The future of the medical technology market

Addressing challenges and utilising opportunities

Ecorys: Kimberley van den Bergen, Wija Oortwijn, Arthur ten Have, Kim Weistra, Cynthia Nieuwdorp, Tessa Huis in ‘t Veld, Lars Meindert, Emalie Hurkmans

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Samenvatting

De toekomst voor de wereldwijde medische technologie (MedTech) markt is veelbelovend, met de snelle opkomst van nieuwe MedTech producten. In opdracht van het Nederlandse ministerie van Volksgezondheid, Welzijn en Sport (VWS) presenteert Ecorys een duidelijke toekomstschets van de MedTech markt, de hieraan gerelateerde kansen en uitdagingen voor de verschillende stakeholders, en doet aanbevelingen om deze toekomstige kansen optimaal te benutten en de uitdagingen het hoofd te bieden.

Ecorys heeft in de periode van juni tot september 2018 een literatuurstudie, vijf verkennende interviews, dertig interviews met verschillende stakeholders (inclusief zorgverleners, zorgverzekeraars, MedTech bedrijven, internationale vertegenwoordigers en overheidsinstanties), aanvullend verdiepend literatuuronderzoek, en een online Delphi panelsessie uitgevoerd. Daarnaast is er gedurende het onderzoek een expert panel, bestaande uit vier toonaangevende experts, geraadpleegd.

De volgende trends zijn geselecteerd vanwege de verwachte invloed op de MedTech en gezondheidszorg markt van de toekomst: digitale transformatie, robotisering, gepersonaliseerde zorg, zorg op afstand, preventie, predictie en vroegtijdige behandeling, value based healthcare (VBHC), patiënt ownership en regulering (MDR, IVDR en AVG). Deze trends zijn niet onafhankelijk, maar beïnvloeden onderdelen van de gezondheidszorg, en hebben daarbij invloed op de kwaliteit, toegankelijkheid en betaalbaarheid van de zorg. Voor elke trend hebben wij kernpunten geïdentificeerd die moeten worden aangepakt, om gebruik te maken van de toekomstige mogelijkheden en om uitdagingen het hoofd te bieden.

De digitale transformatie leidt tot hoge verwachtingen binnen de gezondheidszorg, met name met betrekking tot de elektronische patiëntendossiers, cloud-opslag/computing, toegang tot en gebruik van Big Data, Kunstmatige Intelligentie (Artificial Intelligence, AI) en blockchain. Data hebben een sleutelpositie in de transformatie van de gezondheidszorg, waardoor het mogelijk wordt voor nieuwe partijen, als Alibaba, om toe te treden tot de gezondheidszorgmarkt. De gezondheidszorgmarkt zal profiteren van de toename in kennis die deze innovatieve bedrijven vanuit buiten de gezondheidszorgsector met zich meebrengen. Dit zou kunnen leiden tot een toename van publiek-private partnerschappen. In reactie hierop passen traditionele MedTech bedrijven hun bedrijfsstrategieën aan en proberen verscheidenheid te brengen door zich te ontwikkelen van producenten van kapitaalgoederen naar serviceverleners, inclusief software- en app-ontwikkeling en data-services. Technologieën die gedreven worden door algoritmes, zoals Big Data, Internet of Things (IoT) en AI, brengen uitdagingen rond fundamentele rechten met zich mee. De overheid moet de rechten van burgers beschermen en

een leidende rol vervullen in de regulering van Big Data. Een oplossing hiervoor zou kunnen zijn om de voorwaarden voor (persoonlijke) datacollectie en gebruik aan te bieden, en om de benodigde wettelijke kaders te ontwikkelen voor de toepassing van AI-gedreven gezondheidszorg oplossingen.

Verwacht wordt dat het gebruik van MedTech **robotica** (bv. sociale, dienstverlening, chirurgische robots en exoskeletten) toe zal nemen voor sociale robots in de toekomst. Voor chirurgische robots zullen de ontwikkelingen doorgaan, maar baanbrekende kansen in vergelijking met bestaande technologieën worden niet verwacht. De kosteneffectiviteit van deze interventies en hun effecten op de kwaliteit van zorg blijven onduidelijk. De rol van zorgverleners zal waarschijnlijk veranderen omdat MedTech oplossingen, niet alleen robotica, streven naar een hoger efficiëntieniveau, en extra vaardigheden vragen van zorgverleners. Verwacht wordt dat de overheid een rol zal spelen in het begeleiden van veranderingen op de arbeidsmarkt van de gezondheidssector, door een kader te bieden voor de aanpassing van onderwijs en het leiden van de verandering van de organisatie van de zorg.

Gezondheidszorg wordt steeds meer individueel aangepast aan behoeften en karakteristieken van patiënten. **Gepersonaliseerde zorg**-applicaties omvatten 3D-printen, genoomtechnologieën en smart-apps, evenals digitale sensoren die informatie-uitwisseling rondom behandelingen en bijwerkingen faciliteren. Daarnaast zijn **zorg op afstand**, het verplaatsen van intramurale zorg naar poliklinieken, eerstelijnsgezondheidszorg en de huiselijke sfeer, vereisten voor de digitale transformering en verweven met de ontwikkeling van digitale technologieën (bv. consumer and medical wearables). Verwachtingen rondom deze trends zouden kunnen worden overschat en toekomstige ontwikkeling is mogelijk vertraagd. Zorg op afstand brengt ook financiële uitdagingen met zich mee, vanwege de kans op onnodige zorg en daarmee stijgende ziektekosten. Echter, nieuwe (digitale) technologieën en medische informatie verschuiven de macht van traditionele gezondheidszorgbetrokkenen naar de patiënten. Dit stimuleert **ownership van patiënten** en autonomie en beïnvloedt het aanbod op de consumentenmarkt.

Daarnaast is er een constante verschuiving van behandeling naar **preventie, predictie en vroegtijdige behandeling**. Nieuwe vergoedingssystemen (bv. risk-sharing) zijn nodig om meer mogelijkheden in deze gebieden te bieden. **VBHC** is een concept dat steeds meer gebruikt wordt wanneer er gesproken wordt over kostenefficiëntie. Het koppelt de kwaliteit van zorg heel direct aan vergoeding, maar het bewijs rondom gebundelde betalingen is niet overtuigend, en veel voorwaarden moeten worden nagekomen (bv. betalingssysteem, gezondheid informatiesysteem) om deze trend te versnellen. Ondanks dat patiënten/consumenten mogelijk een grotere rol in hun (zelf)behandeling, diagnose en

behoud van gezondheid, zullen vragen en krijgen, met behulp van zorg op afstand en persoonlijke diagnostische testkits, wordt er een tegenstelling geobserveerd door trends richting VBHC.

Regulering (MDR, IVDR en GDPR) stimuleert de afstemming van producten in termen van kwaliteit en veiligheid en het geeft burgers meer controle over hun persoonlijke informatie. MedTech bedrijven geven aan dat ze bang zijn om de ruimte te verliezen om te innoveren door strikte regulering, specifiek ervaren door het MKB. Het faciliteren en stimuleren van ontwikkelingen van gezondheidstechnologieën door onderzoek, samenwerking en waarborging van commercieel gebruik en publieke toegang is specifiek nodig bij producten waarvan de kosteneffectiviteit en impact op het gezondheidsbudget niet direct duidelijk is.

Tot slot, veel van de onderscheiden vraagstukken die de toekomstige gezondheidszorgmarkt en MedTech betrokkenheid vormen, delen een aantal stakeholders die je in eerste instantie niet binnen de MedTech of gezondheidssector zou verwachten. Het is nodig om sectoroverstijgend te kijken, omdat veel kwesties alleen opgelost kunnen worden door te zoeken naar samenwerking met andere sectoren, waardoor een verscheidenheid aan (andere) stakeholders betrokken zal zijn. De rol van de overheid zal vooral gefocust moeten zijn op het sturen en coördineren van deze initiatieven omtrent alle relevante stakeholders en het promoten van de doelen van het zorgstelsel. Acties op nationaal niveau zullen cruciaal zijn in het versnellen van concrete digitale oplossingen in het zorgstelsel en de gezondheidszorg en zullen in lijn moeten zijn met Europese acties.

Summary

The outlook for the global medical technology (MedTech) market is promising, with new MedTech products rapidly emerging. Ecorys was commissioned by the Dutch Ministry of Health, Welfare and Sport (VWS) to present a clear picture of the future of the MedTech market, the related challenges and opportunities for different stakeholders and suggestions on how to move forward.

From June until September 2018 Ecorys conducted a desk study, 5 explanatory interviews, 30 interviews with various stakeholders (including healthcare providers, health insurers, MedTech companies, international representatives, government agencies), additional in-depth research, and an online Delphi panel session. In addition, an expert panel consisting of four leading experts, was consulted during the course of the project.

The following trends have been selected to have an influence on the MedTech and healthcare market of the future: digital transformation, robotisation, personalised care, remote healthcare, prevention, prediction and early treatment, value based healthcare, patient ownership, and regulation (MDR/IVDR and GDPR). These trends are not autonomous but rather influence health system elements, and have an impact on the quality, accessibility and affordability of care. For each trend, we identified key issues that need to be addressed to fully utilise the opportunities and tackle the challenges for the MedTech market in the next 10 years.

The digital transformation is raising high expectations for the health sector, especially with regard to electronic patient records, cloud-storage/computing, access and use of Big Data, Artificial Intelligence (AI) and blockchain. Data is a key enabler in transforming healthcare, thereby providing opportunities for new parties, such as Alibaba, to enter the healthcare market. The healthcare market will benefit from the increased knowledge that innovative companies outside the healthcare sector will bring. This might result in an increase in public-private partnerships. In reaction, traditional MedTech companies adjust their business strategies and try to diversify from producers of capital goods to services providers, including software and app development and data-services. Algorithm driven technologies such as Big Data, Internet of Things (IoT) and AI are parallel with the challenges to fundamental rights. The government must protect the rights of citizens and take a leading role in regulating Big Data management. This can be done by providing the conditions for (personal) data collection and use, and developing necessary regulatory frameworks for the application of AI-powered healthcare solutions.

The use of MedTech **robotics** (e.g. social, service, surgical robots and exoskeletons) is expected to increase in the future for social robots. For surgical robots, the developments will continue, but breakthrough opportunities compared with existing technology are not expected. The cost-effectiveness of these interventions and their effects on quality of care often

remain unclear. The role of healthcare providers is expected to change as many MedTech solutions, not only robotics, aim to increase efficiency, often requiring additional skills. The government is expected to play a role in guiding the transformation of the healthcare labour market, providing for a framework for the adjustment of education and guiding the transition of the organisation of care.

Healthcare is becoming more customised to individual needs and characteristics of patients. **Personalised care** applications include 3D-printing, genome technologies and smart apps, as well as digital sensors that facilitate information exchange about treatment and side effects. In addition, **remote healthcare,** moving intramural care to outpatient clinics, primary care and the home environment, is a requirement for the digital transformation and interlinked with the development of digital technologies (e.g. consumer and medical wearables). Expectations for these trends might be overrated and the future development is possibly delayed. Remote healthcare brings financial challenges as it may result in unnecessary care, thereby increasing the healthcare costs. However, new (digital) technologies and medical information are shifting the power from traditional healthcare parties to patients. This is stimulating **patient ownership** and autonomy and is influencing the supply on the consumer market.

Furthermore, there is a constant shift from treatment to **prevention, prediction and early treatment**. New reimbursement models (e.g. risk-sharing) are necessary to provide more opportunities in these areas. In addition, **value based healthcare (VBHC)** is a concept that is increasingly used when talking about delivering value for money. It directly links the quality of care to reimbursement, however the evidence around bundled payments is not compelling, and many conditions need to be fulfilled (e.g. payment system, health information system) to speed up this trend. Although patients/consumers may demand and receive an increasing role in their (self) treatment, diagnosis and maintenance of their health, e.g. with the help of remote care and personal diagnostic test kits, a contradiction is observed with trends towards VBHC.

Regulation (MDR, IVDR and GDPR) increases the harmonisation of products in terms of quality and safety and it allows citizens to gain more control over their personal data. MedTech companies indicate that they are afraid to lose room to innovate as a result of stringent regulation, which is particularly felt by SMEs. Facilitating and stimulating the development of health technology through research & collaboration and safeguarding commercial use and public access is especially necessary for products of which the cost-effectiveness and impact on health budget is not immediately apparent.

In conclusion, many issues identified in shaping the future healthcare market and MedTech involvement share a list of stakeholders which are not necessarily the usual suspects in the MedTech or health sector. It is necessary to look beyond the sector, as many issues can only be dealt with by seeking collaboration with other sectors, involving a multitude of (other) stakeholders. The role of the governments will need to focus on steering and coordinating these initiatives involving all relevant stakeholders and promoting the objectives of the health system. Actions undertaken at a national level would be crucial to accelerate concrete digital solutions in public health and healthcare and should be in line with European actions.

Introduction

The outlook for the global medical technology (MedTech) market is promising, with new MedTech products, such as 3D printing and robotics rapidly emerging. New MedTech products can play an important role in the prevention, diagnosis and treatment of diseases. Further, it may support elderly, chronically ill and/or disabled people in their daily activities.

MedTech trends are accompanied by other trends, such as the introduction of new European regulation for market access of MedTech, the introduction of value-based health care, and the awareness that data sharing may have certain risks. All these trends have an impact on the relevant stakeholders involved (e.g. industry, regulators, patients, health professionals, health insurers), and as such on the quality, accessibility and affordability of healthcare.

Ecorys was commissioned by the Dutch Ministry of Health, Welfare and Sport (VWS) to provide an overview of the most important trends, as well as the related challenges and opportunities for both the MedTech and healthcare market in the Netherlands in the next 10 years.

Recently, a report was published on the current status of the MedTech market and trends impacting the Dutch MedTech market. The authors valuated the MedTech market at an estimated €4.7bn in 2016, based on manufacturing and wholesale prices. The intramural and extramural care are valued at €2.4bn and €2.3bn, respectively.[1] Many trends relevant for the Dutch MedTech market are observed, including amongst others:

- Patient care is gradually shifting from intramural to extramural care;
- Hospitals are shifting to use less invasive health technologies;
- MedTech is more focused on the individual patient, and healthcare is becoming increasingly personalised;
- There is a continuous shift from treatment to prevention;
- MedTech companies focus increasingly on service models instead of customer-centric businesses.

MedTech stimulates these trends, initiates new trends and is influenced by these developments. Our study builds on this report as well as on the RIVM horizon scan[2], which was also commissioned by VWS to inform their policy on technological advances. This latter report identifies selected emerging trends and technologies, amongst others e-health, robotics and 3D printing, that will influence the MedTech market in the next 10 years. Whereas new health technologies will primarily address actual medical and/or societal needs. Successful development

[1] KPMG. (2017). The MedTech market in the Netherlands, available at file:///C:/Users/indra.vandervalk/Downloads/the-medtech-market-in-the-netherlands.pdf.

[2] RIVM. (2018). Thematic foresight studies, available at https://www.vtv2018.nl/en/Thematic-foresight-studies.

and implementation of new health technologies is best realised by a coordinated effort from all stakeholders. This goes along with realising that the implementation of new technologies may involve different competences and necessitates changing roles of health professionals as well as of patients, this requires a multi-level strategy on national and European level with public and private stakeholders. Based on the identified trends and expert opinions, the authors recommend that stakeholders join forces at the national level and an agenda setting activity is suggested to optimally combine technological developments and medical, as well as societal needs.

Through this study, we outline a clear picture of the future of the MedTech market, the related challenges and opportunities for different stakeholders and how to move forward. For this purpose, we address the following research questions:

1. Which developments will mainly (re)shape the Dutch MedTech market and healthcare over the next 10 years?
2. Which opportunities and challenges does MedTech have with regard to the quality, accessibility and affordability of healthcare?
3. What do these opportunities and challenges require from all relevant stakeholders?
4. What can we learn from other countries?

Definitions and scope

In this study, we use the definitions for MedTech as specified in the new European legislation on MedTech. Medical devices are any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by a manufacturer for the diagnosis, prevention monitoring, prediction, prognosis, treatment or alleviation of a disease or an injury or disability and are for this study limited to devices under the Medical Device Regulation[3] and the medical devices for in-vitro diagnostics under the In-Vitro Medical Device Regulation.[4] Medical technology also includes the concept of connectivity and the use of information technologies and includes medical devices with IT connectivity. MedTech products include a wide variety of products and range from diagnostic products, surgical products to medical aids. Examples include point of care devices, care products (incl. stoma, incontinence materials and wound management materials), body scanners, hearing implants, e-health/homo automation/robotics, oxygen machines, visuals aids, heart valves, pacemakers and replacement joints for knees and hips.

Approach and methods used

From June until September 2018, we conducted four steps (see Figure 1), comprising of several data-collection methods:

- an explanatory desk study;

[3] European Parliament. (2017). Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

[4] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

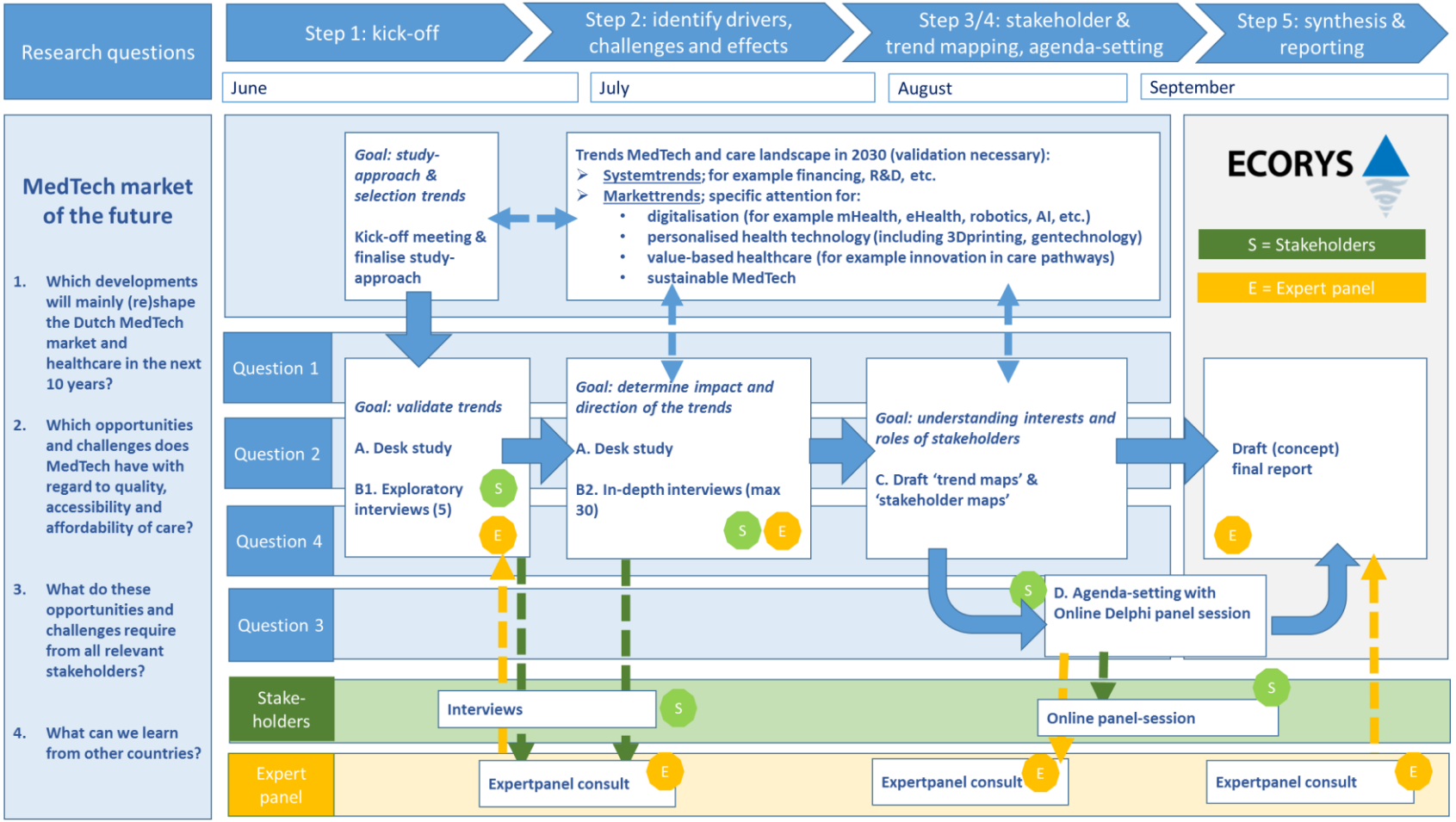
- 5 explanatory interviews;
- 30 interviews with various stakeholders;
- additional in-depth desk research, and
- an online Delphi panel session.

In addition, an expert panel consisting of four leading experts, was consulted during the course of the project.[5]

The annexes of this report include a detailed description of the abbreviations, the methodology, the references, the interview guidelines and questionnaire for the Delphi, as well as the interviewed parties and online Delphi panel session participants. The study methodology, (explanatory) interview parties, interview guidelines, the online Delphi panel statements and participants are consulted with and agreed upon by VWS.

[5] Members of the expert panel: Dr. Nick Guldemond, Dr. Ken Redekop, Prof. dr. Maroeska Rovers, Dr. Eddy Adang.

Figure 1 Approach



As stated above, this report builds upon the results of previous studies and sector scans. Therefore, our study started with an explanatory desk research to select important trends for the future of the MedTech market. Publications used to select the trends include: Rabobank (2015),[6] RIVM Report Horizon Scan Medical Technology (2018), KPMG (2015, 2017)[7] and EY (2017).[8]

The report will discuss the trends presented in Table 1, which are deemed relevant for the MedTech market of the future. *Annex II* provides a detailed description of the trends.

Table 1 Trends influencing the MedTech and healthcare market of the future

Trends
I. Digital transformation
II. Robotics
III. Personalised care
IV. Remote healthcare
V. Patient ownership
VI. Prevention, prediction and early treatment
VII. Value based healthcare
VIII. Regulation (MDR/IVDR and GDPR)

Source: The selected trends were validated during the five explanatory interviews with different stakeholders[9], with VWS and by the expert panel.

Based on 30 additional in-depth interviews - with representatives of healthcare providers (5), health insurers (4), MedTech companies (6), international representatives, e.g. MedTech Europe and MedTech Scan (5), government agencies (4), and other relevant stakeholders, amongst others NEFEMED, FHI, FME (6), including industry representatives – insights on future developments of the selected trends and their effects (opportunities and challenges) on the MedTech market and healthcare landscape were gathered in a systematic way. The input from the interviews is used to understand the interests and roles of the various stakeholders on the selected trends.

It is acknowledged that the selected trends are not autonomous and influence health system elements, thereby impacting the outcomes: quality, accessibility and affordability, as presented in Figure 2.[10]

6 Raaphorst, F. (2015). Medische Technologie Industrie 2015; Verkenning - sectoren, spelers en trends. Utrecht: Rabobank.

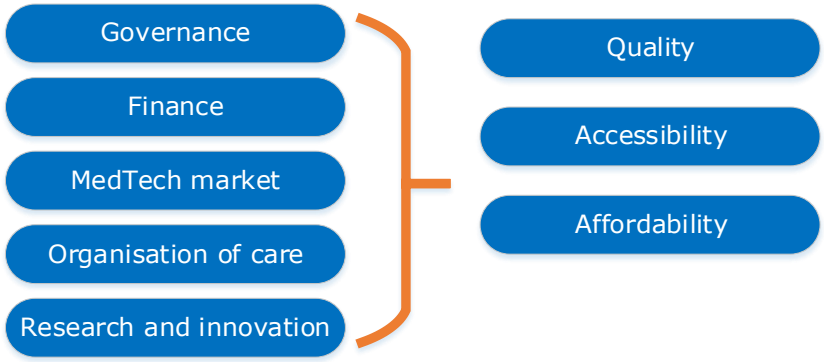
7 KPMG, 2015, “Collaboration – The future of innovation for the medical device industry”, KPMG, 2017, “The MedTech market in the Netherlands”.

8 EY, 2017, Äs change accelerates, how can medtechs move ahead and stay there?”.

9 Re-Shape, Patient Federation Netherlands, FHI, Medical Delta Delft, Rijnstate.

10 http://www.wpro.who.int/health_services/health_systems_framework/en/.

Figure 2 Health Systems Framework



Based on WHO Health Systems Framework

Health system elements include:

- **governance**, ensuring effective evaluation and monitoring, accountability and appropriate regulations;
- **financing** ensuring adequate funds;
- **MedTech market**, providing access to products and technologies of assured quality, safety, efficacy and cost-effectiveness;
- **organisation of health care** and service delivery including a well-performing health workforce and well-organised healthcare organisations;
- **research and innovation** a well-functioning system that ensures analysis, production and use of information on health determinants, performance and standards.

Based on the interviews and desk research, we identified the drivers and challenges for each trend, with an indication of the associated uncertainty of the future development of the trend and its (potential) effects on quality, affordability and accessibility of healthcare. The information on the relevant stakeholders involved and on the trend were combined and are presented as infographics in this report.

We used an online Delphi panel session to ask the stakeholders to give their opinion on statements relating to the different trends, opportunities and challenges. We first developed statements based on the findings from the desk research and interviews, which are clustered into the five health system elements (governance, financing, MedTech market, organisation of care, and research and innovation). These statements were sent as an online Delphi session to a panel of 30 representatives of different stakeholders, of which 24 had been interviewed, and which also included our expert panel. The goal of the online panel session was to identify key elements of a concrete agenda for relevant stakeholders to fully utilise the opportunities and tackling the challenges for the MedTech market in the next 10 years.

The different methods, e.g. desk research, interviews and Delphi panel session, provided valuable insights and often highlighted similar points of attention for the MedTech market. The input was in general fairly consistent, during the interviews

different perspectives were highlighted, at the same time contradictions were visible in the panel session.

Reading guide

In Chapter 2, we briefly introduce the selected trends. In addition, we describe the challenges and opportunities for the most important trends on the MedTech market (addressing research questions 1 and 2). Best practice examples from other countries are presented in text boxes throughout the chapter (addressing research question 4). In Chapter 3 we discuss the future of the MedTech market, including a description of the current market, disease specific product developments, the hospital of the future, business strategies and new entrants (addressing research question 2). In Chapter 4, we provide the areas for action indicated by various stakeholders during the online Delphi panel session (addressing research question 3). Finally, we provide an overview of strategic considerations and recommendations for public policy, the industry and the MedTech market participants in order to optimally utilise the opportunities and to address the challenges of the MedTech market in the next 10 years.

Eight important trends

Digital transformation, robotics, personalised care, remote healthcare, patient ownership, prevention prediction & early treatment, value based healthcare and regulation (MDR/IVDR and GDPR) are in themselves not autonomous but much more interrelated trends. Policy and regulation influence both the MedTech market and the healthcare landscape. MedTech trends have an influence on how the health system is shaped, which products are used and how itis applied in practice , thereby impacting the affordability, quality and accessibility of care.

Eight trends I. digital transformation, II. robotics, III. personalised care, IV. remote healthcare, V. patient ownership, VI. prevention, prediction & early treatment, VII. value-driven healthcare and VIII. regulation (MDR/IVDR and GDPR) that will (re)shape the Dutch MedTech market and healthcare in the next 10 years are identified using desk research and explanatory interviews. The related opportunities and challenges, and best practice examples from other countries are identified using 30 interviews with various stakeholders.

I. **Digital transformation** is an ongoing trend and is reflected in technologies already used in the healthcare sector, e.g. electronic patient records, cloud-storage/computing and consumer electronics (incl. tablets, smart phones, TV). The generation of, access to and use of big data, Artificial Intelligence (AI) and blockchain are new developments and these developments provide additional opportunities and challenges. For example, mobile phone-based health applications for disease monitoring and home surveillance, consumer and medical wearables aimed at self-monitoring and life-style monitoring, as well as AR and VR technologies and robotics broaden the range of possibilities to provide intramural care to outpatient clinics, specialised centres', primary care, and the home environment.

II. **Robots** can be categorised in social, service, surgical robots and exoskeletons.[11] The number of service robots, surgical robots and exoskeletons that serve a medical purpose is still limited but may increase in the future. With 'robots' in this report, we therefore mainly refer to mechanical robots.

III. Healthcare is also becoming more **personalised to the needs and characteristics of individual patients**. This is driven by empowered digital literate patients and digital innovations that enhance information exchange and allows various professionals in health and social care to tailor their services to the needs of individual patients. This in turn improves the success rates of treatment by measuring possible side effects. In addition, genome-based technologies make it feasible to tailor treatment to genetic profiles. In addition, 3D-printing has already led to the development of implants

[11] See footnote 2, p. 34.

designed for patient's specific needs (e.g. for hip/knee replacements) and will continue to breakthrough under the right conditions.[12]

IV**. Remote healthcare** empowers patients,[13] as they are able to access health services more easily. New and mobile technologies may make the promises of telemedicine more realistic. Remote health care is expected to impact the provision of care for elderly through monitoring and surveillance.

At the same time the line between medical devices and consumer devices is blurred, where consumers use every day technologies including apps on phones and wearables for their health, sport, fitness, wellness and lifestyle purposes. Consumer market developments stimulate new opportunities for the remote healthcare market, and vice-versa.

V. The position of patients/consumers is changing and driven by the digital transformation, personalised care, remote healthcare, regulation and the focus on prediction and prevention. Patients are no longer simply recipients of healthcare, but are self-managing emancipated participants, in combination with their social network. There is and will be an increased focus on **patient centeredness and patient ownership**: patients are seen as co-producers of data as they increasingly have health technologies available to actively measure certain (surrogate) outcomes and aspects which are meaningful for their daily lives, and which enable active engagement. The indication and dispensing of medical devices is expected to be increasingly function oriented. These trends will ultimately increase their self-management, autonomy, independence and self-reliance. At the same time, this movement could create risks of over-diagnoses and over-treatment

VI. The focus on **prevention, prediction & early treatment** is accelerated by machine learning, Artificial Intelligence (AI), genome technologies and smart apps integrated with medical devices providing real-time access to patient data. Data driven technology involves open data exchange between parties if it is deployed as a learning system and healthcare data originates from patient records, demographic data sources and (consumer)measurement equipment.[14] Health data allows health professionals to create better patient profiles and predictive models to more effectively anticipate and predict diseases. Combining Big Data with analytics, AI and machine

[12] Ort, R. & Dees, B. (2018). Technologiemonitor 2018, available at https://stt.nl/stt/wp-content/uploads/2018/08/TechnologieMonitor2018.pdf?utm_source=e-mailnieuwsbrief&utm_medium=email&utm_campaign=AWTI+e-mail+alert.

[13] A growing number of studies on measuring the outcomes of tele monitoring interventions exists (e.g. regarding single and multiple chronic conditions ranging from diabetes, hypertension to heart failure). See Inglis, S.C. and Set., E. Annex I.

[14] RIVM. (2018). Thematic foresight studies, available at https://www.vtv2018.nl/en/Thematic-foresight-studies.

learning may provide valuable new insights and can optimise existing technologies.[15]

VII. Value based healthcare is outcome based and seeks to directly link quality health care to reimbursement. The four cornerstones of this movement are 1) health information technology standards; 2) quality standards, 3) price standards; and 4) incentives.[16] Value driven care assumes cooperation between healthcare providers and MedTech companies and requires confidence in the professional skills of healthcare providers.

VIII. Policy related trends influencing the MedTech market include the trends towards value-based healthcare, increased patient-centeredness and the ambition to focus from treatment towards prevention, prediction, early diagnoses and early intervention and/or treatment. Further, general **regulations**, such as the **GDPR**[17] are influencing the healthcare market and MedTech specific regulations, i.e. the **MDR**[18] and **IVDR.**[19]

Opportunities and challenges per trend

Below, we provide infographics per trend. The infographics depict a general description of the trend, its future development, possible impact on the MedTech market and healthcare landscape, and it provides an overview of the challenges and opportunities for the various stakeholders, i.e., patients/consumers, health insurers, MedTech companies and governmental agencies.

The opportunities and challenges per trend are displayed by the following illustrations.

15 Maaden, T et al. (2018). Horizon Scan Medical Technology. Bilthoven: RIVM, p. 51.
16 Value-driven health care – a purchaser guide (2007), available at http://www.bailit-health.com/publications/purchaserguide_020707.pdf
17 Regulation (EU) 2016/679 protection of natural persons with regard to the processing of personal data and the free movement of such data
18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
19 Regulation (EU) 2017/746) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

I. Digital Transformation

Digital transformation concerns "The coupling of granular, real-time data (e.g., smartphones, connected devices, smart appliances, wearables, mobile commerce, video surveillance) with modern technologies (e.g., cloud native apps, big data architectures, hyper-converged technologies, artificial intelligence, blockchain) to enhance products, processes, and business-decision making with customer, product and operational insights."

FUTURE DEVELOPMENT

The digital transformation is raising **high expectations** for the health sector in the immediate and medium term. The following digital transformation technologies are considered to be influential for the health sector: electronic patient record, cloud-storage/computing, generation, access and use of big data, artificial intelligence, and blockchain.

MARKET IMPACT

New and growing markets for data management, analyses, (data-driven) services by (or supported by) non-traditional providers offering new products and services (e.g. wearables, apps).
Data-information companies are preparing to enter or scale-up in the health information market, potentially resulting in monopoly positions.
Better organisation of care may reduce management support functions.
Increased corporisation could lead to enhanced market power for MedTech providers changing the position of health insurers.

ECORYS

PATIENTS/CONSUMERS

- **Quality and efficiency** of service provision, organisation of care, and research may improve as patients/consumers provide more information by using devices monitoring their health status.

  The digital transformation creates a more active role for patients in terms of responsibility and empowerment.

! **Privacy risks** and risks of explicit and in particular hidden data transfer involve diminishing authority over personal (including DNA), medical, and social information. Sufficient health literacy of the population is a prerequisite for patient empowerment.

  Uncertain if **data ownership** (new security technologies stimulates patient ownership) enabling patients to become more independent and perhaps also more insecure.

  In addition some patients will decide not to share data with anyone, resulting to smaller datasets possibly leading to confounding results if patients who opt out are different from the patients who opt in.

HEALTHCARE PROVIDERS

- Data-driven developments potentially create **new, more effective data- driven business models:** they are important generators/providers and users of (personal) health data. New business models require the transformation from data providers to data analytic services, which includes changes in staffing and management approach.

! Health care providers are traditional and/or bureaucratic organisations with rigid structures.

  Unclear reimbursement situations, may dampen interest to innovate.

  Potentially vulnerable for **unwarranted use of patient data** as new business model.

  Potential substitution of (manual) labour by the digital transformation, which will influence the job market for healthcare providers.

I. Digital Transformation

HEALTH INSURERS

- Potential to use an array of medical, personal and clinical data for insurance policies and purchase management. Additional business model is feasible based on **data-sharing** with external parties.

  The digital transformation is a condition for implementing value based reimbursements and other payment innovations and as such may be a potential for cost savings.

! **Data security** responsibility. Increased opportunities for implicit selection criteria creates privacy concerns when insurers combine medical information with third-party personal information (Facebook, Google).

MEDTECH COMPANIES

- **Service-oriented** business model propositions: data-based services added to MedTech equipment for monitoring, management and decision-support.

  MedTech products can be improved based on collecting realworld health outcomes data, which is also a step towards value based healthcare. Data collection offers opportunities for companies to demonstrate the value of products and services.

! Ownership of data generated by MedTech will increasingly be seen as a **'public' good** that is to be shared with providers and patients. Power vis-à-vis providers increases when making use of 'service-models' and lease services. Expect a payer-decides situation, e.g. where insurers could place demands on MedTech companies.

  The digital transformation opens opportunities for new parties to enter the market, MedTech companies need to adjust strategies to stay on the market and to prevent take-overs.

GOVERNMENT

- Potential for **cost savings** due to substitution of care. Remote monitoring and virtual visits, for example, could decrease the need for in-person consultations and artificial intelligence could predict outcomes and avoid unnessary surgery (e.g. digital heart twin). The digital transformation is a condition for implementing value based reimbursements and other payment innovations.

! **Combining health data** for fraud detection, judicial information, prevention mechanisms jeopardising privacy rights.

  Increased role in financing and provision of care at local level governments, but not well versed in medical ethics.

  Data security responsibility.

ECORYS

II. Robotics

Increased use of MedTech robotics. A robot is defined as a device with (a) **sensors** to receive information about the environment and/or instructions from a human; (b) **algorithms** to make decisions based on the information received from the sensors; and (c) motors/actuators to make mechanical **movement,** and/or devices to make **sounds** and/or display images. Robots categorised by function include 1) social robots; 2) service robots; 3) surgical robots; and 4) exoskeletons

FUTURE DEVELOPMENT

The number of robots that is currently used in healthcare is still very limited, but may increase in the future, especially social robots. For the three **other types of robots, opportunities are less straightforward.** It will probably take a long time before robots capable of multiple physical activities become available.
For **surgical robots, developments will continue**, but breakthrough opportunities compared with existing technology are not readily expected. Exoskeletons are still at a very early **stage of development.**

MARKET IMPACT

New entrants from (industrial) robotics manufacturing are first movers and may improve competition, but generally lack consumer orientation. Social robots may help to alleviate the shortage of caregivers (nurses) by saving time otherwise needed to calm down elderly. However, many social robots do not fall within the definition of MedTech. Position of health care professionals and caregivers may become weaker due to less demand of their services.

ECORYS

PATIENTS/CONSUMERS

- **Social robots** may increase the quality of life of patients/clients. **Service robots** may be a tool to help patients at home in self-management. **Surgical robots** may reduce patient days and make procedures less invasive. **Exoskeletons** may have a large impact on people with disabilities, rehabilitation and prevention of injuries.

! **Acceptability of social robots.**

Surgical robots are not proven cost-effective for several indications.

HEALTHCARE PROVIDERS

- **Social robots** may alleviate the shortage of caregivers (nurses). **Surgical robots** may increase the quality of work. **Exoskeletons** could be used by informal caregivers and healthcare professionals. Apart from surgical robots, the largest impact is expected for other robots in care and non-clinical settings including homes.

! The claim that caregivers may become more effective and efficient, as they can limit time-consuming tasks (social and service robots) is not proven. Cost concerns may force reduction in professional workforce leaving promised quality enhancements as a secondary consideration.

Position of health care professionals and caregivers may become weaker due to lesser demand of their services.

Caregivers are seldom involved in the design of robots, this may negatively influence the acceptability and effectiveness.

II. Robotics

HEALTH INSURERS

- Insurers may benefit from improved quality of care and increased efficiency, if proven.

! While robotic surgery has been demonstrated to be safe in many areas of orthopaedic surgery, their long term benefits and use in other areas including trauma are yet to be demonstrated. Cost containment pressures should be carefully matched with quality considerations and perceptions, as insurers may become increasingly pitched against health professionals and caregivers.

MEDTECH COMPANIES

- Existing Medtech companies can make the shift towards new markets in predominantly the care-segment, requiring a consumer/patient-driven approach for service and social robots. Companies experienced in (industrial) robotics can diversify and enter the healthcare market.

! Market development of social and service robots is seen as 'disappointing' due to a variety of reasons. The claim of human-like experiences is considered too ambitious by developers. Robotics firms often have an industrial background and are not used to work for consumer-driven markets.

GOVERNMENT

- Government may take a pro-active stance in (funding) research and registries, developing capacity to evaluate emerging, new technologies and strike the balance between innovation, patient safety and data security. Thereby increasing knowledge on quality of care and potential efficiency gains due to the application of robotics.

! The potential of robotics to reduce healthcare costs and improve the quality of care is still an open debate.

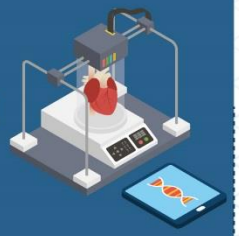
Possible substitution of labour by technology, leading to unemployment pressures for specific jobs. Retraining of certain personnel may be required because new jobs may emerge.

Approval/reimbursement of technology is hampered by lack of specific expertise and appraisal (Health Technology Assessment) frameworks for MedTech.

Robotics require use of Artificial Intelligence and large volumes of data, which may not be feasible under the current laws.

ECORYS

III. Personalised care



Healthcare is becoming more customised to **individual needs** and characteristics of patients.This means that organisations need to align and integrate around the needs of people. Smart apps, digital sensors and algorithms are example which facilitate this by information exchange about treatment and measuring side effects. **The increase of genome technologies** (sequencing) will enable personalised care. Additive manufacturing (AM), such as **3D-printing** for implants and Artificial Intelligence (digital heart twin) are examples of new MedTech personalised care applications.

FUTURE DEVELOPMENT

Remote healthcare in combination with personalised care are focus areas of MedTech companies. Personalised care can only expand alongside the digital transformation. Therefore this is a trend which will continue, but not as quickly as expected.

MARKET IMPACT

Personalised care as such and genome technologies will not have a big influence on the MedTech market. Personalised implants will develop, but are similar to current non 3D-printend MedTech products. Patients are willing to travel further distances to receive the best care, providing more pressure on the current system and certain hospitals/healthcare providers. Technologies such as 3D printing and robotics may replace or relieve certain healthcare jobs (e.g. via robotics).

ECORYS

PATIENTS/CONSUMERS

- Detailed knowledge about the significance of measurements (biomarkers) facilitates **tailored treatments.** This may increase the effectiveness and result in less side effects.
- ! Risk of **abuse of data**: sharing of the genetic profile and related privacy risks. Information provision needs to be organised differently since patients require different treatments.

  Higher costs: more data is needed to enable individual care pathways.

HEALTHCARE PROVIDERS

- Providing better tailored and increased quality of care.

  Hospitals could **prioritise certain strategies** using health-care regions (network care).
- ! Personalised care is feasible in theory but seems difficult to implement in practice. Cooperation between universities, hospitals, research institutes, industry, patient organisations and insurance companies is necessary to develop personalised care.

III. Personalised care

HEALTH INSURERS

- Personalised care may sometimes result in higher costs or increase efficiency; at the same time treatment is more tailored resulting in better health outcomes.

  Health insurers could choose lower premiums if consumers are willing to share more of their data.

! Diagnosis of diseases can be more specific (e.g. via gen-diagnostics), however **financing** is a barrier for its use. For example, the costs of diagnostics are not included in the diagnosis treatment combination (DBC) structure. A system change is necessary to reimburse certain innovations.

  Increased information asymmetry. Consumer/patients are increasingly empowered with information about behaviours, risks and outcomes which insurers do not have. At the same time, insurers have information that individual consumers do not have.

MEDTECH COMPANIES

- Commerce is in **the lead, resulting in opportunities for new products such as the digital heart twin.**

! **Certification process** is difficult as personalised care is often not a standard product. Quality checks and control on safety increases. The question remains as to who is responsible for safeguarding the quality of personalised care?

GOVERNMENT

- Personalised care and 3D printing is promising, as it could create more efficient, tailored treatments and better health outcomes.

! A more **proactive role of the government is needed:** the government is often reactive in the area of personalised healthcare, at the same time there is a lot of commercial pressure from MedTech companies, as well as pressure from individuals and universities to invest in this area.

  Regulators face a difficult environment because MedTech, including implantable devices, for particular patients are within reach on a greater scale (they often fall within the custom-made device exemptions). One could expect an extended role of an European or Dutch Inspection to also safeguard quality of personalised care.
  The impact of personalised care on the health system, e.g. in terms of safety and cost-effectiveness are difficult to measure as evidence may not be available or not requested; this necessitates the need for evidence to inform decision-making, such as collected via health technology assessment, and post-marketing-surveillance (e.g. via registries).

ECORYS

IV. Remote healthcare

Intramural care is moving to outpatient clinics, primary care, and the home environment. E-health and telemedicine and technologies aimed at **sharing** and **measuring patient data**, such as consumer and medical wearables, IoT and cloud-based Big Data analytics are enabling the delivery of care at a distance. This also applies to technologies (e.g. lab diagnostics) and robotics aimed at **self-monitoring**, and life-style monitoring.

FUTURE DEVELOPMENT

Remote healthcare is a **requirement for the digital transformation** and interlinked with the development of digital technologies. Delocalisation of healthcare will be a trend, however, the expectations might be overrated and its future development is possibly delayed.

MARKET IMPACT

Remote healthcare and customised care are important trends on which MedTech companies are focused. The remote healthcare trend stimulates consumer market developments. Delocalisation of intramural services to the home environment, an increase of diagnostic and other specialised centers, concentration of care, aftercare facilities and disappearance of certain healthcare facilities (e.g. nursing homes). Certain healthcare providers will become unnecessary.

ECORYS

PATIENTS/CONSUMERS

- Convenient and easy-to-access care. Remote healthcare empowers patients/consumers and increases **patient engagement.** Patients are able to collect more data which improves the opportunity of earlier intervention, for example for patients with diabetes, or heart failure.

! Sufficient health literacy of the population is a prerequisite. Some groups of patients are not suitable for remote healthcare: Are devices **easy to use** by patients?

Are consumers aware of differences between consumer wearables and medical wearables, e.g. heart monitor of smartwatches and fitness trackers versus medical device? This may pose health risks.

HEALTHCARE PROVIDERS

- **Remote patient monitoring** (RPM) enhances health professionals' ability to monitor and manage patients in non-traditional healthcare settings.

Focus on the best healthcare at the best location for the patient; regional hospitals may offering remote healthcare and remote diagnostics.

! Who will be (socially) responsible in case of high risks based on, for example, sensor measures at home? Lack of evidence on the effectiveness RPM interventions. Scepticism regarding consumer wearables; lack of knowledge on accuracy of data.

Financial challenges: how will remote healthcare be financed and offered cost-neutral, with decreasing hospital beds? Risk of cooperation between healthcare providers that could have a negative influence on competition on the market. Certain specialists will disappear.

Lack of equipoise or equal distribution (preference for or against remote healthcare) may make it difficult to assess the effectiveness and cost-effectiveness of remote care interventions properly.

IV. Remote healthcare

HEALTH INSURERS

- The **market changes**; MedTech moves from the hospital environment to specialised centers, primary care and the home environment.
- ! Higher risk of false positive outcomes and negative externalities increases the risk of more unnecessary care, and therefore may increase the healthcare costs.

MEDTECH COMPANIES

- Development of a **new group of products**, smaller and simpler in use.
- ! Integration of biotech and medical technology, for example with continuous monitoring of body functions. **High requirements** on the use of medical technology, humans can make mistakes.

GOVERNMENT

- Increase of patient-centred care results in more satisfaction (addressing needs) which is beneficial to patients, healthcare providers and other key stakeholders.
- ! Higher risk of false positive outcomes and negative externalities increases the risk of more unnecessary care, and therefore may increase the healthcare costs.

ECORYS

V. Patient ownership

The position of patients/consumers is changing. This is driven by the digital transformation, customised care, remote healthcare, regulation and an increased focus on prevention. There is an increasing use of data collected via or integrated with medical devices which provides real-time access to patient data, improving shared decision-making and the position of patients. Product-oriented MedTech innovations are bundled with services enabling real-time patient involvement and targeted care. New tools include **genome sequencing** and commercially available medical technologies, such as **mobile phone-enabled self-monitoring** or digital **laboratory tests.**

FUTURE DEVELOPMENT
This is a trend which already commenced from the IT side, and will continue in the coming years.

MARKET IMPACT
New technologies will disrupt the current healthcare system: medical information is shifting the power from traditional healthcare parties to patients, and new players will enter the market (e.g. Apple providing personal health records). Therefore opportunities arise for third parties (e.g. parties that connect medical records from hospitals, law firms, insurance and health providers). Patient behaviour also influences the supply on the consumer market, e.g. apple watches.

ECORYS

PATIENTS/CONSUMERS

- Data collection and ownership of data give patients/consumers autonomy. It enables consumers to be informed and to steer their own care and/or treatment.

! Patients may not be able to make the best informed choices regarding their care pathway.

The shift towards more demanding patients creates a changing position for **patients** and requires a different role of healthcare providers. At the same time the demand side (patients) does not always connect with the supply side, providing a challenge for the role of patient organisations.

Patients own a lot of information, which increases behavioural risks and requires for health literacy. Some patients are **not ready to share their data;** (chronically) ill people appear to be more ready to share their data, whereas healthy people are less willing to share their data as they are anxious about what will happen with it. Potential benefits of sharing data and risks for patients should be clearly presented by all involved stakeholders (e.g. healthcare providers, health insurers, MedTech companies, government).

HEALTHCARE PROVIDERS

- The opportunity to provide more **patient centered care**, such as monitoring technology, remote consultations, online access to records and care plans, especially for patients with long-term chronic conditions.

! It is not clear to what extent healthcare providers are skilled to deal with the new position of patients

Are healthcare providers and patients sufficiently enabled to make a shared decision?

V. Patient ownership

HEALTH INSURERS

- Change of position of patients will influence the way in which healthcare benefit packages need to be offered, this creates opportunities to excel.
- ! At the same time, the changing position of patients creates challenges on how healthcare benefit packages need to be offered - it increases competition between insurers. Social media influences the expectations from patients/consumers, and the reputation of the health insurer is at stake.

MEDTECH COMPANIES

- Focus on different products that are more customised to the individual patient, e.g. wearables.
- ! Differences between consumer and MedTech goods. Competitors arise from the consumer market, entering the health market (e.g. Apple watches, ECG monitoring devices, blood pressure monitors).

GOVERNMENT

- Patient ownership potentially leads to increased patient satisfaction and increases the patient-centeredness. This improves the quality of care.
- ! In some cases MedTech will increase the demand for services, while often the cost-effectiveness of MedTech products is not known - this requires action to introduce a more formal evaluation system for MedTech. In parallel it will be important to monitor the impact of such inititiaves or policies (e.g. by requiring health technology assessment) to control costs without delaying access to new innovations.

The government is expected to (further) develop and support **policies** to place healthcare users at the centre of care. Policymakers need to foster innovation and effective collaboration by creating a supportive environment. This includes the development of a shared vision on patient-centredness and engaging all relevant stakeholders.

VI. Prevention, prediction and early treatment

There is a constant shift from treatment to prevention, prediction and early treatment. This is enabled by the use of machine learning, artificial intelligence, algorithms and smart apps integrated with medical devices providing real-time access to patient data, as well as eHealth solutions and telemedicine. Prevention includes disease prevention, as well as preventing deterioration of chronic diseases. Relevant disease areas where this trend is visible include diabetes, cancer and neurological disorders. A type of prediction relates to 'predictive biomarkers', which predict the effectiveness of a particular treatment.

FUTURE DEVELOPMENT

MedTech companies are becoming more focused on preventive products. Prevention & prediction will influence the health market, as well as the MedTech market. However, to reach the full potential of this trend, some obstacles need to overcome, especially relating to financing.

MARKET IMPACT

New reimbursement models are necessary (e.g. risk-sharing) to provide more opportunities in these areas. There is a continuous cost pressure on the collective health system with risks of segregation and social inequality. Increased focus on prevention, prediction and early treatment influences the labour market (e.g. specialised nurses in general practices).

ECORYS

PATIENTS/CONSUMERS

- Patients are more **engaged** in improving their own health and are better informed about their genetic profile. Patients are more focused on prevention and staying healthy, e.g. through the use of wearables.
- ! Prevention and early diagnosis expects a more active role from patients in terms of **responsibility** and empowerment. Sufficient health literacy of the population is a prerequisite.

HEALTHCARE PROVIDERS

- Prevention (by using machine learning, artificial intelligence, etc.) offers increased opportunities for **specific diseases**, e.g. for preventing deterioration of chronic diseases.
- ! The role of healthcare providers needs to change: increased access to data requires systems' compability and creates the opportunity/challenge to work together with MedTech companies/sharing data. Increased focus on service agreements and **risk sharing.**

VI. Prevention, prediction and early treatment

HEALTH INSURERS

- Focus on **healthy lifestyles** and prevention improves health outcomes and could result in cost savings; offering additional insurance on good service in hospitals or offering rewards on healthy lifestyles.

! **Financing of health services.** Privacy issues regarding the use of data.

MEDTECH COMPANIES

- Medtech companies have strategies focused on preventive care and minimum invasive care, as well as offering full pathway services, in which genetics, early diagnostics and bio-markers play an important role. Opportunities for innovative, cost-efficient and holistic healthcare approaches to preventative and diagnostic medical care.

! Improved cooperation and data & knowledge-sharing with healthcare professionals. Preventive healthcare is not yet a business model, financing of care pathways is an important barrier.

GOVERNMENT

- Cost savings through prevention, prediction and early detection - e.g. by substitution more expensive care, and reducing the number of avoidable hospitalisations.

! There are several **ethical & financial considerations that need to be answered,** e.g. though public debate or citizens councils and/or via health technology assessment of MedTech: How can we keep the collective health system in place with cost pressures and how can we deal with the risks of segregation and social inequality as a consequence of the shift towards prevention, prediction and early treatment? Is there a need to focus on specific diseases? What if you discover that a disease is non-treatable?

ECORYS

VII. Value based healthcare

Value based healthcare links quality of care to reimbursement. Value is created from health outcomes which matter to patients relative to the cost of achieving those outcomes. The four key elements for implementing value based healthcare are 1) health information technology standards; 2) quality standards, 3) price standards; and 4) incentives.

FUTURE DEVELOPMENT

This is a trend that is increasingly seen, however at a step-by-step pace. This is due to the transformations that are needed to implement value based healthcare, including measuring health outcomes in practice, strengthening primary care, building integrated health systems, implementing appropriate payment schemes, and enabling health information technology.

MARKET IMPACT

The shift to bundled payment results in slower growth of the MedTech sector. Manufacturers need to demonstrate value to a new and broader set of stakeholders, including hospital administrators, payers and patients. Savings can be used outside the health sector. Potentially less independent position of medical professionals and vertical integration in care organisations. Collaboration between providers may result in enhanced market power, making it more difficult for health insurers to bargain lower prices/higher quality. Required transparency of treatment outcomes will provide winners and losers in the market.

ECORYS

PATIENTS/CONSUMERS

- **Lower cost of care** at sustained or improved levels of **quality.**
- ! Patients should be willing to increasingly accept preventive care and/or less costly options with proven results. This might create less **individual freedom** - in contrast to the trend of patient ownership and could require more action from patients (e.g. increased physical exercise, more support for family member(s) requiring care).

HEALTHCARE PROVIDERS

- Efficiencies in care provision and improved **patient satisfaction.**

  Healthcare providers could benefit from standardisation and protocol development for certain MedTech products.

- ! Individual providers may or may not reap financial benefits, and may hold on to established positions.

  An integrated patient perspective requires **coordination** between departments and between care organisations which relies on support from professionals.

  Increased protocol in care goes along with **resistance** and may restrict the professional autonomy of health professionals.

  The de-implementation of not cost-effective interventions/procedures requires behavioural change.

VII. Value based healthcare

HEALTH INSURERS

- A healthier population with fewer claims translates into less drain on insurance premiums and investments. Value based reimbursement also allows health insurers to increase efficiency by bundling payments that cover the patient's full care pathway, or for chronic conditions, covering periods of a year or more.

! Determining value is a **complex** task requiring large amount of data which can be compared.

Value based reimbursement is based on patient pathways, crossing provider and accountability levels.

MEDTECH COMPANIES

- Products and services aligned with positive health outcomes and reduced cost. MedTech companies are generating data that could be used to show an decrease in costs (e.g. less surgical procedures), which makes health insurers more willing to pay.

! The ability to prove added value will provide MedTech companies with a strong competitive edge over rivals. However, many MedTech interventions are intermediate products (e.g. imaging and diagnostics).

Ownership of data generated by MedTech products will increasingly be seen as a 'public' good that is to be shared with providers and patients.

GOVERNMENT

- Creating value by optimizing outcomes and decreasing cost due to better management of chronic diseases, prevention of hospitalizations and medical emergencies.

! Government to support investments and the standardisation of data collection, protocol development, and quality control.

ECORYS

VIII. Regulation (MDR, IVDR and GDPR)

The MDR and IVDR will ensure a high level of health and safety protection when using medical devices, and free and fair trade of these products throughout the EU. Improved quality, safety and reliability of medical and in-vitro devices, strengthening of transparency of information for consumers, enhanced vigilance and market surveillance.

The GDPR strengthens existing rights, provides for new rights and gives citizens more control over their personal data, including: easier access to their data, a new right to data portability, clarity to their right to erasure ('right to be forgotten'), and right to know when their personal data has been hacked.

FUTURE DEVELOPMENT

Regulation is an important development, not necessarily a trend but a requirement for proper functioning of the (MedTech) market. The implementation of regulation on (in vitro diagnostic) medical devices, and GDPR will definitely influence the MedTech market and health sector in the future.

MARKET IMPACT

Improved harmonisation of products in terms of quality and safety. Potential negative impact on the position of SME's. Increased risk that the EU position will change in terms of becoming less attractive, creating market opportunities for America, China and India. MedTech companies could potentially not enter on the Dutch market (relatively small), because the EU healthcare market is fragmented.

ECORYS

PATIENTS/CONSUMERS

- Improved confidence in the **safety** of medical devices. Higher quality of MedTech products and state of the art products.

  More control over personal data collection, and how this information is used. Healthcare data is often fragmented collected and stored; the GDPR ensures more information about the purpose and location of the data collected, thereby reducing fragmentation.

- ! Risk that certain new innovations will not enter the market, or certain products will disappear from the market or that device production slows down which may impact (early) access to new, innovative products.

  Awareness of the difference between a product falling under MDR versus a **consumer good** in terms of safety and reliability.

  The GDPR could create a barrier for diagnosing purposes as the patient has the right to be forgotten.

HEALTHCARE PROVIDERS

- Improving confidence of healthcare providers in the safety of medical devices and improvement of **data-protection.**

- ! Regulation can potentially increase the **administrative costs,** as providers need to comply with the new requirements. This may be difficult with a lack of transparent standards.

  Increased demand for clinical expertise supporting the MedTech companies, as well as the need for additional education to adhere to the regulation.

VIII. Regulation (MDR, IVDR and GDPR)

HEALTH INSURERS

- Less risk of unsafe medical devices. Improvement regarding **data-protection**.
- ! Higher **costs of compliance** and risk of penalties when non-compliant with the GDPR regulation. Companies must take special precautions when personal data are transferred to non-European countries that do not provide an EU-like data protection framework.

MEDTECH COMPANIES

- Stimulation of **fair trade** and improvement of quality of products, reducing the risks of bad publicity.

  Market opportunities for larger MedTech players arise due to the differences between general and highly specialist applications become more visible.
- ! Higher cost of compliance due to review of product portfolio's, maintaining records, evidence and best practice procedures. Potentially more difficult **market entrance,** especially for SME's: approval procedures from notified bodies are likely to be more stringent. Risk of less innovation and new technologies, also from academic organisations/university hospitals.

  The GDPR makes it more difficult to collect patient data and potentially imposes a burden in terms of requirements related to communication, storage, data-processing, data collection, and consent.

GOVERNMENT

- Improving the quality, **safety and reliability** of medical devices. It also strengthens the transparency of information for consumers, enhancing vigilance and market surveillance.
- ! Need to strengthen regulation of medical devices, which has traditionally been less stringent compared to pharmaceuticals. Risk of implementing re-active regulation at the moment when problems arise (pace of regulation).

  Regulation is never fully developed and always needs adjustments and updating.

ECORYS

Impacts of trends and best practice examples

In this Chapter we summarise the main impacts of the trends with regard to the quality, accessibility and affordability of healthcare. In addition, we provide some lessons to be learned to address key challenges identified across the trends: data security, innovation partnerships and financing models. These examples are based on both desk research and the interviews conducted, and are meant to be inspirational for relevant stakeholders.

Impact on quality, accessibility and affordability of care

The trends are wide-ranging and will impact all dimensions of healthcare (prevention, diagnosis, cure and care), including quality, accessibility and efficiency. Although many technological developments have the potential to improve all these dimensions, it is in most cases too early to judge how it may turn out. There are several reasons for this.

History shows that technological developments tend to increase the cost of healthcare.[20] Improvements of the quality of care are typically most tangible in cure settings, although many MedTech interventions in use have not been evaluated, and as such their cost-effectiveness is not (yet) known. In care settings many MedTech innovations are aimed at a reduction and/or substitution of labour. Whereas this may be imperative from an cost containment perspective, the impact on the quality of care is often not known.

Innovations in the governance and management of the healthcare sector are typically very slow. Introduction of information technology within public organisations (like large corporate organisations) is a necessity, but recent history is full of disappointments, both in terms of actual capabilities of new systems, required organisational changes, skilled personnel needed, and investment cost.

Important tangible benefits are foreseen in products aimed at enhancing the autonomy of patients. This includes the use of exoskeletons, service robots, remote services and monitoring of patients. However, autonomy of patients and accessibility to non-reimbursed technologies is also depending on the level education, literacy, and social-economic status (e.g. income) This situation is posing a risk of health inequality, and need to be carefully observed in terms of equal access to healthcare.

New MedTech products are also expected to support and enhance prevention strategies. Increased information, screening and detection may help prevent diseases and/or improve treatment opportunities. Preventive interventions in the end always have impact on the freedom of individual decision making and personal autonomy. At the same time preventive

[20] https://www.vtv2018.nl/en/health-care-expenditure.

strategies can create over-diagnosis, over-treatment and medicalisation. It is important that the use of technology is appropriate, evidence-informed, and taking patient-centeredness into account.

The digital transformation and the related services being developed highlight the importance of information and information management as well as its main resource (patient) data. Whereas the potential of these new technologies is large, it is increasingly becoming clear that the control over data is not only a privacy issue. Those institutions and organisations that can control data and its use will be in charge of developing its applications. Without this control, the possible benefits may accrue to other parties. This may jeopardise potential benefits in terms of efficiency and quality as a result of a reduced capacity for stewardship over the health system.

Lessons to be learned I Data security, integrity and data sharing

Electronic health records (EHR) are quite promising in relation to streamlining information management. This reduces cost, increases accessibility and timeliness and ease of use including data sharing. Numerous benefits are attributed to EHR and some have materialised already.

One of the challenges is the design and security of the personal data. Many health information systems developed in the past and currently in use suffer from inherent weaknesses related to control over personal data from patients, security of data and possible misuse in general. The shrinking trust in government in society, and the uncertainties about the role of government in the use of the data it collects under its own responsibility, add to the difficult compromises struck in the management of medical data, limiting the potential benefits.

One of the emerging technologies that present an increasingly viable alternative to centrally managed databases is the use of 'blockchain technology'. The central claim being an inherent secure technology for management and sharing of data in a fully transparent, decentralised system, which provides full control to users on who can read and use their data. The development and application of blockchain technology is being fully utilised across sectors where trust and efficiency are in high demand, such as the financial sector, notary services, archives, etc. The technology could have far-reaching implications on how the system of data-sharing in the health system is set up and its implementation would require guidance, coordination and commitment from the government to convince partners to invest in it.

EHR (Estonia)
An interesting example of a pioneering country in this respect is Estonia. It has built its EHR using a commercial, privately managed KSI blockchain technology. It claims to have spent only USD 10 per inhabitant to make it operational. Each patient can determine which provider can see what type of information in his/her dossier. She/he can also determine who has actually access to the information and when. According to information from Estonia, 95% of the providers are using the system. More than 99% of the prescriptions are managed through the systems, and 100% electronic billing has been reached.

An important design parameter concerns the use of a public, private or consortium-based blockchain network. The public solution (e.g. bitcoin) is extremely transparent, but also difficult to control (open access) and requires large resources (energy) in operation and maintenance. In the past years private companies have been setting up their own blockchain technology which they sell to users. An important drawback here is that the responsibility for the integrity of the system is fully outsourced to a private party.

A promising new alternative is so-called consortium-based systems where the responsibility for the proper functioning system is shared by a designated group of stakeholders, allowing e.g. government to participate, increasing transparency and trust without jeopardising the efficiency of privately managed blockchain and closed networks. The government in the Netherlands could consider to support such a healthcare consortium to test blockchain technologies and support dialogue, benefiting from valuable lessons from other sectors (e.g. financial sector). The aim of such a network could be the development of protocols and standardisations, advancing harmonisation of healthcare information.

Lessons to be learned II Innovation, collaboration and partnerships

Early collaboration on the development of innovations between industry, regulators, patients, end-users and experts could reduce the downstream risk of rejection to use the technology.

EXCITE International (Canada, US, UK, and NL)
EXCITE is a global collaboration of industries, regulators, health systems, patients, scientists, payers, and end-users to help start-ups with proof of concept and clinical trial development and execution to secure adoption of breakthrough medical technologies. Providing an Early Technology Review to develop MedTech aligned with all relevant stakeholders.

Initiatives that stimulate cooperation and evaluation could increase global adaption of innovation and could reduce costs. EXCITE is one of the examples that develop coalition and cooperation between all relevant stakeholders.[21] EXCITE enables early discussions between developers and relevant health system stakeholders, including government, health care providers and research to determine what information is needed to get the product successfully adopted. The evidence collected can be used for regulatory or licencing approval and reimbursement and purchasing reviews. In the Netherlands, EXCITE International already established a partnership with Radboudumc developing national collaborations around three programmes: MedValue's early HTA and decision analysis, clinical trial units, and the ReShape Innovation Centre.

The Dutch Innovative Medical Devices Initiative (IMDI) is a public-private partnership. The UMCs, Technical Universities, health care institutions and industry collaborate in eight large Centres of Research Excellence (CoREs) to realise innovations.[22] The themes that the Centres of Research Excellence work on include medical imaging and imaging processing, minimal invasive technologies and rehabilitation and homecare technologies. The IMDI programme will run until 2019.

The government should continue to support programmes as IMDI and EXCITE, stipulating the importance to initiate early discussions between developers and relevant health system stakeholders, including government, health care providers and research to determine what information is needed to get the product successfully adopted. The evidence collected can be used for regulatory or licencing approval and reimbursement

[21] http://www.exciteinternational.com/site/home.

[22] http://www.imdi.nl/.

and purchasing reviews. It is important that all relevant stakeholders, including patients, and the payers, are involved in such programmes. The government could act as facilitator in bringing all stakeholders together, creating a level-playing field.

Lessons to be learned III New financing models

Public Private Partnerships between hospitals and large MedTech companies are increasing. Specific market circumstances are important for their success. For hospitals with limited access to financing options, it presents a mode to enable renovation/upgrade hospital infrastructure. For MedTech companies, the proposition becomes attractive depending on tax incentives (VAT) and flexibility. Currently low financing cost (interest) (availability of cheap capital) are conducive to these arrangements. The textbox presents the example of the partnership between Karolinska Institute and Philips in Sweden. Also, in the Netherlands such partnerships are operational. For example, the ADRZ hospital in Goes outsourced its new operating theatre to the manufacturer (Siemens). The hospital will annually pay the manufacturer rent for the use of the facilities. In the UK, the procurement and maintenance of medical equipment in many hospitals has been outsourced for 10-30 year periods to specific vendor-independent Managed Equipment Service companies.

Philips partners with Karolinska (Sweden)
In Sweden, Philips entered into a long term agreement (14 years) to supply and maintain new medical equipment for the Karolinska University Hospital. Performance based revenue models are integral part of the contract.

As part of the agreement, Philips will establish a research and innovation hub at the new hospital with the aim of bringing together clinicians and researchers from industry and academia to facilitate idea generation and exchange. In this way Philips and Karolinska are better able to manage the 'technology risk', i.e. unknown technology development, of these long term agreements.

Other examples of partnerships are also available, e.g. NHS and Google' Deep Mind business work together to analyse information on kidney disease to improve treatment. Medtronic and Diabeter (Value based Healthcare price 2017) is a Dutch example of how a MedTech company invests, through acquisition in VBHC initiatives.[23]

[23] https://www.medtronic-diabetes.nl/onze-innovatie/diabeter.

In such programmes, it is essential to jointly work together on how to create the best results for patients and the health system (efficiency-equity trade-off). Clear agreements between all partners are necessary to succeed. This means that clear objectives need to be specified, with accompanied roles and responsibilities.

NHS and Google (United Kingdom)
In 2016 the Royal Free NHS in the UK signed a landmark partnership with Google's Deep Mind business. In a five year contract DeepMind will gain access to new and historical patient and treatment data for 1.6 million patients in 3 hospitals. The goal of DeepMind is to analyses information of patients with kidney diseases. According to Deep Mind the NHS pay a 'modest service fee' and DeepMind has no intention to use the information for commercial use. The partnership included the use of an independent review panel installed by Deep Mind.

According to the British Information Commissioner the NHS violated existing data protection laws and failed to inform patients appropriately.
(New Scientist, Fierce Healthcare)

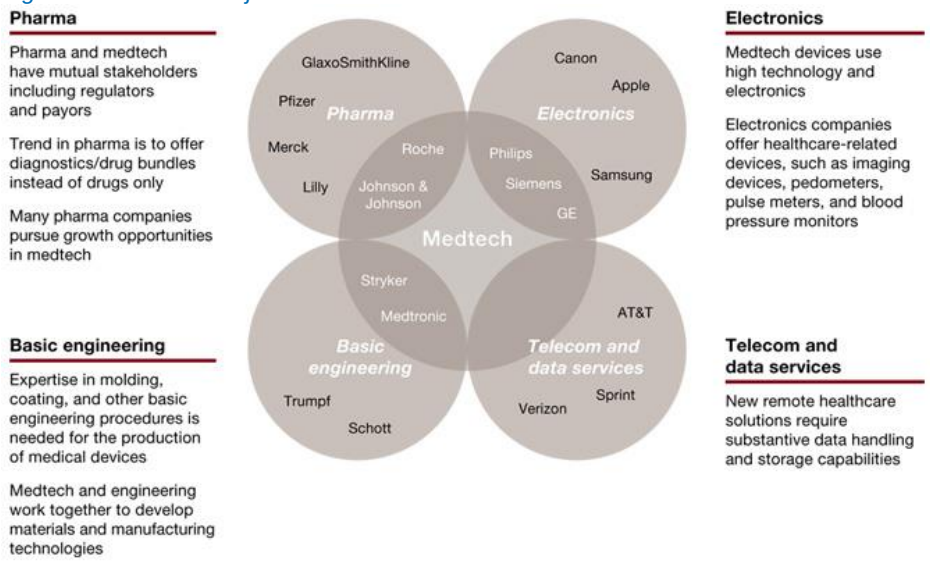
The future landscape

In this chapter we describe how the Dutch MedTech market and healthcare landscape will look like in the future, including the type of MedTech products and new entrants. In addition, we discuss the strategies of market parties to make the MedTech market more sustainable and future-proof.

MedTech is used in all healthcare sectors, including the cure sector, long-term care sector, and at municipality level. Also, the MedTech industry is strongly linked to several other innovative industries including pharma, electronics, engineering and telecommunications, and data services, [24] as shown in figure 3. Remote healthcare solutions require data handling and storage capacities. Basic engineering procedures are needed for the production of certain MedTech products and many MedTech use high technology and electronics. In addition, many pharma companies pursue growth opportunities in MedTech, e.g. via personalised medicine (e.g. companion diagnostics).

In order to discuss the future of the Dutch MedTech market, it is necessary to first provide an overview of the current market.

Figure 3 MedTech's adjacent industries



Source: Behner, Erhhardt, Luebben et al, 2017.

Current state of play

In the report of the MedTech market in the Netherlands the Dutch MedTech market is estimated at €4.7bn in 2016, making up approximately 4% of the European market and 1% of the global market.[25] It was estimated that 500-700 medical technology suppliers are active on the Dutch MedTech market. Of these suppliers, 95%-97% are small and medium enterprises

[24] Behner, P., Ehrhardt, M., Luebben, E., Richert, F. (2017). Digital readiness in medtech. How a diverse business is adapting to Industry 4.0, available at https://www.strategyand.pwc.com/reports/digital-readiness-medtech.

[25] KPMG. (2017). The MedTech market in the Netherlands, available at file:///C:/Users/indra.vandervalk/Downloads/the-medtech-market-in-the-netherlands.pdf, , p. 20.

(SMEs). Larger companies are mainly subsidiaries (roughly ten) of large multinationals, whereas in the area of diagnostic imaging some leading Dutch companies are active on the international market. SMEs often work closely together with healthcare providers and academic institutions, of which a large portion is developing MedTech in e-health, patient monitoring and medical instruments. SMEs increasingly expand their business outside the Netherlands because getting reimbursement for MedTech is time-consuming and difficult because of procurement rules and regulation.

Supplier power differs greatly between care products, diagnostics and imaging, ophthalmic, cardiology and orthopaedics depending on the homogeneity of the products, the complexity of the technology and scale requirements. Large academic hospitals seem to prefer international operating large suppliers or wholesalers, whereas general hospitals tend to choose a small number of wholesalers/producers as main suppliers.[26]

The future – developments in MedTech products

MedTech products need to adapt to technological developments, regulatory uncertainty and customer expectations, creating increasingly customer centric products.[27] This includes the ongoing development of interconnected devices, miniaturisation and service integration. Looking at the impact of trends in MedTech from a disease perspective is not straightforward in the context of this study. Most developments are generic in nature and in principle could contribute to detection, diagnosis and treatment of a broad variety of diseases and ailments.

However, it is highly likely that the ongoing digital transformation will have the broadest impact potentially affecting almost all diseases and ailments through enhanced detection and diagnosis capabilities. This not only affects the sensory capabilities of technology, but also actuating modalities such as electric pulses (pacemaker, brain stimulator), and mechanical stimuli (e.g. vibration).

Robotics is expected to have an impact on neurological disorders, diseases of the musculoskeletal system, helping in the often long rehabilitation cycle and assisting people with disabilities, since the main patient groups served by

[26] KPMG. (2017). *The MedTech market in the Netherlands* KPMG. (2017). *The MedTech market in the Netherlands* , p. 31-32.
EY. (2017). As change accelerates, how can medtechs move ahead and stay there? Pulse of the industry 2017, available at https://www.ey.com/Publication/vwLUAssets/ey-as-change-accelerates-how-can-medtechs-move-ahead-and-stay-there/$FILE/ey-as-change-accelerates-how-can-medtechs-move-ahead-and-stay-there.pdf.

rehabilitation services are for neurological pathologies. Severe-incident injuries can be addressed through exoskeletons. Mental health is already a proven field for the application of e-health. Treatment of dementia may profit from advances in robotics, both through social and service robots.

3D-printing is already known to have an impact in dentistry and ear implants. First results are also reported in terms of tissue printing benefiting the treatment of burns,[28] but also potentially the opportunities for artificial organs and implants for musculoskeletal disorders (knee/hip).

Remote health care is very generic in its application, but will improve treatment through telemedicine, as well as keep patients out of clinical settings due to increased opportunities for monitoring health conditions at home or in daily life.

New entrants to the MedTech market

The digital transformation provides opportunities for other players to enter the MedTech market (e.g. **Google, Amazon, Apple, Alibaba, Microsoft**). Amazon has ambitions in the medical supply chain, adapting Amazon technologies for the healthcare market, thereby implementing more consumer-like technology systems. Apple is launching medical clinics for its employees. Google is entering the healthcare and wellness market via parent company Alphabet (see textbox) and Alibaba invested in Wlycloud (telemedicine imaging services). Digital technologies and AI can be used for personal health and health system apps and the above mentioned entrants will use their expertise to establish an intersection between digital technologies and health system delivery. Also, entry barriers for entrants specialised in software-based and customer focused services are lowered.[29]

Consumer and MedTech markets are getting more blurred. The consumer technology market is influencing the health and MedTech industry with self-care, fitness, health monitoring and sleep devices. Products are ranging from devices that measure heart rate, stress with ectodermal sensors, respiratory rate, body temperature, blood oxygen levels, blood pressure, to peanut allergies.[30]

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28 He, P et al. (2018). Bioprinting of skin constructs for wound healing. Burns Trauma.

29 EY. (2017). As change accelerates, how can medtechs move ahead and stay there? Pulse of the industry 2017, available at https://www.ey.com/Publication/vwLUAssets/ey-as-change-accelerates-how-can-medtechs-move-ahead-and-stay-there/$FILE/ey-as-change-accelerates-how-can-medtechs-move-ahead-and-stay-there.pdf.

30 https://www.businessinsider.nl/dna-testing-delete-your-data-23andme- ancestry-2018-7/?international=true&r=US.

Investments Alphabet
No other company in the Silicon Valley is investing so heavily in healthcare-related companies as Alphabet. It has invested in more than 60 companies with a very diverse portfolio, ranging from genetics to telemedicine. Examples include **23andme**, the most well-known direct-to-consumer genetic testing company with one of the biggest DNA databases in the world. **Doctor on Demand**, a telehealth company helping people talking to physicians from afar; **Flatiron Health**, a company building a data platform dedicated to oncology or **Impossible Foods** developing plant-based meats and cheeses. A total of USD 1.5 billion has been invested. Between 2013 and 2017 Google is reported to have filed 186 health related patents in particular in the field of AI with a focus on diabetes, genetic information and bio-electronics.
(Sources: Forbes, The Medical Futurist, Ernst & Young)

Hospital of the future

Trends and products relevant for the MedTech market of the future have similar requirements as those for the hospital of the future. These include, amongst others:

- higher public demands for more and better healthcare services;
- UMCs will be expected to concentrate, specialise and focus on high-value and highly-complex services;
- hospitals will embrace new services and innovation, such as personalised medicine and genome-based diagnosis. This will be based on new MedTech that requires specific skills;
- hospitals limit the resources on the main site to also cover specialised home care and provide services at shared facilities;
- focus on patient experiences and innovations to become more patient-centred.[31]

Dealing with the future - business strategies

Consolidation on the side of hospitals and intense downward pressure on prices make it increasingly costly for MedTech companies to sustain a large sales force. At the same time, the resulting margin squeeze limits companies' abilities to take advantage of opportunities in the emerging areas of outcome-based health care and digital health.

In response, MedTech companies are looking for new business models combining opportunities to sell services rather than hardware while linking up to VBHC concepts by transforming their pricing methods based on the value created for patients,

[31] Ribera, J. (2016). *Hospital of the Future, a new role for leading hospitals in Europe.* IESE, Accenture.

providers and payers.[32] The role of MedTech companies includes providing robust and verifiable data to healthcare providers and healthcare insurers on the added value of the devices.[33]

Healthcare systems around the globe aim to evolve toward more accountability for outcomes and move to value-based reimbursement. However, the definition of value in MedTech is not fixed and is constantly evolving. Value frameworks are developed to stimulate discussions and focus on the economic value, including health care quality and longer-term costs.[34]

A key element in the strategy of large MedTech companies is the shift from a producer of capital goods to a company providing clinical or even patient services. This ongoing transformation is expected to add value to their proposition and enhance client orientation, keeping price competition at product level at bay. This requires different ways of participation, collaboration and contributing to the value chain rather than providing goods.

Data-driven analytics can measure and improve health outcomes, minimising variations in care and demonstrating value, this however requires collaboration between all relevant stakeholders.[35] Large MedTech companies are increasingly involved in healthcare pathways and processes; Philips in the area of logistics & radiology, Siemens at the operating room, Johnson & Johnson with portable technologies and Medtronic with Clinics for the treatment of diabetes. The extent to which smaller companies will be able to use these new strategies remains to be seen.

Ambitions of MedTech companies range from leading the world of digital transformation, improving customer experiences and adopting patient-centered designs, quality systems and operational excellence, to innovations backed by clinical and economic innovation.[36] MedTech companies may become more focused on patient pathways, ranging from prevention to treatment from a disease or technology perspective.

32 BCG (2018). “Next-Generation Pricing Is Transforming Medtech”, available at https://www.bcg.com/publications/2018/next-generation-pricing-is-transforming-medtech.aspx.

33 Deloitte (2018). “MedTech and the Internet of Medical Things, how connected medical devices are transforming health care”, available at https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-medtech-iomt-brochure.pdf.

34 Oortwijn, W. on behalf of the HTAi Policy Forum. From Theory To Action: Developments In Value Frameworks To Inform The Allocation of Health Care Resources. Background Paper 2017 Policy Forum.

35 Harvard Business Review Analytical Services, Medtronic (2017). “Three keys to unlocking data-driven health care, available at http://www.medtronic.com/content/dam/medtronic-com/global/Corporate/Initiatives/harvard-business-review/downloads/data-driven-healthcare_paper_hbr_av_corpmark.pdf.

36 As shown by the business strategies and business propositions on the websites of amongst others Philips, Medtronic, Johnson & Johnson.

MedTech companies are collaborating and partnering with technology companies and digital entrants. **Philips and PathAI** work together on improvement of breast cancer diagnosis with the use of AI in pathology research. **Microsoft and Stryker** bring HoloLens - a mixed reality solution - on the market to improve the process for designing operating rooms for hospitals and surgery centres. **Medtronic** works together with **IBM Watson Health** to develop new ways to address diabetes. **Johnson & Johnson** initiated a start-up called Verb working together with **Google Verily** to develop a better and cheaper surgical robot to facilitate medical surgeries.

Areas of action according to stakeholders

The future of MedTech has been further explored by asking different stakeholders to comment on statements via an online Delphi panel session. The statements are related to Big Data management, stimulating innovation, creating interoperable systems, responsiveness to disruptive innovations, solving labour market problems, value-based healthcare and cooperation amonst stakeholders.

Statements were in the online Delphi panel session clustered into the five health system elements. The resulting areas of action (see Table 2) are based on the input from 15 stakeholders, including healthcare providers (4), healthcare experts (3), MedTech representatives (4) and international stakeholders (3). Annex V shows an overview of the statements and questions posed during the Delphi panel session, as well as the responses per statement.

Table 2 Areas of action according to relevant stakeholders

Actionable areas	
	Government
Big Data management	Big Data management needs to be regulated to ensure safety, liability, data ownership and privacy issues.
Interoperable infrastructure	A country-wide and international compatible and interoperable infrastructure for data with a clear governance for data management is needed for the digital transformation of the health system.
Attractive environment for innovation	The implementation of EU regulation (MDR/IVDR) creates harmonization but also potential barriers, especially for SMEs when entering the MedTech market. It would be helpful to provide support to SMEs regarding the implementation and compliance. In addition, new financing models could enable early adoption and implementation of new innovative MedTech products.
	Finance
Value-based healthcare	The transition towards value-based health care needs to go along with new payment and service models.
Mitigate risks of customised and remote care	Personalised and remote care targeting individual patient pathways baer the risk of overtreatment and this may lead to increased total health care costs. These risks need to be mitigated.
	MedTech market
Prepare for new market entrants	The digital transformation provides opportunities for other players to enter the MedTech market (e.g. Google, Amazon, Apple, Alibaba).
Align education & roles with the future needs	Existing education and training programmes should be aligned with the skills and competences needed for the future MedTech market. To catch up with the rapid progress of the MedTech industry the role of health professionals regarding innovation needs to change.

Actionable areas	
	Organisation of care
Integrated healthcare system	New MedTech solutions can support a shift from secondary care towards primary care, it may increase self-care and it may enable concentration of complex care. Better cooperation between primary and secondary health care is needed to stimulate the uptake of new MedTech solutions.
	Research and innovation
Stimulate cooperation	Increased cooperation between MedTech companies and other key players in the health care sector is needed to enable the early development and uptake of user-centred innovations.

The following sections will elaborate in further detail on the key areas of attention per health system element.

Governance

Big Data management

The current uptake of digitalisation is considered insufficient and it is clear that the management of Big Data brings a lot of challenges, which are currently not addressed by self-regulation. The optimal balance between governmental leadership and self-regulation is not clear-cut. The majority of the respondents agree that the government should take the lead[37] in regulating big data management to ensure safety, and privacy issues. The question therefore seems no longer a question of "should" the government take the lead, but rather a question of "how".

Are patients currently in control of their data and will they be in the future?[38] If so, patients need to be educated and facilitated. They need to know who takes the lead regarding data transferability, informed consent, data protection and control. The MDR, IVDR and GDRP are in place to secure appropriate and safe use of data, but one can expect practical guidelines and/or rules are needed to inform patients about their rights.

Issues such as safety and liability relating to Big Data are cross sectoral, cross border, multi-level and multi-stakeholder. The government should steer initiatives involving all relevant stakeholders, making it a joint effort of regulators, healthcare providers, research institutes, insurance companies, IT, MedTech companies and patient /consumer organisations.

Interoperable data infrastructure

One of the challenges for the development of the MedTech market and which impact the healthcare landscape is the lack of interoperable information systems, not only within the Netherlands, but also between countries. Fragmented data and

[37] 10 out of 15 stakeholders agree/fully agree and 5 out of 13 neither agree nor disagree with the following statement: "The government needs to take the lead in regulating Big Data management to assure safety, liability, data ownership and privacy issues".

[38] Question asked by a technology representative.

incompatible technologies are major challenges for all health systems and has negative consequences for the efficiency, effectiveness of services and transparency. Standardisation and international data exchange are also a requirement for the use of Big Data & IoT. MedTech solutions are seen as standalone solutions if uptake and adaption are compromised, because of the lack of an interoperable data infrastructure.

A country wide compatible and interoperable infrastructure for data could provide for a solution,[39] but is difficult to achieve. An optimal structure is unclear, a large registry is needed in the first place and will be implemented with EUDAMED. At the same time the infrastructure for digitised data collection should be driven by clinical utility and system integration and interoperability of patient and clinical data is necessary. Due to the lack of an interoperable data infrastructure, new parties could enter the market, offering easy solutions for data management. The lack of interoperable data infrastructure could also stimulate bottom up incentives that stimulate implementation of digital platforms, e.g. Health-RI offering access to all data, tissues and images available.[40]

Attractive environment for innovation

A clear regulatory framework, financial support, low market uncertainties are all elements that create an attractive environment for innovation. Regulations such as the MDR and IVDR provide greater consistency and will result in European harmonization of access to MedTech products. European certification can give a competitive advantage and could increase the attractiveness to enter the European market. It increases a uniform framework to assess the quality and safety of MedTech products. In a network economy, increased collaboration between multinationals, SMEs and start-ups will benefit from more uniform and harmonised regulations when entering the market. This is beneficial for new businesses and services models, as well as for R&D.

However, entering the MedTech market for SMEs is considered more difficult by the majority of the stakeholders[41] with the new regulations, since SMEs won't have the required resources and experience. Also, a longer implementation period due to compliance to the new regulations will increase financial barriers. In addition, uncertainty regarding the functioning of the new regulatory system during the transition periods, and the difficulty to determine the effectiveness of products, could create barriers for market parties. This increases the risk that

39 2 out of 14 stakeholders fully agree, 5 agree, 5 neither agree nor disagree, 2 disagree with the following statement: "A country-wide compatible and interoperable infrastructure for data with a clear governance for data management is needed for the digital transformation of the (Dutch) health system".

40 https://www.health-ri.org/.

41 8 out of 12 stakeholders fully agree, 2 neither agree nor disagree, 2 disagree with the following statement: "The implementation of EU regulation (MDR/IVDR) creates a barrier for SMEs to enter the MedTech market".

innovative SMEs will decide to enter other (non EU) markets. At the same time, the implementation of EU regulation (MDR/IVDR) could hamper the relative attractiveness of the EU market for (large) international MedTech companies compared to other regional markets, as stated by the majority of the stakeholders.[42]

Another barrier mentioned by stakeholders that could hamper early adoption and implementation of new innovative MedTech products is an innovation adverse/risk avoiding attitude. The more disruptive technologies are, the greater impact it will have at systems level, but most health systems lack the flexibility to implement highly complex technologies with ease.

If the Netherlands wants to stay attractive as a country, stimulating MedTech innovations, current barriers should be addressed. The main barriers include: difficulties to enter the market for SMEs because of the implementation of MDR/IVDR (which is an European barrier) and evaluating the added value of MedTech products, the lack of interoperable data systems, and the innovation-averse structure of the Dutch health care system.[43]

Potential solutions can be found in providing support to SMEs with the implementation and compliance by creating and stimulating the set-up of informal MedTech R&D business networks, start-up communities and health-tech platforms to bring resources and expertise together to adapt and anticipate market needs and stimulation of innovative SMEs via the innovation mission of the Ministry of Economic Affairs.[44]

Financing

Besides regulation, new financing models could enable innovation, early adoption and implementation of MedTech products. The majority of the stakeholders have the opinion that alternative financing options, e.g. leasing, value-based pricing, bundled payment schemes based on evidence based clinical pathways, could provide a solution to these problems.[45]

Valuebased healthcare

Valuebased pricing is one of the possible alternative financing options mentioned. Value based healthcare is evidence-based and should introduce impactful technologies that protect patients from less-effective or less-safe technologies. It is thereby necessary to balance individual patient pathways and emphasise the standardisation of care pathways.

42 8 out of 13 stakeholders agree/fully agree with this statement, 2 neither agree nor disagree and 3 disagree.
43 See “Align education & roles with future needs”.
44 https://www.rijksoverheid.nl/documenten/kamerstukken/2018/07/13/kamerbrief-naar-missiegedreven-innovatiebeleid-met-impact. LINK WERKT NIET.
45 8 out of 13 stakeholders agree/fully agree, 5 neither agree nor disagree, with the following statement: “New financing models (e.g. leasing, PPPs) will enable early adoption and implementation of new innovative MedTech products”.

Value based healthcare also emphasises sustainability, since early assessment of the potential value of MedTech steers developments and prevents ineffective technologies from entering the market. However, systems are needed to decide whether to continue with a potential valueable innovation and use of new MedTech and under what conditions. Dutch insurers appear to still be very cautious in linking reimbursement to outcome based parameters.

The trend towards outcome based financing of healthcare provision also leverages the supply of integrated service models, making use of digital technologies. In this service model, payment is based on the value created for the patient by a network of actors that all have a shared goal. It is based on an agreement in which tasks, roles, responsibilities and revenues for each actor are described.

Mitigate risks of personalised and remote healthcare

Remote healthcare is a rapidly growing area influencing the MedTech sector. Half of the respondents have the opinion that customised and remote care targeting individual patient pathways, in combination with a focus on prevention and prediction can increase the risk of overtreatment.[46]

Remote healthcare is unavoidable, the question is who monitors remotely collected outcomes and how frequently. How will benefits and costs be distributed across primary and secondary health care? Once data is within the domain of a physician's office will they be liable once data are transferred for an adverse event that could have been prevented? Will responsibilities shift from the hospital to outpatient clinics, primary care and the home environment, if so how will this be financed? These questions need to be addressed to prevent overtreatment, liability issues, professional practice challenges, patient dissatisfaction and confusion in the future.

MedTech market

Prepare for new market entrants

The digital market provides opportunities for major platform-based companies to use their expertise at the intersection between digital technologies and health system delivery. According to all respondents, it is inevitable that larger tech parties (e.g. Google, Amazon, Apple, Alibaba) will enter the Dutch healthcare market.[47]

Therefore, it is necessary to think along the potential future scenario's: if larger tech parties will enter the Dutch market this

[46] 6 out of 14 stakeholders agree/fully agree, 2 neither agree nor disagree and 6 disagree, with the following statement: "Customised and remote care targeting individual patient pathways bare the risk of overtreatment and this may lead to increased total health care costs".

[47] 13 out of 13 stakeholders agree/fully agree with the following statement: "The digital transformation provides opportunities for other players to enter the MedTech market (e.g. Google, Amazon, Apple, Alibaba)".

will provide new opportunities, but it is necessary to decide to what extent big-tech companies will become part of the health system and what requirements are essential in terms of data protection, privacy, patient safety, etc. A solid framework should be in place to protect vulnerable stakeholders and prevent misuse. New players might increase competition, and also enables healthcare organisations to focus on their core mission/priority areas. However, the question is: “How to stimulate and improve regulated competition that leads to a well-functioning healthcare system?”.

Align education & roles with future needs

Existing education and training programmes should be aligned with the skills and competences needed for the future MedTech market. This requires cross-sectoral collaboration to address the increasing technological and sociological complexity and to gain experience with integrated technologies. Current healthcare professionals need education to apply the available MedTech solutions now and in the future. Healthcare education needs a stronger focus and mind-set on innovation and requires lifelong learning programmes.

Adjustment of curricula of medical students, nursing students and post-graduate education of professions is necessary to prepare students and current professionals for the future healthcare market. Certain specialisms potentially require less professionals in the future, and others will be desired more, e.g. data-analysts, and technical professionals. Potential shortage of MedTech specialists in the future may thereby hamper the development of new innovative MedTech products, and the implementation and application in daily practice.[48] Also, the roles of primary and secondary care providers will change and it is necessary to redefine these roles.

However, training skills and competences are not the only issue. Task reallocation and collaboration between Medical Specialists (MDs) and MedTech specialists are also essential.

In order to catch up with the rapid process of the MedTech industry, the role of health professionals regarding innovation needs to change, according to the majority of the stakeholders.[49] Technical physicians, professionals that understand healthcare and MedTech can strongly enhance the innovation culture. Health professionals feed MedTech innovations, and they are often early adopters of technologies, when there is adequate evidence on improved health compared to existing alternatives.

[48] 2 out of 10 stakeholders fully agree, 2 agree, 3 neither agree nor disagree, 3 disagree, with the following statement: “Shortage of MedTech specialists hamper the development of new innovative MedTech products in the Netherlands”.

[49] 8 out of 12 stakeholders agree/fully agree with this statement, 4 neither agree nor disagree.

Organisation of care

Integrated healthcare system

All stakeholders agree that new MedTech solutions (e.g. remote monitoring, point-of-care diagnostics, smart implants, drug delivery systems and AI apps and software) could support a shift from secondary care towards primary care.[50] It may increase self-care and may enable concentration of complex care. Integrated technology solutions for (high) complex care in expertise centres might improve efficiency. With the increase of self-care one could expect a reduced need of primary caretakers, requiring re-education, and training for other more complex matters. More effective cooperation between primary and secondary health care will stimulate the uptake of new MedTech solutions.

With the focus on personalised medicine, it is crucial to work in an interdisciplinary manner in order to stimulate the uptake of MedTech. The focus on the individual patient due to trends of patient ownership, remote healthcare, prevention & prediction and digitalisation creates potential risks of segregation that need to be addressed. As prevention, prediction and early diagnosis and treatment will be part of the future of healthcare, financial models for health insurers and MedTech companies need to be aligned (see section on financing and alternative financing models).

Research and innovation

Stimulate cooperation between all relevant stakeholders

The majority of the stakeholders have the opnion that increased cooperation between MedTech companies and other key players in the healthcare sector enables the early development and uptake of user-centred innovations.[51] Collaborative R&D networks stimulate creativity and better use of resources. This requires a functional network of partners with expertise, facilities, access to resources and engagement of end-users. Cooperation will help to shape a shared view on desirable new technologies, aligning it with care pathways and the needs and values of all involved stakeholders, including industry, regulators, patients, health insurers, experts and scientists. However, IMDI is currently seen to be mainly driven by academic interests.

[50] 12 out of 12 stakeholders agree/fully agree with the following statement: “New MedTech solutions can support a shift from secondary care towards primary care, it may increase self-care and it may enable concentration of complex care, as well as lead to supra-laboratories”.

[51] 7 out of 10 stakeholders agree/fully agree with this statement, 2 neither agree nor disagree and 1 disagrees.

Moving forward

In this final chapter, we summarise all the evidence collected and provide an overview of the key issues that need to be considered to fully utilise the opportunities and tackle the challenges for the MedTech market in the next 10 years. We structured these issues according to six themes:

1. Data is key in transforming healthcare,
2. Protection of fundamental rights,
3. Education & change of organisation of care,
4. Business strategy of MedTech companies,
5. Research, development and cooperation/collaboration,
6. Cross-sector actions.

1. Data is key in transforming healthcare

The ongoing digital transformation has raised high expectations about its 'disruptive' potential for the labour-intensive healthcare sector. The advantage of the healthcare sector being (perceived) a 'laggard' is that it can **learn from other sectors about how to deal with the digital transformation**.

It is evident that the generation, collection and use of personal information is central to developing new (MedTech) solutions in healthcare. The importance of digitalised personal health data is therefore a key economic resource and enabler to increase efficiency and quality.

Parties that have access to health data are considered to have leverage over the development of new healthcare solutions. Hence, **management of health data is the crucial element** that will determine to a large extent what kind of new MedTech solutions will be developed, how quickly, under which conditions and against which price.

In the prevailing business models, where data is mainly collected for free (undisclosed) as a by-product from using other services (e.g. search engines, social media, personal genome analysis for genealogy purposes, hospital management systems, etc.), patients, health professionals, hospitals, insurance companies, imaging companies, laboratories, all sit on a potential 'goldmine'. Their access to data and role as generator of data make them important partners for companies that are leading the digital transformation, e.g. IT companies, advertising/tech giants like Google and Facebook, or retailers like Amazon. Companies who increasingly operate under monopolistic conditions worldwide.

Given the key importance of personal data, the role of the **government needs to concentrate on the conditions under which these data can be collected and used.** The government should (help) consider and weigh different objectives, such as ensuring privacy for patients, appropriation of commercial benefits of personal data, maintaining public access to health data and its applications, healthcare cost-

containment by avoiding future dependence on (new) parties with unchecked market powers. The digital transformation in which patients are central requires concrete actions from the government, set in collaboration with all stakeholders, including MedTech companies, healthcare providers, patients and healthcare insurers.

2. Protection of fundamental rights and due process

Algorithm driven technologies as Big Data, IoT and AI bring new fundamental rights challenges.[52] The government should take a leading role in regulating Big Data management to assure safety, liability, data ownership and privacy issues. The increased reliance on technology in care may affect quality of care in the sense that **attention by humans may become a premium healthcare good** that is not available to everyone. The government's role as a protector of fundamental rights, will also have to be reflected in the application of AI-powered health care solutions by developing a proper regulatory framework.[53] **The ability to verify the proper functioning of algorithms and the quality of data algorithms make use of will be important to guarantee future quality of care and maintain equal access to care**.

In order for technological solutions to be sustainable as well as equitable these solutions should be open to scrutiny and organisations employing them should be held accountable for their application. This also includes the government as a user of these solutions, e.g. in the application of detection and prevention of diseases and the use of health data for other purposes in the areas of crime, social assistance.

Although patients/consumers may demand and receive an increasing role in their (self) treatment, diagnosis and maintenance of their health, e.g. with the help of remote care and personal diagnostic test kits, a contradiction is observed with trends towards VBHC. Even though outcomes like personalised care in the form of customised solutions do play a role in VBHC. **An increased use of protocols/standards/guidelines may potentially reduce the freedom and autonomy of patients**.

A similar development is seen with health professionals who perceive their professional autonomy to be threatened and reduced by other trends.

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52 Vetzo, M.J., Gerards, J.H., Nehmelman, R. (2018), Algoritmes en *grondrechten*. The Hague.

53 European Parliament, Committee on Legal Affairs (2016). MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION, available at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-582.443+01+DOC+PDF+V0//EN

3. Education & changes in the organisation of care

The key promises in the application of new data-driven technologies in healthcare are the improvement of the quality of care and the reduction of costs by increased efficiency. The role of stakeholders is expected to change as **many technical solutions aim to increase efficiency by replacing person-hours**. Obviously, this is expected to reduce the size of the healthcare labour market, possibly exacerbated by the expected reduction of the workforce due to the aging population.

The scope of skills required to work in the healthcare field will change, requiring traditional health professionals to be able to work with new technologies, while new types of professionals (e.g. IT, data-experts, engineers) will play an increasing role in making the health care system work. The government is expected to have a role guiding this **transition in the labour market, as well as providing for a framework for the adjustment of education**, e.g. curricula, post-graduate education and lifelong learning programmes**,** that prepare for working in health care markets. This is an enormous challenge which can only be tackled by joining forces (e.g. of the government, universities, medical providers, and MedTech companies).

New technological opportunities may strengthen ongoing developments such as a shift from secondary care towards primary care by increased reliance on remote health care and self-care. In the same way it may support the concentration of complex care in specific centres and the consolidation of lab capacity into supra-laboratories. Better and financially sustained cooperation between primary and secondary health care will thereby stimulate the uptake of new MedTech solutions.

4. Business strategy of MedTech companies

The excitement about making real progress in the healthcare field with the perspective of large, new markets promising enormous returns on investments, create a huge enthusiasm about the impact and value of the future data-driven MedTech sector.

The digital transformation provides opportunities for other players to enter the MedTech market. The sector will be enhanced with knowledge held by the largest and most innovative companies in the world. The role of existing Dutch (or European) players in this market is uncertain. **Traditional companies are trying to diversify from producers of capital goods to service providers including software & app development and data-services**. The extent to which these companies will remain leading in the long run is an open question. Although considered very large, big-tech companies

could buy a company such as Philips or Siemens, if they would consider this to their advantage.

Competition policies play an important role in safeguarding existing companies, providers or insurance companies in case suspicion arises that new companies would project their established market power into the health markets in an undesirable way.

New regulations such as MDR and IDVR will limit some of the freedom currently enjoyed by the MedTech sector as compared to pharmaceuticals. MedTech companies indicate that they are afraid to lose room to innovate as a result of this. This is felt in particular by **SMEs that may lack the resources to absorb the additional cost of regulation**. Governments may want to monitor this development in order to preserve a diverse market structure.

The public interest and nature of health data combined with innovative IT services and algorithms held by the private sector points to the likelihood of public-private partnerships. Therefore, the role of private companies is expected to increase. The challenge will be to strike a balance between the long-term interest of the health system as a whole in terms of equity and efficiency, versus the short-term dependence upon private sector knowledge to spur innovation.

Increased cooperation between MedTech companies and other key players in the health care sector enables the early development and uptake of user-centred innovations. Helping to shape the environment in which innovation and creativity of big and small companies in the MedTech, pharma and health IT sectors can flourish, with respect to both R&D and market uptake.

5. Research, development and cooperation/collaboration
Facilitating and stimulating the **development of health care technology through research & collaboration** and safeguarding their commercial use and public access may be a traditional but tested avenue for promoting interesting market conditions for the development of existing and new MedTech companies both at national and European level.

Health Technology Assessment (HTA) in the field medical devices is an area to further stimulate.[54] HTA aims to evaluate the properties, the direct and indirect effects of health technology to inform legitimate decision making. In the Netherlands, HTA in the field of MedTech is currently focused on evaluating assistive devices in the cure sector (via ZonMw

[54] Campbell, B. et al. (2017). *A New Health Technology Assessment System for Devices: the First Five Years.* International Journey of Technology Assessment in Health Care.

programme).[55] At the European level, joint HTAs of new MedTech are conducted to determine the relative effectiveness of products. Joint HTAs increases the harmonisation of evidence collection, reduces the costs of appraisal and compliance costs for MedTech companies, and European collaboration have shown to provide opportunities for governments to initiate joint price negotiations.[56]

6. Cross-sector actions

Many issues identified in shaping the future healthcare market and MedTech involvement share a list of stakeholders which are not necessarily the usual suspects in the MedTech or health sector. Solutions will not only be found by the traditional parties (e.g. healthcare providers, health insurers, patients) but also by the knowledge and competences of other parties such as knowledge institutions and MedTech companies.

Many new technologies used in the health sector are also developed outside the health sector. The position of the health sector is therefore often reactive. Consequently, many issues can only be dealt with by seeking **collaboration with other sectors, involving a multitude of (other) stakeholders.** The role of the national and EU governments will need to focus on steering and coordinating these initiatives involving all relevant stakeholders and promoting the objectives of the health system.

Actions at the national level would be crucial to accelerate concrete digital solutions in public health and healthcare and should be in line with European actions.

EU level actions are already taken in three areas: citizens' secured access to and sharing of health data across borders; better data to advance research, disease prevention and personalised health and care; and digital tools for citizen empowerment and person-centred care.[57]

55 https://www.zonmw.nl/nl/onderzoek-resultaten/doelmatigheidsonderzoek/goed-gebruik-hulpmiddelenzorg/

56 https://ec.europa.eu/info/law/better-regulation/initiatives/com-2018-51_da.

57 https://ec.europa.eu/health/ehealth/events/ev_20180515_en