often placed to keep it open. It is very cost-effective in patients treated within the first 12 hours of a cardiac arrest. But the procedure is used on many other patients, too. For these groups the evidence of a benefit is less clear, and thus the extended use of the technology may not be justifiable in cost terms. The third category encompasses all the technologies and treatments whose benefits are small or are supported by little scientific evidence (43).
The second category is the most difficult to deal with, since most health professionals will tend to look exclusively at the effectiveness of the treatment or technology, without taking into account whether the health gains measure up to the expense (36, 44). Monitoring the use of (new) technology with real world data after approval might offer insight into whether the cost-effectiveness of a certain technology – usually studied in small, well defined patient populations – also applies to other patient groups.

Can technology lower healthcare expenditure?
The question whether or not technology can help to contain rising healthcare expenditure is difficult to answer. As we have seen above, lower prices will not always result in lower expenditure due to rising demand, sometimes fuelled by technology creep. Still, single technologies can (and sometimes do) result in cost decreases, either because they cost less than the technology or treatment they replace or because they deliver higher quality outcomes for the same price. In general, cost decreases can occur only when the new technology fully replaces an old technology/treatment. This, however, is easier said than done: there are usually few financial, social or even cultural incentives for *not* using older technology, although discouraging the use of 'obsolete' technology – for example in clinical guidelines – helps to phase out older technology (1, 32). As a result, most new technologies – however efficient or cost-effective they may be – enter the health

[2] Cost-effectiveness measures the relationship between monetary inputs and the desired outcome (i.e. mortality, quality of life). Highly cost-effective technologies can be either relatively cheap (casts, blood glucose meters) in relation to their health gain or, in the case of biventricular pacemakers, for example, very expensive, yet yielding very high health gains (i.e. preventing death).

system as an ‘add-on’; an addition to what is already available. The costs of using this technology also ‘add on’ to the current health budget. The thematic report on technology within the Public Health Foresight Report 2018 points out that the highest potential for cost reduction through technology lies outside the field of medical devices, i.e. beyond the scope of the MDR/IVDR. Technology that plays an important role in streamlining processes in healthcare – for example by increasing the efficiency and speed of information exchange between health professionals – has a high potential for cost reduction (49, 50).

Many benefits of medical technology end up outside the healthcare domain

Many of the positive effects of medical technology end up in domains other than healthcare and are usually not incorporated into evaluative studies. These benefits can include increased labour participation and higher tax incomes. According to Pomp, people who feel healthy will work longer and can enjoy an increase in labour participation of around 30% (51, 52). These effects predominantly occur when technology is used to treat the working age population. Because no medical device example was identified in the literature, we illustrate this using a medicinal product example: the treatment of rheumatoid arthritis with biologicals (TNF-alpha inhibitors) has led to a decrease in sick leave, which has resulted in a saving of at least €1,800 per patient per year (52).

Furthermore, new technology for treating patients with chronic disease living at home can reduce the need for formal and informal care in two ways. First, technology likely improves the quality of life of patients, by making care more predictable through monitoring devices, by restoring their mobility (e.g. through an exoskeleton or simply a mobility scooter, wheelchair or walker) or ability to communicate (voice-activated computers or tablets). Second, the technology itself (for example sensor-technology or service robots) can take over certain tasks from informal caregivers, such as making sure the patient is safe, takes his medicines or remembers appointments. These patients subsequently need less formal *and* informal care. Less use of formal care leads to lower healthcare expenditure. But less use of informal care may also lead to economic benefits for society: informal care is not free and caregivers often have to stop work, drop out of school or give up volunteer work to provide it (53). Furthermore, a lower care burden for informal caregivers usually raises their quality of life and can sometimes even improve their survival (54, 55).

Cost drivers and technology in healthcare

Table 2 lists important cost drivers that should be taken into account when assessing the effect of a specific technology or types of technology on healthcare expenditure. For example, given the nature of social robots (discussed in more detail in Section 3.5), these will, in all likelihood, be used most in elderly care, and more specifically in care for people with dementia. Therefore, the demand for social robots depends on demographical changes (population ageing) and epidemiology (increase in the number of people with dementia). Furthermore, demand for social robots will be influenced by both the means of elderly people (can they afford it?) and whether or not these robots are reimbursed under health insurance or social support programmes (which is at least partly dependent on government health policy). The price of social

robots, however, depends on other factors, such as consumer income and willingness to pay, which affects the bandwidth of prices manufacturers can charge for their technology. Prices are also influenced by whether or not the market is competitive and whether or not the government or health insurers are able or willing to maximize prices. The framework given in Table 2 is still a draft based on literature and interviews used in this study. In order to create a more fine-tuned (conceptual) framework, more research is needed.

Table 2: Draft framework of cost drivers for technology in healthcare

		Price	Volume
Autonomous drivers	- Demography		↑ / ↓
	- Epidemiology		↑ / ↓
	- Income growth	↑ / ↓	↑ / ↓
Technology-related drivers	- Implementation (R&D, acquisition, training, maintenance, etc.)	↑	
	- Competition	↓	
	- Widening indication		↑
	- Substitution	↓	
	- 'Add-on' technology		↑
Social and political drivers	- Technology creep		↑
	- Social dynamics (early adopters, marketing potential, etc.)		↑
	- Health policy (incl. reimbursement)	↑ / ↓	↑ / ↓

3.4 Selection of emerging medical technologies with significant expected impact

3.4.1 Initial list of emerging medical technologies

Using the existing resources listed in Table 1, an initial list of emerging medical technologies was put together. This list included examples of specific applications when available. The list was not exhaustive, but provided an overview of current developments that may be promising.

A few considerations related to the initial list should be highlighted. First, this horizon scan is limited to the scope of the MDR and the IVDR; however, some of the technologies identified may comprise different applications, some of which are outside this scope. Second, some of the technologies represent an overarching category for several more specific applications. For example, digitalisation covers eHealth, but also artificial intelligence (AI) and virtual reality. In fact, eHealth is itself an umbrella term for a great variety of applications. Other medical technologies identified apply to a specific patient group or medical specialism; for example, cancer screening techniques.

3.4.2 Technologies with a major impact: interviewees

Interviews with experts/opinion leaders in the broad field of innovative medical technology addressed the question which emerging medical technologies they expected to have a major impact. Several experts

named some type of digitalisation or ICT in healthcare, such as eHealth, sensor technology or AI. Other technologies named by the interviewees as potentially having a major impact in the next 5–10 years were 3D printing, robotics, regenerative medicine, nanotechnology and personalised medicine. Experts also stated that general developments in healthcare (as opposed to specific technologies) may have the greatest impact. In this category, developments with regard to the collection, exchange and use of data (data-driven technologies) were mentioned by several interviewees as technology that may have a major impact. One interviewee indicated that the potential impact of low-tech products should also not be underestimated. For example, the availability of good-quality incontinence pads has high societal impact. Several interviewees emphasised the importance of well organised technological implementation. Without this, the potential impact of most technologies will not be achieved. One interviewee commented that this is not only true of innovative technologies; the potential of quite a number of existing technologies is not fully used, simply because they are not implemented in the right way.

3.4.3 Selection of three technologies for more elaborate analysis

The project team discussed the initial list of emerging medical technologies and prioritised technologies on the basis of their expected impact, fuelled by the literature and interviewees. This prioritisation resulted in three technologies to be analysed in more detail in this report: (1) eHealth, (2) robotics, and (3) 3D printing. A brief explanation of why these three technologies were selected is provided below. A more detailed analysis is included in Sections 3.5–3.7. A number of other technologies with a potentially greater impact are briefly described in Sections 3.8–3.9.

eHealth

In essence, eHealth is the use of modern information and communication technologies – internet technology in particular – to support or improve health and healthcare (see also Section 3.5). eHealth was selected as one of three technologies for more elaborate analysis because it was expected to have a major impact on healthcare for the following reasons:

- eHealth applications are able to fulfil future medical or societal needs in many ways. For example, self-management will become more important as the number of people with chronic disease increases and technology can potentially offer considerable help and responds well to people's wish for self-control.
- eHealth may affect the organisation of healthcare in enabling healthcare to be delivered at a distance, possibly resulting in people visiting a doctor less often or people being treated in primary care instead of secondary care.
- eHealth has the potential to have great budgetary impact both in a positive and in a negative sense, dependent on the way specific applications affect the organisation of care.
- The impact of eHealth may be particularly high in cases where it substitutes traditional treatments. The replacement of traditional treatments by eHealth applications is possible in some cases and the number of examples is expected to increase in the coming years.

- Some eHealth applications apply to a very large target audience, while others apply to specific patient groups such as older people, nursing home residents or (young) people with mental illnesses. Overall, eHealth applications have the potential to provide benefits for all patient groups.

Robotics in healthcare

Robotics is the branch of technology that deals with the design, construction, operation and application of robots. A robot has been defined as a machine that has: (a) sensors to receive information about the world around it, (b) algorithms to make decisions based on the information received from the sensors, and (c) motors/actuators to provide mechanical movement (modified from the Public Health Foresight Study 2018) (1). The most frequently mentioned applications of robotics in healthcare were social robots, service robots (an aid for people in institutionalised care or at home), and surgical robots. Robotics in healthcare was selected as one of three technologies for more elaborate analysis because it was expected to have a major impact on healthcare for the following reasons:

- The use of service robots was expected to fit in with future healthcare needs, particularly because of the increasing number of older people and the complex care demands of vulnerable older people.
- Robotics has the potential to support people treated in the home situation for a longer period.
- Robotics can potentially improve the outcome of surgery, thereby possibly shortening hospitalisation. This also fits with the increased expectations of patients and healthcare providers with respect to the potential of healthcare.
- Service robots could help healthcare workers to carry out their tasks more efficiently, which in turn could play a role in addressing increasing care needs.
- Surgical robots are generally expensive. Therefore, their adoption could have a substantial budgetary impact. Moreover, in many cases they are probably add-on technology, not substitution.
- Certain robots are designed to address social needs such as loneliness, which is one of the needs identified in the future care demand report.

Medical 3D printing

3D printing is a type of additive manufacturing, which is defined as a process of joining materials to make objects using 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies (56). Applications of 3D printing in healthcare include surgical planning tools like 3D models of the target area (e.g. a heart or tumour), surgical guides to assist in placing orthopaedic implants, and the production of personalised implants or external support devices such as braces and splints. 3D printing was selected as one of the three technologies for more elaborate analysis for the following reasons:

- Surgical planning using 3D-printed models is currently mostly add-on technology, but it could potentially substitute the use of combinations of traditional diagnostic medical imaging techniques.

- In niche populations, 3D printing can fulfil unmet medical needs, e.g. 3D-printed implants may offer patients with complex orthopaedic problems a treatment that is not possible with traditional procedures. This can address increased expectations with respect to the potential of healthcare.
- When 3D surgical planning, including the use of surgical guides, evolves sufficiently to encompass the preparation of a personalised implantation kit, it may be able to offer substantial budgetary advantages. For example, it could lead to a reduction in the time and effort required for preoperative planning, and it could markedly change the logistic needs related to available stock and reprocessing.
- In future, when 3D printing becomes more routine, efficient and economical, it could lead to the replacement of standardised devices by personalised devices, which may induce greater impact.
- The 3D printing of less complex devices, e.g. dental applications, can be performed at the point of care, leading to a potential impact on the organisation of healthcare and concerns about quality and safety management for such applications.

3.5 eHealth

What is eHealth?
eHealth covers a range of tools and services. There is no universally accepted definition. The WHO defines eHealth as the use of information and communication technologies (ICT) for health (57). In the Netherlands, Nictiz defines eHealth as the use of contemporary information and communication technologies – internet technology in particular – to support or improve health and healthcare (58). The European Commission, however, has adopted a more elaborate definition: 'the use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health' (59). The interviewees emphasised that eHealth relates not only to disease management, but also to prevention and the social implications of disease (e.g. information sourcing, knowledge sharing, interaction with other patients).

A specific part of eHealth is m-health, i.e. mobile health, referring to the use of mobile electronic devices. In their Green Paper on m-health, the European Commission took over the WHO definition: 'Mobile health ("mHealth") covers medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices' (60, 61).

eHealth applications
According to the European Commission, eHealth covers areas such as:
- health information and data sharing between patients and health service providers, hospitals, health professionals and health information networks;
- electronic health records;
- telemedicine services;

- portable patient-monitoring devices;
- operating room scheduling software;
- robotised surgery (dealt with in Section 3.5). (62)

According to the European Commission, m-health also includes applications (apps) such as lifestyle and wellbeing apps that can connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by SMS, and telemedicine provided wirelessly.

As indicated in Chapter 1, this report focuses on products (potentially) falling under the scope of the MDR or the IVDR (27, 28). However, in the area of eHealth/m-health it is not always easy to classify products as a medical device or IVD; there is a large grey area (63).

Expected developments within the next 5-10 years
According to interviewees, the generation, interchange and use of digital data will be the key element of eHealth developments in the coming years. Data will increasingly be generated by patients themselves, via m-health tools, such as apps, wearables and biometric sensors. Moreover, with the European General Data Protection Regulation patients will have access to their own personal data generated by healthcare professionals, while the need for cybersecurity measures will increase. The profusion of data may foster the development of applications and tools for the prevention, diagnosis and treatment of disease.

The pace of development and implementation of innovative eHealth applications, however, differs per healthcare setting and disease area. Driven by patient demands and business opportunities, diabetes has been forecasted as an example of one of the major developmental areas (64, 65). eHealth applications include insulin administration based on real time glucose sensors, and instructions to adjust behaviour to prevent foot injury with the aid of shoe insoles that monitor pressure distribution on feet.

Potential benefits
Interviewees pointed at increased self-management as a major potential benefit of eHealth. Driven by personally owned data, and also self-generated data, patients/customers will have increased knowledge on, and insight into, their own health, which will empower them to make informed decisions. From a patient perspective, the value of eHealth is also to get more trust in care and to get motivated for lifestyle interventions. eHealth applications may also be used to evaluate interventions on an individual level and to assess the influence of lifestyle on disease. The results of such studies may be of value for personalised healthcare. According to interviewees, eHealth may shift the focus in healthcare from treatment to prevention of disease.

It was emphasised by the interviewees that the adoption of eHealth by healthcare professionals is slow. This is partly due to the fact that eHealth is not part of healthcare professionals' terms of reference (with a few exceptions in mental healthcare). Other factors of influence are for example knowledge of healthcare professionals as well as patients, costs/reimbursements, culture, relative advantage, and the ability to be

adapted to fit the local context (66). A recent report indicated that consultation via eHealth between healthcare practitioners, especially in relation to diagnostics, increases efficiency and stimulates knowledge sharing (67).

Risks and barriers
One of the risks of eHealth mentioned by interviewees is increased medicalisation and overtreatment, due to improved and readily available diagnostic tools. Overestimating the effects of eHealth use is also a concern (e.g. applications focusing on changes of behaviour may not be as effective as expected, because behaviour is also determined by the social system surrounding the patient). Another concern is the difficulty of establishing the added value of eHealth applications, and as a consequence the difficulty for HTA bodies to decide on reimbursement. It is simply not feasible to perform a randomised controlled trial for every eHealth application entering the market.

Regarding ICT systems needed to harvest the benefits of eHealth, lack of compatibility and interoperability between systems is a well known area of concern. According to interviewees, there are too many stand-alone solutions, ignoring the whole (regional, national) digital healthcare system at large. Moreover, the digitalisation and renewal of digital systems are progressing slowly, being partly hindered by privacy and security concerns.

eHealth may have an impact on the organisation of healthcare (see also below). Differences in financing/reimbursement systems between various healthcare domains (e.g. hospital care, primary care, long-term care) may, however, be a barrier to change. Within domains there may also be financial implications. For example, physiotherapists mentioned their potential loss of income due to the replacement of face-to-face sessions by a web-based exercise application (68). Introduction also requires a shift in culture amongst healthcare professionals. For example, professional autonomy should be partly set aside, e.g. in order to enable data sharing.

Expected impact on healthcare
From the interview results and information available in the literature, the impact of eHealth is expected to arise in three main areas (60, 69):

a. impact on the organisation of healthcare;
b. fulfilling (unmet) medical or societal needs;
c. impact for individual patients.

Ad a. The delivery of healthcare will no longer be time- and place-restricted. Online treatment, video consulting and e-consulting will become commonplace, and eHealth applications may shift the diagnosis, monitoring and treatment of disease from hospital care to primary care, or even care at home (e.g. by point-of-care diagnostics, teledermatology). As pointed out by interviewees, eHealth is expected to improve efficiency in planning, organisation and communication in healthcare. A combination of high expectations and business opportunities will lead to new collaborations and new business models, services and products. The expectation is that commercial parties other than those that are currently active in healthcare will enter this market. This may

lead to disruption of the way healthcare is currently organised. However, literature data reveal that several barriers still need to be overcome, including the workflow disruption related to the implementation of eHealth and the redefined roles of healthcare professionals (70).

Ad b. The interaction between healthcare professionals and patients/ consumers is expected to change due to eHealth applications. In theory, patients will no longer be passive recipients of care, but well informed consumers, empowered to take their own health decisions, or at least take them in consultation with healthcare professionals. They will (partly) gather their own health data by sensors and wearables. Due to the increasing possibilities of collecting and combining data, algorithms will evolve to support clinical decision making. Patient autonomy, independence and self-reliance is expected to increase, and the self-management of disease will enhance people's participation in society. However, a recent literature review reveals that necessary alignment with clinical processes and the undermining of face-to-face communication between patient and professional are considered to be barriers to the adoption of eHealth (70). In the case of self-monitoring, it is suggested that other factors, such as disease controllability, will also act against adoption. A patient's willingness to self-monitor decreases when monitoring does not lead to (perceived) better treatment (71). Moreover, there is a large group of people lacking sufficient health literacy and digital literacy to adequately make use of eHealth applications (72, 73).

Ad c. The identification of risk factors, diagnosis and management of disease will become more accurate, easier and quicker. This may impact healthcare outcomes in a positive way. However, a review of the literature reveals that a lot more research is needed to establish the impact on the quality of care (70).

In none of the above-mentioned areas is there strong evidence in the form of data or figures for or against the supposed benefits of eHealth implementation. So, one could question whether its impact(s) will indeed be as outlined above. This makes it difficult to reliably assess the expected impact from either a healthcare perspective or a budgetary point of view.

Expected budgetary impact
As mentioned above, eHealth has the potential to improve the quality and effectiveness of care and to reduce expenditure, but it is as yet difficult to assess the added value of eHealth in healthcare. A recently published systematic review shows that there have been roughly equal numbers of reports of failure and success of eHealth interventions (70).

The budgetary impact of eHealth/mHealth applications will depend on the type of intervention (add-on or substitution), the costs compared with the total healthcare expenditure on a disease and the effectiveness compared with standard care. It is therefore difficult to predict any impact on budget for this technology as a whole. Interviewees stated that eHealth applications might increase healthcare expenditure through medicalisation, over-testing, overdiagnosis and overtreatment, but, as yet, there is little evidence to support these claims. On the other hand,

assertions have been made that eHealth can reduce healthcare expenditure (74, 75). So far, there is not much evidence to support this either. However, in the past two years cost-effectiveness studies on eHealth interventions have begun to emerge. Most of the evidence points to eHealth/mHealth interventions supporting self-management by people with chronic conditions, such as diabetes mellitus type 2 or chronic heart failure, or interventions focusing on mental health care, e.g. for depression, anxiety or eating disorders (70, 76-80). For example, in the case of chronic heart failure, eHealth interventions seem to lead to a reduction in hospital days, i.e. a reduction in costs. Yet, no reductions have been found in heart failure-related hospital admissions, mortality or overall costs (76, 80). On the contrary, total expenditure (budgetary impact) increased, likely due to the costs of implementation, such as acquiring equipment, installation and training. These kinds of cost increase are, however, likely to be temporary (76).

Cost-effectiveness means not only reducing costs, but also increasing clinical effectiveness. In the case of eHealth/mHealth, the health gains have proven to be difficult to assess. A recent systematic review of the economic evaluations of eHealth/mHealth for the treatment and prevention of depression, for example, has shown that, although cost-effective according to UK standards, most interventions show only marginal health gains (QALY gains) (77).

For a more reliable assessment of the likely budgetary impact of eHealth/m-health implementation, more information needs to be generated. Studies should cover not only the cost-effectiveness of eHealth/mHealth, but also the effect of eHealth on processes and workflows in healthcare. For example, does eHealth lead to more efficient workflows in healthcare, which extend beyond the professionals who are directly involved in healthcare provision? If so, eHealth might lead to more efficient hospitals or primary care centres, and thus reduce healthcare expenditure. It should be noted, however, that some of the major benefits of eHealth/mHealth interventions may well lie outside the healthcare domain. If diagnostic tests can be performed at home, for example, and patients don't spend time in a doctor's office or hospital, they can use that gained time to return to work (direct economic benefit) or for volunteer work or education (indirect economic benefit), which may in turn lead to an improvement in their quality of life (67).

3.6 Robotics

What is a robot?

Robotics is the branch of technology that deals with the design, construction, operation and application of robots (81). For the purpose of this report a robot is defined as a device that has the following characteristics: (a) sensors to receive information about the environment and/or instructions from a human, and (b) algorithms to make decisions based on the information received from the sensors, and (c) motors/actuators to provide mechanical movement, and/or devices to make sounds and/or display images (modified from the Public Health Foresight Study 2018) (1).

The Public Health Foresight Study 2018 also states that the main function of a robot is the automation of physical labour and intelligent interaction with the world (1). The study does not, however, specify the degree of automation of physical labour, nor which types of intelligent interaction are referred to. Therefore, surgical robots (most of which are strictly speaking telemanipulators because surgeons are making the actual movements of the surgical instruments) also fit this definition. A number of social robots perform no physical action but interact with a person nonetheless by speech, sound emissions, body movements and/or presentation of information on a screen, which may also show an avatar or a real person that communicates via video with the patient (82). Therefore, both non-autonomous surgical robots and static social robots are included in this study.

In many publications, the term robot is used but not defined. Instead, other technological applications like eHealth, domotics, remote care and AI applied in a computer programme are also called 'robots'. Apparently, a clear definition of 'robot' has not been broadly established.

The actions of true robots are controlled by a computer algorithm, unlike telemanipulators, which are remotely controlled by a person. The algorithm may be a static algorithm, which will give identical actions in identical situations, an adaptive algorithm, which 'learns' from previous experiences (machine learning), or a 'deep learning' algorithm, which learns through the experiences of others (human, robot, literature, etc.) which are shared in networks.

Current and potential applications of robots
An internet search identified many robots that fall within the above definition and that can be deployed in either cure or care. As indicated in Chapter 1, this report focuses on products (potentially) falling under the scope of the MDR or the IVDR (27, 28). However, in the area of robotics it is not always easy to classify a product as a medical device; there is a large grey area which we will try to indicate as such where applicable in this chapter. In order to provide a complete picture, we also include products that are probably outside the scope of the MDR/IVDR. On the basis of its function it is possible to categorize robots into four main groups[3]:

1. Social robots
   These robots are designed to emulate or support social interaction with a person. They can be deployed for a variety of social interactions such as entertainment, distraction from anxiety, education, supervision, memory support, training of social skills and social interaction, activation, rehabilitation exercises and telecommunication with caregivers. Appendix 4 lists robots of this type. Most likely, many robots in this category do not serve a medical purpose as specified in the definition of a medical device and are within the scope of the MDR.
2. Service robots
   These robots perform a physical action to support the delivery of

[3] This is not intended as an absolute categorisation of the different robot types. It is merely an attempt to group the robots based on their intended function in order to declutter the vast range of equipment and devices that are called 'robots'.

care. The action may be autonomous or controlled by the care-receiver or care-giver. Robots in this category include a robotic arm mounted on a wheelchair, an automated spoon enabling a person with limited or no arm function to eat without help, and robots in a private house to open doors and fetch items or in logistic support in a nursing home or hospital. Appendix 5 lists robots in this category. Most likely, many robots in this category will be used to alleviate or compensate for disabilities and will therefore be within the scope of the MDR.

3. Surgical robots
   Typically, most surgical robots are telemanipulators, which convert and enhance the actions of the surgeon preforming the operation.
   Surgical robots' instruments can be more complex than manually operated instruments and have greater freedom of movement (multiple axes). The movements of the surgeon can be scaled for greater precision, and human tremor and potentially damaging movements can be filtered out so that accuracy and safety are improved. However, clinical outcomes have been claimed to be comparable to those of conventional open surgical and laparoscopic procedures, with fewer complications, although long-term results are not always available (83). Other surgical robots are designed to function in an environment that is unsuitable for humans – for example, to biopsies while the patient is in an MRI scanner (84, 85). Appendix 6 lists robots in this group. All robots in this category are likely to be within the scope of the MDR.
4. Exoskeletons
   Exoskeletons come in the form of devices for gait training (re-learning how to walk after sustaining an injury or disability) or as devices that are attached to a paralysed person's body to free them from a wheelchair and enable them to stand up and walk. A similar device exists to restore arm function. A simpler form is a glove that improves the hand function of an elderly person so that they can open jars, for example. Appendix 7 lists robots in this category. Most likely, many robots in this category will be within the scope of the MDR.

Expected developments within the next 5-10 years
Social robots
According to several interviewees, the added value of social robots is already widely recognized, especially in terms of distracting and relaxing elderly people suffering from dementia, who are easily upset; training children with autism to improve their social skills; and aiding in the prevention of social isolation. It is expected that the demand for such devices will increase in the coming years. Abdi et al. performed a review of socially assistive robots (86). They found positive outcomes in 28 of 33 studies, but highlighted some methodological issues, which make generalisation problematic. They recommended that future studies should aim at validating the roles demonstrated in this review.
One of our interviewees explained that the current generation of social robots has certainly added value in the support they offer to carers, but their impact could be increased substantially if the robot could become

more reactive (e.g. not only tell an elderly person to take medication, but also check whether they have done so).
The current generation of social robots communicates through algorithms (basically Q&A lists), pre-programmed responses or standard reminders, aided by spoken or typed responses from a remote carer. This means that the possibilities for interaction are limited. Future social robots are expected to mimic a higher level of social skills, based on AI, according to one of the interviewees. AI is developing rapidly, not least because social interaction through AI has lots of potential applications in commerce. This may result in 'companion robots' that are capable of holding a meaningful conversation, linked to the patient's interests. The interviewee foresaw that, using AI, the robot could learn about the patient's background and about their children and relatives, and could even track those people through social media networks and add relevant information into the conversation.

Service robots
Despite the optimistic views that are presented in the media, robots that will provide physical care in the same way as a care giver (e.g. helping the patient to get in and out of bed or go to the toilet, bathing, changing clothes or bandages, injecting medication) will not appear in the next 10 or even 30 years, according to interviewees. The robots listed in Appendix 5 that appear to be able to deliver physical care are in fact not autonomous robots, but devices that are remote-controlled by a care giver. In contrast to the situation for social robots, interviewees do not anticipate major breakthroughs in the area of service robots even within the next 5–10 years. Problems that are challenging in particular are the necessary dexterity and the dynamic environment of the patient which takes a high level of fast acting intelligence.
Bedaf et al. performed a systematic review of robots supporting the independent living of elderly people (87). They identified 107 such robots, of which 6 were at concept phase, 95 at development phase and 6 commercially available. Each of these last supported only a single activity and one was in fact a social robot (Paro). Like our interviewees, Bedaf et al. concluded that it will be a long time before a robot will be capable of supporting multiple activities in a physical manner in the home of an elderly person in order to enhance their independent living.

Surgical robots
The da Vinci® surgical robot has been the gold standard for many years: a versatile robotic system suitable for a growing range of surgical procedures in e.g. urology, gynaecology, cardiology, pulmonology and otorhinolaryngology. The use of and demand for such systems is increasing, and several similar console-based robots are expected to come onto the market within the next 5 years, partly because crucial da Vinci® patents will expire in 2019 (83, 88, 89). Future developments are likely to focus on specific features and further studies are needed to evaluate their clinical applicability and outcomes, comparing them with the achievements of four generations da Vinci® (88, 89).

Appendix 6 lists a number of surgical robots, in various stages of development. Some of these are designed for a single, simple application.

Exoskeletons
Exoskeletons that are designed to restore the functions of a disabled person's limbs, e.g. to get them out of a wheelchair and walk again, are in early stages of development (see Appendix 7). They are relatively bulky pieces of equipment (see appendix 7). Yet there are initiatives to make light weight, easy to wear 'suits' that make use of the person's skeleton and muscular system (90). Work is also being performed on control systems with a 'direct to the brain interface' (91).
Several devices for physiotherapy and gait training are already available (see Appendix 7).

Potential benefits
Social robots
Apart from increasing the quality of life of patients/clients, social robots may help to alleviate the shortage of caregivers (nurses), especially if the expected developments (see above) take place. In this context, terminology is important: One of the interviewees expressed that there is a need for 'time-saving technology', and the term 'work-saving technology' is often used. Interviewees indicate that, if some of the social contacts and activities can be undertaken by robot systems, caregivers could focus on other aspects of care. However, as indicated by one of the interviewees, whether this actually happens will depend on the situation where the robot is deployed and whether its application has been developed as a co-creation with the patient, carers and healthcare organisation.

Other robots
The potential of the three other types of robot is less obvious for varying reasons. Service robots may be a tool to help patients at home in self-management, at the same time relieving informal and professional caregivers. However, as explained above, it will probably take a long time before robots capable of multiple physical activities become available.
For surgical robots, developments will continue, but breakthrough advances compared with existing technology are not expected, although one interviewee indicated that surgical robots could enable the development of surgical procedures that were not possible before.
Finally, exoskeletons are at too early a stage of development to assess their full potential.

Risks and barriers
A potential barrier to the safe and successful introduction of social and service robots is their acceptance by both healthcare professionals and patients. With the introduction of robots in healthcare, aspects of the job will change. Healthcare organisations should focus on complementarity; not replacing carers by robots, but increasing the productivity of carers by the use of robots (82). In the 2012 report on Domotics in Long-term Care (92), the RIVM recommended that healthcare providers should, in dialogue with carers and their patients, formulate a clear vision of how care is delivered with the aid of technology and how this will increase patients' quality of life without creating risks to their safety. The same recommendation is applicable to the use of robots and technology in general, in long term care. This was confirmed by interviewees. The WRR report calls for 'co-creation', even at the design stage of robot

technology (82). While concluding that currently technical ambitions seem to be guiding robot development, an important message from Bedaf in her dissertation is also that a user centred approach to developing a service robot is essential in order to optimise usability and the acceptability by future users (93). This is echoed by Goher et al., who indicate there is a potential for improving assistive technology to increase robot acceptance and fulfil elderly people's needs (94).

One of the interviewees indicated that there are also legal challenges that may hinder the deployment of robots in healthcare. For example, it is unclear who should be held accountable for an incident in which the robot harms, wounds or even kills the person it is supposed to care for (or any other person) or damages goods – the manufacturer or the care organisation that deploys the robot? Until such legal issues are resolved, it may be expected that manufacturers will be hesitant in bringing robots onto the market and healthcare organisations reluctant to deploy them.

There are also financial barriers. One interviewee indicated that some social robots are currently too expensive for large-scale application, and therefore that a business case needs to be made, along with an implementation plan, before robots are deployed. The interviewee knows several examples of healthcare organisations that discontinued the use of a robot after a pilot that failed due to insufficient preparation in this way. According to Jeannette Pols, professor at the VU University of Amsterdam, as quoted in the recent WRR report (82), because the organisation and financing of home care in the Netherlands involves multiple parties, it is difficult to realise successful technology projects.

A general risk to be mentioned in connection with the use of robots relates to cybersecurity. Many robots are connected to the internet. This carries the risks of intrusion, hacking, loss of control, breached data protection and invasion of privacy.

Finally, one of the interviewees indicated that certain ethical issues related to the use of robots must be resolved by society before they are more widely introduced: for example, the acceptability of putting the intimate care of a person in the hands of a machine. The Rathenau Institute has taken this thinking a step further and suggested that the use of robots should be discussed in the context of human rights (56).

What impact is to be expected on the organisation of healthcare?
The number of robots currently used in care is very small, according to the interviewees. According to Vanessa Evers, a professor in social robotics at the University of Twente quoted in the recent WRR report on robots (82), robots should not be expected to take over home care; however, a likely development is the delegation of simple tasks like floor cleaning, changing beds and delivering food to robots, while carers deliver personal care and thus also remain available for the more complex task of assessing the condition of the patient in a holistic way. For the time being, people in care are definitely needed (1). Nevertheless, it can be expected that social robots will be seen more and more in the healthcare environment. How this will impact the organisation of care is still difficult to say; it will depend on future developments in robotics and on how robots are deployed.

In line with the trend in general surgery towards less invasive procedures, the use of and demand for surgical robots is increasing and new technologies are regularly developed to improve on existing systems (88). Depending on the amount of progress made in the coming years, the impact on surgical practice, and associated hospital logistics, may be less or more gradual.

Expected budgetary impact
The possible budgetary impact of robotics on healthcare is hard to assess, mainly due to the lack of both data and economic studies. While there is an emerging corpus of literature on the costs and cost-effectiveness of surgical robots (37, 47, 83, 89, 95-97), searches in PubMed and OVID-Medline yielded no studies on exoskeletons and only one study concerning a specific service robot (98). This is likely due to the fact that many of the robots that we found are still prototypes. Their penetration in healthcare is as yet very limited. Small-scale studies of the use of social robots in long-term care and the education of special needs groups have been undertaken (99), but whether they add value is not yet clear; nor is their potential for cost savings. Service robots that are able to fully or partly replace healthcare professionals are not yet available.

As far as the cost-effectiveness of the use of surgical robots (such as the da Vinci® telemanipulator) in minimally invasive surgery is concerned, most studies agree that the clinical outcomes of robot-assisted surgery are comparable with those of regular laparoscopy. Yet the former is considerably more expensive and usually takes up more time than regular laparoscopic surgery, though recovery times are usually (marginally) better than with standard treatment (23, 36, 37, 47, 96, 97, 100). Gkegkes et al. (2017), point out that the main reason for the low cost-effectiveness of surgical robots is their price (roughly €1.5 million) and maintenance costs (up to €150,000 per year) (37). The market for surgical robots is currently a monopoly market, although this might soon change: in 2019, important patents of the Da Vinci® robot will expire, which might lead to a changing market for surgical robots (89, 95). Companies such as Medtronic, Alphabet (Google), Johnson & Johnson and TransEntrix (see Appendix 7) have developed or are developing their own versions of a surgical robot which, in all likelihood, will gain market authorisation in the next few years (35, 89, 95). This will lead to greater competition between companies and likely result in lower prices and maintenance costs.

Apart from prices, reimbursement should also be taken into account with regard to the possible budgetary impact of surgical robots. In the Netherlands, robot surgery is reimbursed under standard insurance (‘basisverzekering’ in Dutch). Yet robot-assisted surgery falls under the B-segment of care in standard health insurance, so hospitals and insurers are free to negotiate the price and whether or not it should cover the (extra) costs of using the da Vinci® robot (46, 101). The majority of health insurance companies have decided not to pay extra for the use of robots in surgery (47, 101).

With regard to the broader budgetary impact of surgical robots in healthcare, recent studies show that robot-assisted laparoscopic

prostatectomy (RALP) and the use of robot technology for hysterectomy has only marginal beneficial effects on the use of primary care (general practitioners, physiotherapists) and the amount of hospital days compared with regular treatment (96, 97). However, it has been suggested that robot-assisted surgery can have beneficial effects on the health and wellbeing of surgeons: less mental strain, less lower back, neck and shoulder pain, decreased fatigue and stress levels (47, 102). If this is confirmed by other studies, it might mean that surgical robots reduce health complaints and subsequent loss of work days among surgeons, which in turn could have a favourable economic impact.

3.7 3D printing

What is 3D printing?
3D printing is a type of additive manufacturing. There are several types of additive manufacturing, but the terms 3D printing and additive manufacturing are often used interchangeably. 3D printing is defined as a process of joining materials, usually layer upon layer, by the deposition of material using a print head, nozzle, or another printer technology, as opposed to subtractive manufacturing methodologies (56). 3D printing is the fabrication of objects through the deposition of a material using a print head, nozzle, or another printer technology (56). Objects are produced from a digital 3D file, based on for example a computer-aided design (CAD) drawing or a conversion of a Magnetic Resonance Image (MRI) (103).

Current 3D printers can produce objects in various materials, including plastics, metals, ceramics and wood (104). Different printing techniques can also be used, including stereolithography, selective laser sintering (SLS), inkjet printing and fused deposition modelling. A review by Martinelli et al. includes a list of materials and printing techniques (105). Living cells can also be 3D printed, in applications referred to as bioprinting or biofabrication (106). This technology is important for the fields of tissue engineering and regenerative medicine (see Section 3.7). Since such products are outside the scope of the medical devices regulations, and thus the scope of this report, they will not be discussed in this chapter.

3D-printing applications in medical technologies
The medical sector, including dentistry, represents around 13% of the total usage of additive manufacturing, and is therefore the third largest 3D printing market after the industrial and aerospace sectors (107). Dentistry, orthopaedics, cardiology and cardiothoracic surgery are the disciplines best known to use 3D-printing applications, but other disciplines, including maxillofacial surgery, neurosurgery and oncology, are also using them (64, 105, 108, 109). Tack et al. conclude that 3D printing is well integrated in surgical practice and research (109). They also show that the number of scientific papers on this topic has increased sharply in the past five years. Malik et al. report that the fields of maxillofacial, cardiothoracic and orthopaedic surgery seem to be the greatest innovators in the use of 3D printing (108).

According to the interviewees, and as confirmed in scientific reviews (64, 105, 108, 109), the most important types of applications are:

- Surgical planning by creating a 3D model that can be studied before a surgical procedure, e.g. in paediatric cardiology. The procedure can then be run more efficiently and with better outcomes. Such models can also be used for training purposes and for explaining a planned procedure to patients or their next of kin.
- Surgical planning resulting in the design and manufacture of surgical guides. In orthopaedic surgery, for example, such guides are used to indicate how to place a knee implant, i.e. exactly which part of the native bone to remove and where to drill holes for screws to affix the implant. Apart from such routine procedures, guides can also be designed for surgery after complex trauma, or the surgical removal of tumours, enabling the optimal treatment.
- Production of personalized implants in relatively large numbers, e.g. dental crowns/implants and hearing devices.
- Production of personalised implants for individual patients, e.g. hip implants for 2^{nd}/3^{rd} revision patients, cranial implants for brain surgery patients, splints for windpipe support in children with a birth defect in the trachea.
- Production of personalised external support devices, e.g. braces for hands, feet, spine (scoliosis patients).

Expected developments within the next 5-10 years

In general, the interviewees expect that 3D-printing technology will be further developed, more application areas will make use of the technology, and costs will decrease. Malik et al. also foresee that an increasing number of specialties will be able to implement 3D printing in their daily practice, thanks to the increased use of silicon, gels and bioabsorbable materials, and decreases in production time and costs, for example (108).

According to several interviewees, not only the printers and the raw materials, but also (and especially) the software to convert images to printer instructions and to support users in performing surgical planning is expected to be further developed. With the use of big data techniques and AI, future software is expected to enable wider application at an acceptable price, according to one interviewee.

As more application areas introduce the technology, more healthcare institutions can be expected to invest in it, the volume of 3D-printing applications will increase, and older technology may be replaced. According to one interviewee, larger volumes and the substitution of older technology are expected eventually to lead to lower costs. More specific expected developments are discussed in the next section.

Potential benefits

In general, the main advantages of 3D printing stated by Tack et al. in their review are reduced surgical time, improved medical outcomes, and decreased radiation exposure (109). They note, however, that the subjective character of the majority of these advantages and the lack of supporting evidence do not permit conclusive statements. According to Martinelli et al., the opportunities for preoperative planning, the accuracy of the process and the time saved in the operating room are seen as advantages in many studies, but others stress that accuracy is

not satisfactory and see the time needed to prepare the object as a limitation (105).

In the cardiovascular field, the use of 3D-printing technology is not widespread in the Netherlands. It can be very useful for planning procedures for the more complex congenital heart defects (110, 111). However, there is a need for better standardisation of the procedure for collecting images, the segmentation methods and processes, the phase of the cardiac cycle to be used, and the materials employed for printing (112). One interviewee estimates that a big difference can be made in about 150 such heart operations per year.
Other procedures that can benefit from 3D-printing technology are the treatment of aneurysms and heart valve replacements in adults. If the imaging techniques for heart valves can be improved and the printing techniques further developed, it will become possible to use 3D printing in the thousands of heart valve replacements. Treatment will then become more efficient, and patients may also be subjected to less radiation. Currently, 3D printing is mostly used as an add-on technology, but in the future it could become a superior alternative to existing diagnostics based on a combination of CT scans, ultrasound and catheterisation, according to the same interviewee. Only one imaging technique would be needed to provide the information for the 3D model.

For more complex procedures in orthopaedics, 3D printing can provide a substantial benefit in terms of clinical outcomes, according to one interviewee. One example provided was surgical planning including design and 3D printing of surgical guides resulting in maintaining part of the joint function after severe trauma instead of completely immobilising the joint. Another example is reported in the review by Tack et al., who indicated that improved medical outcomes were reported unanimously in complex hip replacements (109). For more routine procedures, such as knee replacements, a large impact on clinical outcomes is not expected, according to one interviewee. Currently, insufficient data exist to substantiate this. This was also reported by the Belgian Health Care Knowledge Centre (KCE) (113). Opportunities in the field of orthopaedics are mostly related to the efficiency of the 3D-printing process, according to two interviewees. They explained that both planning and the operation itself can be performed faster.
One of the interviewees is working on another opportunity: by setting up a database of MRI scans and X-ray photographs for routine procedures like knee replacements (approximately 20,000/yr), and matching these using computer-based learning techniques, he thinks it may be possible to design surgical guides based on X-rays alone, which is faster and cheaper than using MRI scans.

External support devices for scoliosis patients are traditionally made using the best fitting size available off the shelf. One of the interviewees describes the possibility of combining 3D printing and increasingly available camera techniques and design software. With 3D printing a support device can be made that precisely fits a patient’s body. By using the latest types of smart phone cameras to make a 3D image, and combining this with data from an X-ray, it is possible to design a personalised support device. This means that such devices can also become available in low-resource areas like Africa.

Risks and barriers

According to one of the interviewees, 3D printing can be a disruptive technology as an efficient way to implement patient-specific therapies or to manufacture devices that cannot be constructed otherwise. However, currently such uses are only feasible and/or affordable in niche applications. Existing barriers to widespread application include costs for materials, software and personnel. The use of 3D printing in combination with other technologies, e.g. AI, to create more intelligent software could overcome these barriers and open up availability to the bulk of patients, according to the same interviewee. An example of disruption occurred with hearing devices. Previously, they were hand-made, but within a couple of years 99% of them were 3D-printed.

Martelli et al. conclude that the cost and time needed to produce devices by current 3D technology still limit its widespread use in hospitals (105). They recommend the development of guidelines to improve the reporting of the use of 3D printing in surgery.

Another barrier mentioned by two interviewees is related to the difficulty of gathering clinical evidence on the performance of 3D-printed devices due to the lack of available data, and the long follow-up needed for particular applications such as joint implants. This has implications for the broader acceptance of the technology, as well as for obtaining market access for such devices. The difficulties related to clinical evidence can also complicate acceptance in the reimbursement system, which can present an additional barrier. Furthermore, the way that the application is included in the reimbursement system can influence potential gains and thus the implementation of the technology.

The regulatory framework for access to the market of medical devices (MDR) could also influence implementation of the technology. Currently, discussions are taking place on the definition of custom-made medical devices, including specific debates as to whether 3D-printed medical devices should be considered custom-made. If larger application areas of 3D printing will not be considered custom-made devices, manufacturers will have to provide more evidence in their technical documentation, and undergo more extensive conformity assessments, which would influence manufacturing costs and consequently implementation of the technology. The use of 3D-printing applications brings risks related to quality control of raw materials, the printer and the production process, including correct functioning of the various software applications. The U.S. Food and Drug Administration (FDA) recently issued a guidance document with technical considerations for additive manufactured medical devices (114), which describes relevant aspects. For larger scale applications, e.g. those carried out by specialised companies, these risks can be controlled well. For small-scale applications, e.g. in a dentist’s surgery or at a decentralised place in a hospital, this will be much more difficult.

A different type of risk mentioned by one of the interviewees was the decrease in expertise of surgeons. For example, most practising orthopaedic surgeons have great expertise in placing joint implants, even without surgical guides. If the standard procedure is to include personalised surgical guides, this expertise will disappear but may still be needed in certain procedures.

Expected impact on healthcare
The potential impact of 3D-printing technology on healthcare very much depends on how the technology develops and on how implementation takes place. Interviewees indicate that, if the technology keeps developing as foreseen and if the healthcare system is able to adapt where necessary to take advantage of the opportunities provided by 3D printing, a significant impact can be expected. Malik et al. even conclude that this is an exciting and interesting technology with the capacity to radically change healthcare and revolutionise modern surgery in the foreseeable future (108).

For example, according to one interviewee, if it will become possible to use 3D-printing technology for surgical planning in large application areas like heart valve replacement surgery instead of traditional combinations of diagnostics – i.e. as a substitution technology instead of an add-on technology. This would mean a big change, not only with regard to the procedure itself, but also to the types and volume of diagnostics needed.

In the case of planning joint implant surgery in such a way that only one personalised set of implant and surgical guides is needed during the operation, one interviewee anticipates a substantial logistical impact: fewer implants will need to be kept in stock and, instead of having a range of implant sizes ready for use in the operating theatre, only one size needs to be available. This means that a much smaller set of surgical guides and associated instruments will be needed in the operating theatre, which in turn will reduce reprocessing as well as simplifying logistics within the hospital.

Another critical factor in the potential success of 3D printing in healthcare, according to one interviewee, is whether healthcare professionals are sufficiently aware of opportunities and how this can be achieved. This means that personnel need to be trained in the new technology, and the curriculum for studies in surgery might need to be adapted. In addition, Martelli et al. reported that several surgical teams stressed that the cooperation between many stakeholders was complex, and concluded that it is important that surgeons can accept the support of external technicians without fearing loss over their leadership (105). Furthermore, one interviewee indicated that correctly scheduling both time for pre-operative planning and for the actual procedure in the operating theatre is necessary to benefit from the advantages of 3D printing technology. This also needs to keep pace with developments. For example, as stated by Malik et al., the technology may currently not be fast enough for emergency procedures (108), but in the future, production times can be expected to decrease dramatically, widening the scope of its application.

In order to enable surgical planning in multiple disciplines, one of the interviewees strongly advocated setting up centralised facilities for 3D printing in specialist healthcare institutions. In this way, a substantial volume can be reached, meaning that a quality management system can be implemented, and the necessary technical/engineering expertise to complement the clinical expertise can be achieved in a cost-effective manner.

Expected budgetary impact

As is the case with eHealth and robotics, the impact of 3D printing on the healthcare budget is difficult to predict. The expectations, however, are high (105, 108, 109, 115). A recently published (2018) impact analysis by the KCE found that cost-related information on 3D printing is scarce. While many studies claim that 3D-printing applications are cost-effective or even cost-saving, such claims are rarely backed by quantitative data (113). Available economic studies varied in quality, sample size and time horizon. The KCE concluded that, on the basis of the results of their review, the frequently reported claim that 3D-printed applications will reduce surgical time and costs and improve patient safety cannot be supported (113).

At the moment, 3D printing is still a relatively expensive option for many applications (105, 108, 115). It does, however, hold the promise of low-cost/low-volume production of items (i.e. implants). 3D printing is becoming more competitive for small standard implants and prosthetics, as employed in spinal, dental and craniofacial disorders (115). Currently, the main cost limitation is the often high start-up costs, and, as one interviewed expert pointed out, the acquisition costs of 3D printers and printing materials have decreased in recent years and will probably continue to do so. Yet the software needed to translate images and scans into a 3D-printed model is still expensive. Similar assessments are to be found in the literature (105, 108, 115).

It can be expected, as mentioned earlier, that 3D printing will result in changes in the logistical processes in healthcare: fewer implants need to be kept in stock and transported from place to place. Likewise, a smaller set of surgical guides is needed. Whether this will result in lower healthcare expenditure is uncertain. At the moment, most hospitals use a system of consignment stock (‘consignatievoorraad’) for implants. This means that implants held in stock at a hospital are, from a legal point of view, still the property of the manufacturer and are only paid for once they are used (116). Similarly, the expectation that centralised 3D printing will lead to lower costs (115) is uncertain. While economies of scale will in all likelihood result in lower production costs, centralising production will cancel the benefit of being at the ‘point of care’. Production time and transportation costs will then have to be taken into account as well.

As mentioned above, 3D printing also holds promise as a time-saving instrument, either by making preoperative planning easier (e.g. by making a 3D model of a heart) or by providing tailor-made surgical guides or implants at the point of care (108, 109, 115). Whether or not this will result in lower healthcare expenditure depends on many other factors. Time saving in healthcare does not automatically lead to lower healthcare expenditure, as the time saved will often be used to deliver more healthcare, thus increasing the overall volume. Whether 3D printing will also result in lower prices partially depends on the system of reimbursement. In the case of the Netherlands, the DBC/DOT financing structure (also known as Diagnosis Related Groups or DRGs) does not make a distinction between MRI scans and 3D-printed models. Both are considered to be paid out of the budget allocated to a specific DBC/DOT. If 3D printing does indeed become a standard procedure,

lower prices will have to be negotiated first, for a decrease in healthcare expenditure to occur.

3.8 Other medical technologies with a potentially major impact

Besides the technologies discussed in detail in Sections 3.5–3.7, the literature search and interviews addressed many other technologies in the field of medical technology and *in vitro* diagnostics that may have a major impact on healthcare in the coming years. In this section, a number of examples are briefly mentioned, providing a broader perspective on technological developments that can be expected in the near future.

Tissue engineering and regenerative medicine
Regenerative medicine is the branch of medicine that develops methods of regrowing, repairing or replacing damaged or diseased cells, organs or tissues. The broad field of regenerative medicine includes tissue engineering. Tissue engineering uses scaffolds, cells, biologically active molecules separately or in combination to improve or replace biological tissue or even whole organs (117). Applications using engineered viable human cells or tissues has great potential impact. However, they are classified as Advanced Therapy Medicinal Products (ATMPs) (118) and are excluded from the MDR, and thus outside the scope of this report. They will not be discussed here.

Biodegradable materials for medical applications
Biodegradable materials for medical applications are emerging. Biodegradable materials are biomaterials that are broken down and resorbed or excreted by the body after completing their temporary function. They can roughly be subdivided into metallic materials, such as magnesium and its alloys, and (synthetic) polymeric materials, such as polyesters and polyamides (119). Biodegradable materials without living cells are within the scope of the MDR. Materials that are biodegradable may have a number of advantages over traditional polymeric and metal biomaterials. Permanent materials used for implants may cause adverse effects such as physical irritation, accumulation of metal in tissues and chronic local inflammation. Moreover, a second surgery in order to remove the implant after healing to avoid potential adverse effects may be necessary. Moreover, implants for children do not adapt in line with the growth of the child. Biodegradable materials for these applications may offer the advantages of having sufficient strength until surrounding tissue has healed, not causing an inflammatory response, and being metabolisable by the body after having fulfilled their purpose (120).

An example is the biodegradable vascular scaffold (BVS). Like a permanent metal cardiovascular stent, a BVS is inserted into a blood vessel to alleviate a blockage. The scaffold supports the vessel during the critical period of healing, and is then resorbed by the body (121). Another example is the use of magnesium-based orthopaedic implants for bone fracture fixation. Orthopaedic implants replace a missing joint or damaged bone, but may also be bone screws used as fastening elements in prosthetics (122). Permanent metals may induce stress shielding, resulting in re-fracture, and have to be removed after healing. Magnesium-based implants degrade via corrosion, possess adequate

mechanical strength, and have been reported to stimulate new bone formation (122).

Materials-Driven Regeneration

Another emerging development in the field of regenerative medicine is in situ tissue engineering using synthetic material, called Materials-Driven Regeneration. In comparison with ATMP, tissue engineering without the use of living cells has other criteria to meet with regard to regulation and licensing for market authorisation: unlike ATMPs they are likely to be regulated by the MDR. Scientists have managed to create a bioresorbable heart valve without the use of living cells as an alternative to current prostheses, which have the disadvantages of limited durability and complications. Kluin et al. used a synthetic approach to populate a slow-degrading elastomeric valvular implant with endogenous cells to form new valvular tissue inside the heart. The pulmonary valve was implanted in sheep and showed functionality up to 12 months, during which a layered collagen and elastic matrix gradually replaced the implant (123). This shows great potential for children with heart valve defects, as this type of valve will adapt in size as the child grows, thus eliminating the need for multiple operations. In the coming years, research from the group of Kluin et al. will focus on the recovery of complex organs and their functioning. This not only requires functional tissue such as heart tissue or kidney tissue, but also, for example, new bone, cartilage and blood vessels (124).

The developments described above are expected to emerge in the coming years. When more mature, developments may lead to more personalized and less invasive treatments (125, 126).

New IVD techniques

The majority of emerging medical technologies that surfaced in this horizon scan are medical devices under the MDR rather than the IVDR. However, the field of *in vitro* diagnostics (IVDs) also offers many promising innovations that are expected to emerge in the coming years. These innovations may offer major advantages for patients, such as more personalised and faster treatment. As one of the interviewees indicated, diagnostics in general – including IVDs, but also, for example, medical imaging – are very important for effective and efficient healthcare, as they form the basis for decisions and choices in treatment. This paragraph offers a few examples of innovative IVD technologies.

Liquid biopsy

A liquid biopsy involves the identification and analysis of biomarkers for cancer or other diseases in non-solid biological tissue, primarily blood. This technique is mainly used as a diagnostic and monitoring tool for diseases, including cancer (127). Unlike traditional biopsies, which require invasive procedures including surgery, liquid biopsy is largely non-invasive, which is a great advantage for the patient and offers opportunities for screening applications (128). Biomarkers for liquid biopsy include cell-free DNA, microRNA and circulating tumour cells. Cell-free tumour DNA is shed by a tumour into the bloodstream, and is much more abundant than the actual tumour cells. Therefore, it provides an opportunity for non-invasive diagnoses and monitoring of

cancer. The abnormal distribution of DNA methylation is a characteristic of many cancers. The methylation of cell-free DNA may be analysed using blood samples, and is promising as a biomarker for cancer diagnosis, prenatal diagnosis and organ transplant monitoring (129).

In June 2016, the FDA approved the first liquid biopsy test for on a cancer patient, to detect mutations relevant to the treatment of non-small cell lung cancer (130). Several companies are developing test kits, and studies are under way on biomarkers for a variety of cancers, including blood-based biomarkers for prostate cancer (131), bladder cancer (132) and breast cancer (133). When available, liquid biopsy is currently complementary rather than an alternative to tumour biopsy or other diagnostic procedures. Comparative clinical studies may find additional indications in the diagnostic evaluation of cancer but also for future screening, diagnosis, prognosis and treatment for other diseases, including cardiovascular disease and diabetes.

Next-generation sequencing

DNA sequencing is the method used to determine the order of nucleotides. Next-generation sequencing (NGS) is an overarching term for a number of modern DNA sequencing technologies, including Illumina, Ion torrent and SOLiD (134), designed to sequence an entire human genome or a small number of individual genes in specific areas of interest by processing multiple DNA sequences in parallel.
NGS may, for example, be used to diagnose (rare) congenital abnormalities at the intensive care unit, which is less invasive, less costly, and even quicker than traditional diagnostic procedures (135). NGS can be further used to determine the carriage of genetic disorders. NGS also has applications in *in vitro* diagnostics. The first NGS platform to receive FDA clearance for IVD use was the Illumina MiSeqDx system, with assays for cystic fibrosis variant genotyping (136).
In the future, NGS may be used for (cancer) molecular diagnostics, e.g. to obtain specific cancer-related gene-sequence information (137). NGS may offer easier access to genetic information. On the downside, there are multiple ethical considerations, such as whether patients should or should not be informed that they are carrying genetic disorders, or even about genetic relationships.

Point-of-care diagnostics

Point-of-care (POC) diagnostics are medical diagnostic tests performed at the time and place of patient care, which can be in an operating theatre, at the patient's bedside or in a GP's surgery. Among the advantages of POC testing is the fact that no medical laboratory is needed, so there is faster access to test results. This may facilitate better and quicker diagnosis – and consequently treatment (since better clinical decisions can be made) – and monitoring. POC testing can allow more people to receive diagnosis and treatment at home or in primary care. Hospital-related costs may be reduced and patients' quality of life may increase as the number of hospital visits decreases.

POC testing includes blood glucose testing, blood gas and electrolytes analysis, screening for drug use or abuse, urine strips testing, pregnancy testing, faecal occult blood analysis, and cholesterol screening. The use of POC diagnostics will increase, and new tests are

emerging. For example, POC is available for more and more infectious diseases including HIV, HPV and influenza (138, 139). In the coming years, there will be a trend towards mobile testing with smart devices. Several POC diagnostic tests are under development, which will result in a new generation of accurate, fast and economical POC tests (139). In order to achieve their potential, continual improvement of the biosensors – the most critical components of POC tests – is paramount.

Rapid developments in POC testing may lead to an increase in usage and correspondingly in patients to be treated. Moreover, the same technologies used in POC tests are often applicable to devices for self-testing. Via this route, they can be expected to play a role in enabling self-management and contribute to possible shifts in the organisation of healthcare. One of the interviewees indicated that the increasing use of self-testing also places a higher demand on the patient, who has to interpret the test results and decide what action to take.

Synthetic biology

Synthetic biology may be regarded as a new subfield of modern biotechnology. It comprises the design and construction of new biological parts, devices and systems, with a strong focus on the engineering aspect of genetic circuitry and genomes (140). Synthetic biology combines the disciplines of biotechnology, molecular biology and genetic engineering. It has applications in biosensors, targeted drug delivery products and engineered human cell products (all beyond the scope of this horizon scan), among others. Synthetic biology also has applications within the IVDR. For example, non-living biosensors composed of genetic circuits in order to detect e.g. cancer cells or pathogens.

Other developments with implications for medical technology

Some developments in the field of medical technology do not comprise one specific technology but enable the emergence of innovative devices – such as nanotechnology. Conversely, there are developments in healthcare that are enabled by medical technology – such as personalised medicine. Both of these developments are in some way binding the subjects that are addressed in this horizon scan.

Nanotechnology

Nanotechnology is the manipulation of matter with dimensions of less than 100 nanometers. Nanotechnology in medicine is a growing area and has applications ranging from complex drug delivery systems to advanced therapy techniques. The field of medical technology also benefits from innovative features that are enabled by nanotechnology. In 2015, the RIVM produced an overview of the field of medical devices using nanotechnology, comprising both products already on the market and those expected within five years (141).

Nanocoatings are being applied to implants, such as vascular stents or orthopaedic devices, to increase biocompatibility and improve integration with surrounding tissues. Nanomaterials with antimicrobial properties are also used in wound care and medical textiles. Moreover, new *in vitro* diagnostic procedures benefit from developments in the field of nanotechnology. For example, nanotechnology-based strategies

are used for early cancer diagnosis using cell-free circulating tumour DNA (liquid biopsy) (142), for the development of highly sensitive and selective biosensors and for a future generation of POC tests (143). Other trends in the field of nanotechnology covered in the RIVM report are the mimicking of naturally occurring structures, e.g. in dentistry and orthopaedics, neurology and cardiology; the improvement of the bioelectrical interface between devices and neural tissue; and the development of batteries to be used in active implantable devices such as pacemakers, so that they have an increased lifetime. The effectiveness of cancer therapies like chemotherapy and radiation therapy can be enhanced by nanotechnology when nanomaterials are injected into a tumour and placed in an alternating magnetic field, generating an increase in temperature (hyperthermia) (141).

Nanotechnology has many more potential applications in the medical field and the further possibilities will emerge in the coming years. Such developments are expected to have a major impact on other innovations in medical technology. In the MDR, specific provisions have been included for nanomaterials. It is still uncertain what kind of impact this may have.

Personalised medicine

Personalised medicine is a medical model for classifying, understanding, treating and preventing disease on the basis of data and information on biological and environmental differences between individuals; medical care is customised to the individual patient (144). The field of personalised medicine is very broad and covers not only the clinical/ biological characteristics of an individual, but also their lifestyle and social, cultural and environmental factors. More and more biomarkers are being discovered that can be detected using novel IVD techniques. NGS is an important development; a lot of effort is now put into genotyping tumours and linking these data to therapy outcomes. In the future, it may be possible to tailor treatments to individuals, thereby improving outcomes. If using a medicinal product, or determining its dosage regime, is coupled to the outcome of an IVD test, the latter is being referred to as a companion diagnostic. The new IVDR includes specific provisions for such products, including consultation of the medicinal product authorities. This is an important step in the process of implementing personalised medicine in a safe and effective way. As indicated in the Public Health Foresight Study 2018 (145), implementing personalised medicine may also require changes in the organisation of healthcare, where currently mostly standardised care processes are being used.

Besides nanotechnology and personalised medicine, medical technology enables other innovations with regard to many aspects of personalised healthcare. These innovations are of major importance in the healthcare system, as they are likely to fulfil future care demands. This report addresses medical technologies that are likely to have a major impact in the next 5–10 years. Many of the subjects covered, including 3D printing, eHealth, regenerative medicine, NGS, companion diagnostics and POC testing are contributing to the development of more personalised and individually targeted healthcare.

3.9 Important developments in healthcare beyond the scope of the horizon scan

This horizon scan of medical technology with a potentially major impact on healthcare has focused on medical technology or techniques within the scope of the MDR and/or the IVDR. However, the implementation of technical innovations must be seen in the wider context of the developing organisation of healthcare and its relationship with the technology industry. Moreover, emerging medical technology does not stand alone, and preconditions must often be met to put technology into service. Certain technological developments may not be within the scope of the MDR/IVDR, but are nevertheless inevitable for the successful implementation of emerging technology. Moreover, some of those technologies may have a comparable impact to MDR/IVDR technologies when considering the future care demand, medical/societal needs, changes in the organisation of healthcare and the development of a sustainable healthcare system. This is certainly the case for developments concerning the collection, use, exchange and storing of digital data. This was emphasised by multiple interviewees and is also mentioned in the literature (1, 146). Therefore, we include a paragraph briefly describing these technologies, even though strictly speaking they are outside the scope of this report.

Data-driven technology, big data, interoperability, artificial intelligence
In interviews conducted in the context of this horizon scan, and in literature and future perspectives in medical technology, often the subject of interoperability of data and data-driven technology comes across. Data-driven technology is the technology required to collect, exchange and perform advanced analysis of large quantities of electronic data from different origins (1). Data in the field of healthcare originates, for example, from patient records at various healthcare providers, demographic data sources, and measurement equipment. Moreover, people are collecting more and more health data themselves, e.g. from wearables, medical devices and sensors, which may be combined with details about their environment (146). Data from all kinds of sources is referred to as big data (21).

Outside the medical field, data-driven technology has become indispensable for many activities, such as navigation, logistics, marketing and retail (1). Healthcare is lagging behind, which is a barrier to the implementation and scaling-up of innovative medical technology. According to one of the interviewees, it is necessary to start by building a good basic data infrastructure, which is a precondition for a healthy healthcare environment. Such an infrastructure implies the interoperability of ICT systems within and between different suppliers of technology but also different healthcare providers. A lack of interoperability will hinder an efficiency shift with regard to data technology and may even result in safety issues. According to one interviewee, many problems in healthcare may actually be caused by poor communication between systems. The risk of privacy-related issues and safety threats is often put forward as a barrier to the adoption of data-driven technology in healthcare.

Combining and interpreting data from different sources that have a link with people's health status may provide valuable new insights. The powerful technologies that are becoming available to analyse and work with big data, while not being devices in themselves, can thus enable the development of novel diagnostic and therapeutic devices. Data-driven technology may enable people to react more swiftly in the case of incidents with regard to exposure and healthcare, and provides a basis for personalised healthcare. Combining this with AI can further improve and optimise technologies. Possibly the greatest impact of the full exploitation of the power of data is improvement in the efficiency of healthcare, as it may lead to major advances in planning, organisation and communication. In future, healthcare will have to be managed by fewer people, so for the qualitative improvement of care one must look at the organisational side.

Data-driven technology may also play an important role in the development of the emerging technologies covered in this horizon scan. In the case of 3D printing, combined patient data and computer-based learning will help to develop personalised products in a better, quicker and more economical way. eHealth applications and wearables generate large amounts of specific data, which may have great value when combined with existing data sources. Service robots may use collected data and AI to improve interaction and deliver more patient-specific care.

Blockchain in healthcare
Blockchain is a database technology best known for being the technique behind the Bitcoin (147). Although there is no single general definition of blockchain, it has certain distinctive elements: (i) transactions between parties are signed using cryptography; (ii) all transactions are sent out in a 'peer-to-peer' network; (iii) one or more transactions are put in a block, which is added to the blockchain; (iv) the moment a block is added to the blockchain, every participant in the network adopts it; (v) there is no single central data store; instead, all parties involved have a copy. Blockchain offers possibilities to deal with applications in the areas of identification, permission to exchange data and the coordination of data exchange in a fundamentally different way. An important characteristic of blockchain is the fact that it is inherently resistant to the modification of data (148, 149).

Besides its straightforward financial and logistic applications, blockchain may also have applications in healthcare. For example, it is suggested that blockchain has significant implications for the interoperability and exchange of health information, and for secured access to patient data. It is suggested that it can reduce complexity as well as the cost of transactions (150). Barriers to data exchange in healthcare include the fact that patients still have only limited access to their patient data/medical records. In the field of data exchange between professionals there is also room for improvement. The underlying reasons are organisational, financial and legal, as well as technical, and technology alone cannot solve all these problems. However, blockchain may be a useful tool with which to implement changes to the roles and responsibilities with regard to data of patients, professionals and healthcare organisations, for example through more transparency and

control over data exchange. Blockchain will not solve the problem of fragmentation in healthcare information, but it may serve as an intermediary between the patient and the available data from different sources.

Although the technical possibilities are promising, the impact blockchain will have in the way healthcare information is stored and exchanged is as yet difficult to forecast (149). Greater knowledge and experience are needed in order to mature the technology of blockchain and will have to point out the actual utility of blockchain in the healthcare practice (149).

4 Discussion and conclusions

Based on the future healthcare demand, this study aimed to investigate which medical technologies, expected to emerge in the next 5 to 10 years, could fulfil medical or societal needs of the future. This investigation resulted in a horizon scan of medical technologies likely to have a major impact on the organisation of healthcare or healthcare expenditures.

One of the main challenges of this investigation was how to select medical technologies that fitted the aim of the study, without undertaking an extensive analysis of all the medical technologies expected to emerge in the next 5–10 years. In order to do this, it was necessary to identify the relevant types of impact to be taken into account during selection. An important factor to consider was that the study should become one of the building blocks for the Dutch Ministry of Health, Welfare and Sports to develop a long-term policy agenda for medical technologies. This meant that the relevant impact types should be in line with the Ministry's mission to safeguard the quality, safety, accessibility and sustainability of healthcare. At the same time, they should be consistent with the values and expectations of Dutch society and meet the healthcare demand of the future. This led to the following set of impact types:

- fulfilling (unmet) medical needs or societal needs;
- impact on the organisation of healthcare;
- budgetary impact;
- Potential for substitution of existing methods;
- impact for a large magnitude of the patient population;
- impact for individual patients.

We propose that this set of impact types can serve as a basis to develop types of impact to consider for future horizon scans with a similar context.

Using this set of impact types, a list of candidate technologies was compiled from the international scientific and grey literature describing emerging medical technologies. In addition to the information from the literature, further input was obtained from opinion leaders in the broad field of medical technology and/or healthcare. In selecting these opinion leaders, it was made certain to include different perspectives, including those of academia, the healthcare sector, industry, health insurance organisations and patients organisations. This meant that the expert judgement of the investigators would be in line with the views of a broad cross-section of society.

eHealth, robotics and medical 3D printing were selected as technologies for more elaborate analysis, as they were expected to have a major impact. A number of other technologies were also identified as potentially having a significant impact, but it was not feasible to analyse all of these in depth during this project. However, short descriptions of these technologies were included.

For all the technologies described, it proved difficult to provide a comprehensive description without stretching the limitation in the scope to confine this study to technologies regulated by the MDR or the IVDR. In most cases, applications based on these technologies have borderline areas or are even clearly outside the scope of the MDR or IVDR. However, as pointed out repeatedly by the opinion leaders and experts interviewed for this study, these might well be the applications/ technologies that will have a greater impact on the organisation of healthcare or on the healthcare budget than the technologies that are fully within the scope of the MDR/IVDR. They may also be instrumental in addressing future healthcare demand or societal needs. Therefore, although not analysed in detail, such applications were included in this report.

In order to obtain information for the three technologies analysed in more depth, we interviewed experts in the particular technology with backgrounds in relevant medical or healthcare disciplines, academia or industry, or as patients themselves. Their input was compared with the scientific and grey literature. In this way, the level of information provided in this report should fit with its purpose to serve as one of the building blocks for the long-term policy agenda for medical technologies the Ministry is intending to develop.

Innovations in medical technologies are constantly emerging. In order to keep track of future developments and to be able to evolve strategies and policies related to technologies or healthcare, a more structural system of horizon scanning should be developed. To do so, further exploration and refinement of the methods used to identify technologies that have the potential to address medical or societal needs would be valuable. Medical innovations are increasingly generated by converging technologies, often resulting in products that are at the borderline between medical devices and medicinal products. Therefore, investigating the possibility of connecting such a system for more structural horizon scanning of medical technology, with a system of medicinal product horizon scanning could be useful. Furthermore, it could be useful to set up interactions or even collaborations in an international context in order to create synergy by sharing experience and knowledge in an efficient way.

As a general observation, the various stakeholders agree that new technologies should primarily address current medical and societal needs. In this context, one of the interviewees indicated that industry is indeed moving towards ‘value-based healthcare’. In order to stimulate the successful development and implementation of new medical technologies based on this principle, a coordinated effort with input from all relevant stakeholders would appear to be the best way forward. This approach should be applied on a micro level (individual developers and healthcare organisations) as well as on a macro level (national associations). Involving different stakeholders – patients, healthcare professionals, insurance companies and regulators – from the early stages of product development will lead to products that are better equipped to address medical or societal needs in a cost-effective manner. In addition, potential safety and regulatory issues can be tackled at an early stage (safety by design).

In order to successfully implement a new technology in a healthcare organisation, preparations by a multidisciplinary team will enable the identification of the necessary financial, infrastructural, logistical, and organisational provisions, so they can be managed in advance. This will also motivate everyone involved to welcome the new technology, which is crucial to making it a success. It should also be realised that the implementation of new technologies may involve new competences and changes in the roles of healthcare professionals as well as of patients.

At a national level, joining forces of stakeholders to optimally combine technological possibilities and medical or societal needs could be agenda setting. Such an effort should guide innovators in their research and development, as well as healthcare organisations and healthcare professionals in making optimal use of the opportunities provided by new and emerging medical technologies. It would also improve regulatory preparedness for future innovations and help the government to design strategies and policies aimed at the optimal development of the healthcare system.

5 Literature

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Appendix 1: Search strategy in PubMed and Google

PubMed search terms used in various combinations:
Medical innovations
Medical technology
Medical devices
Exciting, novel, highlight, trends, breakthrough, milestone, and discovery

Only English articles related to humans were included
Limited to articles published between 2010 and 2017
Search was performed in November 2017

Google search terms used in various combinations:
medical technology, medical innovation, technologies and innovations
Search was performed in November 2017

Appendix 2: Questions used in interviews as part of horizon scan of medical technologies

This appendix presents the general interview guide. The topic list was adapted in response to the specific expertise of the interviewees and the technologies to be discussed. The topic list consisted of three main parts:
Part 1: type of impact and prediction of technologies with major impact;
Part 2: impactful developments in medical technology;
Part 3: budgetary impact.

Part 1: type of impact and prediction of technologies with major impact

1. The scope of this horizon scan is limited by the Medical Device Regulation (MDR) and the In vitro Medical Devices Regulation (IVDR), and therefore this scan focusses on medical technology with a potentially major impact. In your view, what technology in healthcare is covered by these definitions?
2. In your opinion, when does a medical technology have a major impact?
    a. Which factors play a role?
    b. What are the types of impact that are relevant in this context? – e.g.
        i. impact on the healthcare environment/organisation of care;
        ii. magnitude of the patient population;
        iii. impact for individual patients;
        iv. budgetary impact.
3. To what extent it is possible to predict what medical technologies will have the greatest impact?
    a. Could it be that a technology that is not currently in our sights will have a major impact?
    b. From which (non-medical) field could such a technology be expected?
4. What may be the role of medical technology with regard to fulfilling medical needs or societal needs?
    a. What medical needs of patients may be fulfilled by medical technology (e.g. better treatment, more efficient processes, healthcare closer to the home situation)?
    b. What is the potential impact of medical technology on patients with regard to quality of life, life expectancy and participation in society?
    c. What societal needs may be fulfilled by medical technology (e.g. self-management, independence, social needs)?

Part 2: impactful developments in medical technology

5. Which (new) developments in the field of medical technology do you expect to have the greatest impact in the next 5–10 years?
    a. Why specifically these applications/developments?
    b. What are the relevant types of impact (see also question 2b)
    c. In what period is this impact expected (also: where are we now – research or implementation?)
        i. In your estimation, how concrete is the application of this technology in 10 years?
    d. Can you already name specific examples of applications of this technology?
        i. Primary care/secondary care – patient or healthcare organisation, target patient, etc.
    e. The aim of this horizon scan is to describe expected impacts on the healthcare environment and healthcare budget. In what way could the technology you mentioned impact these, and to what extent?
    f. What may be barriers to the success of this technology?
        i. Are these barriers of a financial, legal, practical or ethical nature?
    g. What possible risks does this technology involve?

Part 3: budgetary impact

6. In general: what may be the direct budgetary impact of a new medical technology?
7. What may be the wider budgetary impacts of a new medical technology (e.g. including costs due to secondary effects)? For example:
    a. Training of staff and infrastructural adjustments (ICT);
    b. Upscaling or necessity to specialise concentrate (e.g. in proton therapy);
    c. Compatibility of medical technology in the chain (relevant to the exchange of data);
    d. Open or closed ICT systems and data security;
    e. Changing boundaries between public and private.
8. Is the potential benefit to healthcare from developments in medical technology worth the investment or may it even induce savings?

Appendix 3: Interviewees

General
- Jan Jaap Baalbergen: Leiden University Medical Centre (LUMC)
- Matthijs van der Bijl: Manager Innovations at Health Insurance Organisation VGZ
- Marjon Kallewaard: Director Quality at the Dutch Federation of Medical Specialists (FMS)
- Mira Levi: Cluster Manager Care FME (the Dutch employers' organisation in the technology industry)
- Wija Oortwijn: Partner at Ecorys NL and Assistant Professor at Radboud University Medical Centre
- Roelf van Run: Director at Dutch medical devices industry association Nefemed
- Marie-Hélène Schutjens: Dutch *in vitro* diagnostics industry association Diagned
- Alex Verhoeven: Senior Advisor at the Dutch Federation of Medical Specialists (FMA)
- Astrid Verkaar-Lukkassen: Policy Advisor at Dutch Hospital Association (NVZ)
- Eveline Wouters: lector Health Innovations & Technology at Fontys and professor Successful technological innovations in healthcare at Tranzo (Tilburg University)

eHealth
- Jaco van Duivenboden: Senior Advisor eHealth (healthcare & IT and innovation) at Nictiz
- Nick Guldemond: Associate Professor Integrated Care and Technology, Erasmus School of Health Policy & Management
- Marcel Heldoorn: Manager digital care at the Dutch patient federation
- Remco Timmer: Digital accelerator innovation lead at Philips

Robotics
- Marcel Heerink: Associate lector robotics at Windesheim Flevoland
- Henny Mulders: Senior policy advisor at Actiz
- Lambèr Royakkers: Associate Professor in the ethics of technology at Eindhoven University of Technology
- Maarten Steinbuch: Professor control systems technology at Eindhoven University of Technology
- Renée Verwey: Senior lecturer and researcher at Zuyd Hogeschool and secretary of VenVN (professional organisation of carers and nurses)

3D printing
- Mark Hazekamp: Professor paediatric cardiac surgery at Leiden University Medical Center (LUMC)
- Lodewijk van Rhijn: Professor orthopaedics at Maastricht University Medical Center (MUMC)
- Bram Smits: Public Affairs Officer at Materialise

Appendix 4: Social robots

Name	Description	Additional information
Alice	This is a robot designed to talk to people. It does this partly through algorithms and partly by remote control. It is well known in the Netherlands through the documentary 'Ik ben Alice' made by Sander Burger.	http://www.ikbenalice.nl/ https://www.nrc.nl/nieuws/2015/07/06/hallo-ik-ben-alice-de-zorgrobot-1514381-a1295423
AV1	AV1 is a telepresence robot that enables sick children to follow school lessons. The robot looks like a simple plastic doll and is equipped with a video camera, microphone and speakers. The child following the lesson can turn the camera in a 360° arc so that it can look around the class. The child is, however, not visible to the rest of the class. No comment is given on privacy issues.	https://www.robotzorg.nl/nieuws-robotzorg/ziek-kind-kan-weer-participeren-dankzij-avatar/
Charlie	Charlie is a robot, built on the NAO platform from Aldebaran, that is programmed to help children to deal with diabetes. The robot works with the children for a longer period (whole day). It educates them, it plays games with them and makes conversation with them, and it can take the child for a walk. During the activities the child is given diabetes-related information.	https://www.diabetesfonds.nl/over-diabetes/nieuws/robot-charlie-voor-kinderen-met-diabetes
GiraffPlus	GiraffPlus is extended domotics including a videoconference screen on wheels. The robot works in conjunction with sensors in and around the home as well as on the body, has built-in videoconferencing capabilities and is able to follow the person around. The sensors can measure blood pressure or detect when the person falls down. It appears that most of the performance can be received from a second- or third-generation domotics system and a tablet computer or smart phone with a Skype-like interface.	http://www.giraffplus.eu
iRobi-Q	This robot was originally developed as an educational toy for children. It makes sounds, turns its head, rolls across the floor and waves its arms. Is has a pre-tablet touchscreen on its chest as the main interface. In a study it used to deliver tele-healthcare to COPD patients to increase their adherence to a medication programme and home rehabilitation, improve their quality of life, and reduce hospital readmission compared with a standard care control group.	https://www.icthealth.nl/nieuws/robots-helpen-longpatienten-nazorg/
JustoCat	JustoCat mimics some of the behaviour and sounds of a cat. JustoCat is furry and feels like a real cat. It responds to petting like a real cat by giving head rubs and making purring sounds. Together with a range of other furry animals it may have the same effect on the elderly as Paro the seal.	http://www.robots.nu/justocat/
Kaspar	Kasper is a child-sized humanoid robot designed as a social companion to improve the lives of children with	http://www.herts.ac.uk/kaspar/meet-kaspar

Name	Description	Additional information
	autism and other communication difficulties. By interacting and behaving in a child-like way, Kaspar helps teachers and parents support children with autism to overcome the challenges they face in socialising and communicating with others. It acts as a social mediator, helping children to interact and communicate with adults and other children, by using a range of simplified facial and body expressions, gestures and speech to interact with children and help them to learn fundamental social skills such as imitation and turn-taking – skills that children with autism can find very challenging.	
Kuri	Kuri is a surrogate pet. Kuri is a simple, doll-like robot that rolls around, follows people through the house and responds to questions and petting. It also acts like a webcam with a microphone on wheels and has built-in Bluetooth speakers.	https://www.bosch.com/explore-and-experience/kuri-a-home-robot-for-life/
Mabu	Mabu is a static, doll-like object with a moving head and eyes. It holds a tablet computer. Mabu apparently offers the same support any tablet can offer, such as communication with caregivers, reminders to take medicine and calls for help.	https://www.robotzorg.nl/nieuws-robotzorg/mabu-persoonlijke-zorgverlener-thuiszorgpatienten/
Paro	Paro is a therapeutic robot baby harp seal. It is supposed to be very cute and to have a calming effect on and elicit emotional responses from patients in hospitals and nursing homes. The effect is intended to be similar to that of animal-assisted therapy. Paro is fitted with microphones, tactile sensors covering its fur, touch-sensitive whiskers, and a delicate system of motors and actuators that silently move its limbs and body. It is designed to seek out eye contact, respond to touch, cuddle with people, remember faces, and learn actions that elicit a favourable reaction. Paro also responds to sounds and can learn names, including its own. It produces sounds similar to those of a real baby seal but, unlike a real baby seal, is programmed to be active during the day and to sleep at night.	https://en.wikipedia.org/wiki/Paro_(robot) https://www.skipr.nl/actueel/id23176-paro-verbetert-stemming-dementerende.html www.mxi.nl/robotica
Pepper Phi	Pepper is a hospitality robot that can also be used as an activator for the elderly in care by programming it with dedicated exercise programmes. The robot has arms but these are not designed to do anything other than make gestures. In the Netherlands it is known as Phi.	https://www.robotzorg.nl/product/pepper-robot/
Qbi	Qbi-ball is a robot ball designed to stimulate exercise. It is programmed by a therapist or caregiver to react to a person's body movements or arm gestures. Through these movements the person steers the direction of the rolling ball. Specific therapeutic exercises can be trained in a playful manner.	https://qineto.com/qbi/
RealCare Baby® 3	RealCare Baby® 3 infant simulator (formerly known as Baby Think It Over® or BTIO®) is an infant simulator with	https://www.realityworks.com/products/realcare-baby

Name	Description	Additional information
Drug-Affected Baby	wireless programming and reporting capabilities. It is used in conjunction with comprehensive curriculum and interactive activities. RealCare Baby® 3 engages users by crying to be fed, burped, rocked or changed, and cooing when its needs have been met. It holds users accountable by tracking, measuring and reporting on care events, mishandling (including shaken baby syndrome, poor head support and wrong position), surrounding temperatures, time in a car seat, clothing changes, etc. RealCare Baby® 3 also provides lessons in childcare, early childhood and health skills, child abuse prevention, parenting skills, infant health and wellness.	
Robotkat	Robotkat mimics some of the behaviour and sounds of a cat. Robotkat is furry and feels like a real cat. It responds to petting like a real cat by giving head rubs and making purring sounds. Together with a range of other furry animals it may have the same effect on elderly as Paro the seal.	http://www.robots.nu/silver-tabby-en-creamy/
Romeo	Romeo is a 140 cm tall humanoid robot used in a research project designed to explore assistance for elderly people and those who are losing their autonomy. Its size was determined so as to enable him to open doors, climb stairs and reach objects on a table.	https://www.ald.softbankrobotics.com/en/robots/romeo
Sommox	Sommox is a sleep assistant. The robot tracks a person's sleep and when spooning the sleeprobot, the person will be soothed to sleep, using sounds (medidation, white noise, heartbeat) and guided breathing, tickling the senses to relax body and mind.	https://www.somnox.nl/
Tessa	Tessa is a static object with a doll-like face that speaks pre-programmed messages and reminders. It is used by caregivers to structure the daily activities of the patient and to remind them of any appointments. There is no interaction or physical assistance.	https://www.tinybots.nl/
Zora Marv	Zora is a 57 cm tall robot build on the NAO platform from Aldebaran equipped with sensors that enable it to walk and talk. The robot does not, however, converse autonomously. Via wi-fi a caregiver types in the response the robot is to give to the person talking to it. Zora is used in long-term care, where it is used to encourage people to do their rehabilitation exercises. The robot also shows them how to move. It is also used to calm elderly people suffering from dementia. Zora is not a replacement for a nurse. It does not take care of people; it merely entertains them and is able to demonstrate exercises. De facto it is a burden on staff, with very little advantages. The use of the robot creates issues related to privacy and network security.	https://www.skipr.nl/actueel/id24894-miljoeneninvestering-voor-zorgrobot-zora-.html www.mxi.nl/robotica https://www.skipr.nl/actueel/id29270-zorgrobot-zora-heeft-positieve-effecten.html http://www.zorgictzorgen.nl/ruim-kwart-miljoen-euro-in-regio-utrecht-besteed-aan-15-buiksprekende-zora-zorg-gadgets/

Appendix 5: Service robots

Name	Description	Additional information
Care-O-bot 3/4	This robot can collect objects from anywhere in the house and hand them over to the person in care, including drinks from the fridge. However, the location should be entered in advance and objects should not be close together. The robot also serves as a communications centre and a fall detector (in which case it will alert the emergency services), and it reminds the person to take medication and do self-tests. The robot then forwards the test results. Care-O-bot has been used in various communal areas at a residential care facility. Using a database containing the residents' details, the robot was able to identify and selectively address individual residents. It also offered them a drink if they had not drunk enough.	https://www.care-o-bot.de/en/care-o-bot-3/application.html https://www.ipa.fraunhofer.de/content/dam/ipa/en/documents/Expertises/Roboter--und-Assistenzsysteme/Article_Servicerobots_residential_care.pdf
Jaco	Jaco is a robot arm that assists people with (very) limited hand and arm function. It is mounted on a person's wheelchair and controlled by a joystick. It enables the person to perform daily tasks that require normal arm and hand functions such as eating, drinking, working in the kitchen, picking things from the floor, opening doors and controlling apparatus.	https://hulpmiddelen.spierziekten.nl/hulpmiddelen/product/personal-robot-jaco/
HSR	With a highly manoeuvrable, compact and lightweight cylindrical body and folding arm, the Human Support Robot (HSR) can pick objects up off the floor, retrieve objects from shelves and perform a variety of other tasks. In addition to local, on-site operation by remote control, the HSR can be operated remotely by family or friends, with the operator's face and voice being relayed live, enabling real, human interaction while also helping with daily tasks.	https://newsroom.toyota.co.jp/en/detail/8709541
Kymo (TX40)	Kymo is a laboratory robot designed to prepare chemotherapy medication in a clinic. Normally this hazardous task is done by pharmacy technicians.	https://www.icthealth.nl/nieuws/olvg-laat-chemotherapie-door-robot-bereiden/
LEA	LEA, the 'Lean Empowering Assistant', is an advanced rollator with a motor and built-in communication device (tablet). LEA offers older people or people with disabilities assistance with daily activities, helping users to lead an active life, ensuring safety and facilitating easy communication. It is claimed to be more stable, safer and easier to use than a standard rollator. LEA is also suitable for rehabilitation purposes such as built-in exercises and one-handed operation.	https://www.robotcaresystems.nl/lea-care/
My Spoon	My Spoon helps people with limited arm function to eat and drink without human assistance.	http://www.robots.nu/robotarm-my-spoon/
Obi	Obi helps people with limited arm function to eat and drink without human assistance.	https://meetobi.com/
Rose	Rose is a remote-controlled service robot designed to help elderly and handicapped people with daily activities like unpacking shopping, laying the table, fetching drinks and cleaning. Although Rose is positively displayed in the media, its functionality is very limited. It is human operated, its movements are far from refined	http://robot-rose.com/ https://www.zorgictzorgen.nl/aandoenlijk-techno-optimisme-bij-uiterst-beperkte-

Name	Description	Additional information
	and it is slow.	zorgrobot-rose/
Tiago	Tiago is a service robot designed to assist people with mild cognitive impairment to carry out daily activities. The robot is able to recognise faces and speech and can speak. With its built-in sensors, and aided by sensors in the person's home, it is able to locate the person. It also reminds the person to take medication and attend appointments that are in their diaries (as any smartphone will do). It is also able to pick up items from the floor.	

Appendix 6: Surgical robots

Name	Description	Additional information
Aqua-Beam	AquaBeam is a robot for the treatment of benign prostatic hyperplasia. Visualising the prostate in multiple views on the AquaBeam System monitor, the surgeon maps the exact treatment contour, devising the optimal tissue removal plan for each patient. Once treatment planning is complete, the AquaBeam System autonomously executes the treatment plan, resecting the identified prostate tissue with a heat-free, high-velocity waterjet. Using the surgeon-defined treatment contour, the AquaBeam System software calculates the various flow-rates based on the length, depth, and width of resection required.	https://www.procept-biorobotics.com/aquabeam-system/
da Vinci®	The da Vinci® Intuitive Surgical product line, launched in 1999, is designed to provide surgeons with the capabilities of traditional open surgery while enabling them to operate through a few small incisions. It features a 3D HD vision system for a clear and magnified view inside the patient's body. The instruments can bend and rotate to a far greater extent than the human wrist. The robot translates the surgeon's hand movements into smaller, more precise movements.	https://www.intuitivesurgical.com/products/
Microsure	Microsure is a set of robotic hands that are operated by the surgeon. The Microsure system is designed by and for microsurgeons who want to overcome their physical limitations and enhance their performance. The robot makes it possible to perform vessel surgery with more precision and better stability and also offers enhanced ergonomics for the surgeon. This provides better and more consistent surgical outcomes, and allows the development of new, high-precision surgical procedures that are currently unavailable.	http://www.microsure.nl/ https://www.icthealth.nl/nieuws/robot-helpt-chirurgen-bij-delicate-lymfoedeemoperatie/ https://www.skipr.nl/actueel/id32030-maastricht-umc-voert-eerste-micro-operatie-met-robot-uit.html
Murab	Murab is a robot for precision biopsies. It greatly improves the precision and effectiveness of biopsy gathering for cancer diagnostic operations. Guided by a novel MRI-Ultrasound (US) registration, a robotically steered US transducer, equipped with an acoustically transparent force sensor, autonomously scans the target area and optimally acquires volumetric and elastographic data.	https://www.skipr.nl/actueel/id25182-robot-gaat-biopsie-drastisch-verbeteren.html http://www.murabproject.eu/
Preceyes	Preceyes is a robot designed to assist eye surgeons in vitreoretinal surgery. The Preceyes robot increases surgical precision by scaling movements and filtering out hand tremors, whilst standby functionality improves control and enables to relax during surgery by freezing the instrument position. The system is equipped with a sensor that measures the distance of an instrument from the retina in real time. Providing sensor-based safety and guidance, the robot-sensor combination promises significant safety and performance benefits for retinal surgery. Moreover, the sensor is a source of data for training and evaluation.	http://www.preceyes.nl/

Name	Description	Additional information
RoBo-Sculpt	RoBoSculpt is a prototype of an image-guided bone milling robot designed for precision surgical bone removal. The robot will be able to use high-quality CT image data for autonomous bone removal or the surgeon will be able to drive the robot manually. The robot will enable safer, faster, more accurate and less invasive bone removal and offers surgeons valuable assistance during risky and exhausting procedures in the skull (base) and ear, during cancer removal and hearing improvement surgery. Use of the robot will help to reduce the number of complications, the amount of surgery time required and the amount of bone removed. The robot is currently being developed. Pre-clinical tests are scheduled for 2019.	https://www.tue.nl/universiteit/faculteiten/werktuigbouwkunde/onderzoek/onderzoeksgroepen/control-systems-technology/research/research-areas/mechanical-design/ongoing-phd-research-projects/design-of-an-image-guided-bone-milling-robot/#top
Soteria	Soteria enables MR-guided biopsies of the prostate. Soteria is a unique new system for MR-guided interventions, based on a patented motor principle that enables the physician to perform a targeted prostate biopsy to further improve prostate cancer diagnosis. The robot makes it possible to detect and target the most aggressive part of the lesions and therefore improve treatment for the patient.	http://www.soteria-medical.com/
Stormram 4	Stormram 4 is a 3D-printed biopsy device designed to be used under MRI. Current techniques used to diagnose breast cancer are suboptimal, and there is a need for a small, MRI-compatible robotic system able to target lesions with high precision and direct feedback of MRI. Therefore, the design and mechanism of the new Stormram 4, an MRI-compatible needle manipulator with four degrees of freedom, will be presented to take biopsies of small lesions in the MRI scanner. The robot is able to accurately target lesions under MRI guidance, reducing tissue damage and the risk of false negatives. These results are promising for clinical experiments, pointing to improvements in the quality of MRI-guided breast biopsies.	https://www.robotzorg.nl/nieuws-robotzorg/3d-geprinte-robot-biopsies/ https://research.utwente.nl/en/publications/design-and-characterization-of-stormram-4-an-mri-compatible-robot (85)
Verb Surgical	Verb Surgical, Inc. is developing a digital surgery platform built with technology from Verily (formerly Google Life Sciences) and Ethicon Endo-Surgery, Inc., part of the Johnson & Johnson Medical Devices Companies. Verb's platform will include robotics, visualisation, advanced instrumentation, data analytics, and connectivity. The company's goal is to 'democratise surgery' by making technology and information available to more patients globally, thereby improving outcomes and reducing the overall cost of care.	http://www.verbsurgical.com/

Appendix 7: Exoskeletons

Name	Description	Additional information
Ekso GT	Ekso GT is designed to be part of a rehabilitation programme. The Ekso GT robotic powered exoskeleton is for use with people with weak or paralysed legs caused by stroke, spinal cord injury or other neurological conditions. It is placed over the legs to help with standing and walking, using battery-powered motors to drive the legs. As the user shifts their weight, sensors are activated that initiate steps. Functional gait training using powered exoskeletons helps people to relearn step patterns and weight shifts, with the ultimate aim of helping them to regain as much of their natural gait as possible.	https://www.nice.org.uk/advice/mib93/chapter/The-technology
ironHand	The ironHand is a robotic glove that can strengthen the grip of people with reduced hand function. It can provide extra force for opening and closing the hand in order to address grasping weakness (assistive mode). The embedded software adjusts the amount of extra force to the grip intention of the user. Using advanced technologies, the glove is triggered by an 'intention detection' logic that activates the support only if the user initiates the movement by a natural and intuitive movement intention and maintains the grip pressure as needed.	http://www.ironhand.eu/project_aim
Lokomat	Lokomat is a robot designed to support gait training. Robot-assisted therapy enables effective and intensive training and ensures optimal neuroplasticity and recovery. The robot consists of a treadmill, a dynamic body weight support (in which the patient hangs during the exercise) and robotic gait orthosis that helps the patient to make walking movements. Advantages over conventional treadmill gait training are reduced physical strain for the therapist (so that the therapist can help more patients), an extended training duration, clear feedback for the patient, and the fact that the gait pattern is both physiological and reproducible.	https://www.hocoma.com/solutions/lokomat
March II	March II is an assistive robotic exoskeleton designed by Project March to enable paraplegics to stand up and move autonomously. Advanced sensors and a sophisticated control system are used to give the user full movement control. C March II features custom-made electronics, compact joint design, and an intuitive input device.	https://www.projectmarch.nl/en/march-ii/?rq=march https://tudelftroboticsinstitute.nl/news/first-steps-new-exoskeleton-build-students-delft-university-technology
ExoArm	De ExoArm is an arm support that constantly adapts tot he movements, forces and task performance of the user. During this operation, the user does not have to press any buttons or perform other control actions. ExoArm is at the same time a barrel full of possibilities, filled with instructions and characteristics of the user.	https://www.focalmeditech.nl/dynamische-armondersteuningen
ReoGo	ReoGo is an interactive robot designed to improve upper limb therapy. The portable and user-friendly robot facilitates two- and three-dimensional movements, allowing patients who have	http://motorika.com/product-1/

Name	Description	Additional information
	suffered a stroke or other neurological injury to re-train the brain through measured repetitive motion and advanced biofeedback. Underlying the treatment modality is the clinical principle that carefully designed, repetitive and guided neuromuscular training serves to enhance learning and promote cortical reorganisation, which, in turn, contributes to functional recovery. As a robotic-assisted device, the ReoGo provides up to ten times more repetitions per session than an average non-robotic treatment, thereby improving recovery and treatment outcomes.	
Rysen	Rysen is a rehabilitation robot. Gait recovery after neurological disorders requires remastering the interplay between body mechanics and gravitational forces. Despite the importance of gravity-dependent gait interactions and active participation for promoting this learning, these essential components of gait rehabilitation have received comparatively little attention. Rysen uses an adaptive algorithm that personalises multidirectional forces applied to the trunk based on patient-specific motor deficits.	
Welwalk WW-1000	The Welwalk WW-1000 comes with a range of rehabilitation support functions based on motor learning theory, including the ability to adjust the difficulty level to suit the patient, and to provide feedback about the patient's gait characteristics. The robot's simple construction and functions, such as easy fitting and central touch-panel operation, ensure ease of use in clinical settings.	

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