

# Health at the centre

Responsible data sharing in the digital society



Report

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Diabetes patient Sergej scans the sensor in his arm to check his blood sugar level, 2017. Photo: Roos Koole/Hollandse Hoogte

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## Foreword

In this report, the Rathenau Instituut investigates examples of digital services that enable patients and healthy people to share data with a view to improving their health. We have noted various good initiatives arising in which researchers, patients and healthcare providers join forces with industry to develop data services. These initiatives put health, not data sharing, at the centre. Their aim is to use good quality data to develop targeted, care- and prevention-related digital services meant to promote the health of patients and the general public. Examples include portals providing access to mental health and addiction care services and an app for multiple sclerosis patients. In these examples, the point is not to monetise data but to offer a data service that will help people improve their health. It is possible to put healthcare at the centre if doctors, researchers, patients and developers work together. The Netherlands is good at cooperation and it is precisely in this area of application that our country is leading the way, with algorithms and good quality data producing new insights. This is a genuine opportunity for the Netherlands.

Services of this kind must be of good quality, however, and data must be handled securely and transparently. The data economy has shown how things can go wrong and produce unwanted effects. Health is too important to run such risks. It is not data, but healthcare that should be at the centre of ehealth. We should not be encouraging mass data collection, but encourage personalisation. There are concerns about what happens to people's most sensitive data, and about the problems involved in marrying commercial interests to health and healthcare. And there are questions about whether health data will in fact be used to provide better healthcare, with the individual in control.

This study shows that, while we would like to manage our own health, we may not always be better off or capable of doing so. Many of the Rathenau Instituut's studies address issues of digitalisation, bioengineering, algorithms and artificial intelligence. We have made use of those studies and their conclusions here. Similar to our research in other domains, this report shows that we need 'directed digitalisation' to develop applications that serve a public purpose and that are designed with respect for such values as privacy, autonomy and solidarity.

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## Summary

The digitisation of health data creates opportunities for more personalised healthcare and prevention. When combined, different digital services make it possible to access, share and use electronic health data, including outside the healthcare domain. The public and political discussion no longer centres on the mere digitisation of patient records. A further aim is to activate people to work on improving their health using their own data. The expectation is that by controlling their data, people will be able to take charge of their healthcare. At the same time, it remains to be seen whether this will lead to better healthcare advice, whether people will actually manage their health better, and whether it is even desirable for them to control more of their data. This report shows that responsible and secure data sharing is best achieved by remaining small in scale and by focusing on what is truly necessary. It gives government, the healthcare sector and policymakers the tools they need to ensure that digital health data services are used for the benefit of a 'socially responsible digital society'. The quality of the data and of good and appropriate healthcare are at the centre here, with people being protected against the unwanted use of their data.

### **Previous research on personal health management**

In May 2018, the Rathenau Instituut published the report *Responsible digital health management. More data, more control?* in response to the Processing of Personal Data in Healthcare (Additional Provisions) Act (WABVPZ) and the development and implementation of a system for accessing and sharing health data (Niezen & Verhoef, 2018). The WABVPZ is the follow-up of the Electronic Health Record (EHR) Act, whose introduction was blocked by the Dutch Senate in 2011. Particularly controversial was the mandatory connection to the National Health Data Switchboard (Landelijk Schakelpunt, LSP), as the Senate considered that it did not guarantee secure and protected data or data transfer. The new Act and development of the necessary technical infrastructure are meant to encourage people to take charge of their digital health data and allow them to take decisions about data sharing.

One of the main conclusions of the 2018 report is that stakeholders involved in developing the system of digital access and sharing of health data did not look closely enough at the changes that will be necessary in healthcare practice, at the different types of patients and their needs, at the role of healthcare practitioners in implementation, or at the use of digital data by third parties outside the healthcare system. The report also concludes that public values, such as autonomy and solidarity, are under pressure. People's ability to take independent decisions about

their health by accessing and sharing their health data depends on their being capable of interpreting what these health data actually say about their health. Not everyone can interpret such data correctly, and not everyone wants to make decisions on their own. One consequence of the speed with which digital personal health management is being introduced is a failure to consider whether and how it supports or, conversely, curtails people's autonomy, and what should be done to ensure that autonomy.

### **Electronic data sharing services under scrutiny**

The Rathenau Instituut's report *Health at the centre. Responsible data sharing in the digital society* investigates digital services that make it possible for healthcare professionals, individuals and, potentially, third parties (insurers, companies and researchers) to share health data. Sharing in this way blurs the dividing line between the medical and non-medical domains. *What does this mean for healthcare practice, and for the degree to which people can take and maintain control over their data and, consequently, manage their health?*

We report on four digital services that are emerging in parallel: online portals in the mental health and addiction care sector; lifestyle and medical apps (health apps), personal health environments (PHEs, personal data vaults) and public platforms (collective databases).

We studied eleven cases in all, divided across the four categories of digital services. The case studies are based on a study of the literature (both academic and grey literature publications, including policy documents), forty semi-structured interviews, and conversations with experts and stakeholders involved in developing or facilitating the various digital health data services. Research pertaining to the case studies took place from October 2017 to October 2018. The first steps towards formulating possible actions were taken during a workshop in May 2018 attended by 19 professionals in the field.

### **Findings**

Our research has turned up good practice examples in the development and use of digital health data services. In the mental health and addiction care sector, online portals are used to support shared decision-making by healthcare professionals, patients and, in some cases, their families. Online and face-to-face care are 'blended', and developers increasingly offer healthcare professionals and healthcare providers feedback on how the services are being used. Specific medical apps, such as MS Sherpa (which is still being trialled), help users to better manage their disease. The intention is to use self-learning software to make predictions about the course of a user's illness or state of wellbeing in the near future, so that patients and healthcare professionals can anticipate accordingly. Personal health management improves when healthcare professionals and patients

consult about how to use the app. At present, there are no examples of how PHEs bearing the 'MedicalMe', or MedMij in Dutch, quality mark are being used, as the first PHEs have yet to be certified. We have noted, however, that the two active PHEs in our study (neither of which is MedMij-certified) are both being offered within a healthcare setting and focus on regional cooperation.

In these examples, we see that the responsible parties are cooperating successfully in living labs on using data to improve healthcare and health and to develop evidence-based interventions. In this context, the point is not (only) to collect as much data as possible but to ensure good data quality and meaningful analysis leading to better healthcare.

Our study also shows that the parallel emergence of the various services and their networked nature, combined with more data sharing and data linkage, is accelerating the effects of the digital transformation on healthcare, on individuals, *and* on society as a whole. People not only gain more control over their data but in fact also relinquish control. The monopolisation of health data by large companies is of particular concern because it skews the power relationship between commercial parties and patients even more than it already is. It is also more difficult to monitor the quality of the data being shared and used and the transparency of the analyses, raising questions about the accuracy of advice and about who is liable if something goes wrong. In addition, most of the services currently available are being used by only part of the population, i.e. chronic patients and people in good health. This is a particularly sensitive issue in the complex field of healthcare because there is a risk of people being excluded.

### **Conclusions and possible actions**

We have reached three conclusions. In each case, we discuss which actions can be taken in addition to existing initiatives in policymaking, research and healthcare practice to ensure that the digital transition in healthcare is based on responsible data sharing. This means that everyone has equal access to the services and that we consider the impact of the services on healthcare practice, society and public values. Only if the quality of the data is good, data transfer is protected and secure, and there is no pressure to share data, can digital sharing contribute to such social aims as good quality healthcare, personal health and sickness prevention.

#### **1. There is a lack in frameworks governing the use of digital health data services and no coordination of such use, either in the medical domain itself or in its interaction with the non-medical domain.**

Data sharing extends beyond the healthcare domain. With the various health data services becoming increasingly interlinked, health data will circulate outside the familiar doctor-patient relationship on an ever-widening scale

within a network of public and private partners. So far, rules applicable within the medical domain (e.g. medical ethical reviews) are not being informed by rules outside that domain (e.g. the GDPR) or vice versa. It would be advantageous if they did inform each other, however, since non-medical data can also tell us something about our health.

**a. Establish ownership of the various responsibilities, including liability in medical interventions, more explicitly in agreements**

It is clear that no one 'owns' many of the constituent problems (interoperability, organisational obstacles, privacy, liability if something goes wrong), especially in the less regulated non-medical domain. Clarify existing agreements and allocate responsibilities, for example healthcare professionals' liability when using data originating from their patients' digital services, and the responsibility of individuals when sharing their data with third parties, including an explanation of what could happen if they are not careful about sharing.

**b. Establish broad codes of conduct for the development of services, including services that lie outside the medical domain**

Ensure that common (action-ethical) frameworks and forms of oversight within the medical domain can also be used in or adapted for the less regulated non-medical domain. For example, a code of conduct for developers and service providers, even those that make use of artificial intelligence, would extend the scope of responsibility and awareness beyond data security and privacy alone. Examples include the codes of conduct that the European Commission has already initiated with regard to disinformation and privacy in mhealth, and the Artificial Intelligence Impact Assessment (AIIA) recently launched by Electronic Commerce Platform Nederland and TNO.

**c. Maximise learning from best practices in healthcare**

Governance of healthcare digitalisation, a government task, should no longer focus on encouraging as much sharing of as much data as possible, but on recognising and implementing excellent initiatives. Organise a platform or other mechanism to identify best practice solutions both for the technology itself and for its practical implementation and evaluation.

**2. There are not enough safeguards in the data chain, i.e. the processes of generating, accessing, sharing and using health data.**

Trust mechanisms are underdeveloped in the data chain. This is about trusting ourselves; trusting our capacity to think and act when accessing, checking, interpreting and sharing (or consenting to share) our digital health

data. We must trust that we are not alone in this, but can make the right decisions in cooperation with healthcare professionals and/or our loved ones. We must also be able to trust the quality and reliability of the services and the data that are shared.

**a. Build on the concept of patient confidentiality and supplement it with technological citizenship**

People must trust that they are in fact capable of taking charge of their own data. Develop the concept of 'patient confidentiality' such that it protects data not currently protected under the aegis of medical confidentiality, and promote technological citizenship by continuing to invest in digital skills, by involving the public in digital innovations and, more specifically, by establishing an authority or a fund that provides guidance.

**b. Define precisely what shared decision-making entails**

It is important to clarify who is responsible for initiating shared decision-making between healthcare professionals and patients about data components: the healthcare professional (and which one?), the individual, and/or an independent third party? The combination may differ depending on the healthcare context and service involved. In addition to specified consent<sup>1</sup>, we should be investigating dynamic forms of consent such as those used in MIDATA.

**c. Make safeguards ensuring the quality and reliability of data and data sharing transparent and put appropriate oversight mechanisms into place**

Developers of services should be required to explain how they guarantee the **quality and reliability of data** and data sharing. This not only means that they should, for example, have the necessary CE Mark but also that they should provide explanations that are comprehensible to the user, for example about the medical standards that they have applied. There should be independent quality marks for every type of service. The AP and IGJ 'watchdogs' should cooperate, for example to exclude providers that do not have the MedMij label (or other quality mark for services other than PHEs).

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<sup>1</sup> As from July 2020, individuals will be able to state digitally which healthcare providers are permitted to make which types of data available to certain occupational groups. Specified consent is a further interpretation of specific consent. Specific consent is laid down in the Dutch General Data Protection Regulation implementation act and entails that it must be clear for patients for which processing, of which data, for what purpose the healthcare provider requests permission. With specified consent, as laid down in the Act Supplementary Provisions for the Processing of Personal Data in Healthcare the patient must also be given the opportunity to specify or distinguish which data can be provided to which healthcare provider or categories of healthcare providers. It is important to note that patients will not be obliged to consent to their medical data being shared electronically with other healthcare practitioners.

**3. There are limits to personal health management; equal access to healthcare and health are not sufficiently guaranteed.**

There are threats to the voluntary nature of people's control over their health data. To persuade people to share their data in support of healthcare for themselves and others (and to make it more affordable), we need more comprehensive safeguards addressing the voluntary nature of data sharing and the real benefits for personal health management.

**a. A governance system must be established that will strike the right balance between the individual and the collective interest**

Data solidarity may well erode the voluntary nature of public participation in digital health data services. Developers of services, healthcare providers, patient representatives, government and companies will have to work together on protecting and promoting autonomy, data sharing for the public benefit, and a solidarity-based healthcare system. The fund mentioned under 2a above can also play an important role here, encouraging people to share data but also seeing that they are compensated if something goes wrong.

**b. Never lose sight of the right to not be measured, analysed or coached and the right to meaningful human contact**

People who are uninterested in digital healthcare services must also be able to depend on receiving good quality healthcare and on having equal access to healthcare. Healthcare providers and patient representatives must continue to stand up for these people, even if health insurers and government insist on more efficient and cost-effective healthcare.

**Final remarks**

Concerns about privacy and confusion about responsibilities prevented the introduction of a national EHR in the Netherlands. A new law and additional measures are bringing secure digital data sharing a step closer. This study shows that further steps are needed to ensure responsible digital sharing of people's most sensitive data. This is particularly important in the light of recent revelations concerning the major commercial interests involved in medical data. In the past few years, we have seen personal data being used in a manner that erodes democracy and the rule of law.

The Netherlands is at the cutting edge worldwide in digital healthcare applications, with best practice examples being developed in cooperation with users, healthcare practitioners and researchers. Government should no longer focus on sharing as much data as possible but on encouraging and continuing to implement these best practice examples. The quality of the data, healthcare that respects human dignity

and health itself are at the centre here, with people being protected against the unwanted use of their data.

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# 1 Introduction

## 1.1 Background and main question

For the past ten years or more, healthcare practitioners and policymakers in the Netherlands have been encouraging patients to use digital services, for example a 'national electronic health record' (EHR), to actively manage their own healthcare. The underlying promise is that sharing individual patients' health data will improve the quality and accessibility of care. Digital data on an entire population can be used as input for big data and other analysis to predict the course of a disease or to determine which drugs are more effective for certain patient groups and in which doses. The Netherlands is at the international forefront when it comes to healthcare digitalisation, for example the extent to which healthcare professionals use electronic medical records (Wouters et al., 2017). Dutch patients are also keen to be more closely involved in this trend (Heijmans et al., 2015). The discussion has long since moved beyond the mere digitisation of patient records. It is also about mobilising people to use their own health data to manage their health. Digitalisation not only increases the amount of data, it also makes it easier to share information outside the healthcare sector. This can have unforeseen consequences for the user and for healthcare and health service practice.

The Rathenau Instituut report *Responsible digital health management. More data, more control?* describes how the Dutch government and healthcare providers are encouraging online access to medical data by passing appropriate legislation and regulations, developing the right technical infrastructure, conducting pilot projects and integrating these into healthcare practice (Niezen & Verhoef, 2018). The new legislation gives individuals control over their digital health data and makes them responsible for decisions about data sharing. The report concludes that autonomy and solidarity are important values meriting greater attention, and that not everyone is willing or able to participate in the transition. In addition, the Netherlands still lacks the legal frameworks and safety nets needed to protect the public from being pressured by third parties into providing access to their health data. This means that people can only take charge of their health and personalise healthcare and sickness prevention to a limited extent.

The present report describes the outcomes of our investigation into four significant services that are emerging in parallel and that allow individuals to access, share and use health data, i.e. online portals run by healthcare institutions (which offer patients a 'view' into their own medical records and supporting digital programmes), health apps ('digital coaches'), personal health environments (PHEs, a personal data vault

in which people can store and manage all their health data digitally from a single comprehensive overview), and public platforms (collective online databases, where people can share stories and health data with others). We first describe our research into each of these services and then discuss what our findings say about the way they can be used to manage health.

Our study examines whether using digital health data services enables individuals to take (better) charge of their data and, consequently, to better manage their health, what these services imply for healthcare practice, and how the healthcare system needs to be adapted. Finally, we look at whether the digital healthcare system fits in with the image of society that we all share, in which people and patients operate autonomously where possible, and receive professional help where necessary.

## **1.2 Digital healthcare data: trends**

The promise described above has provided the basis for developing the various digital health data services examined in this report. Delivering on that promise also required innovation by parties outside the healthcare domain. Legislation has been enacted to create a legal framework for using these services. This section describes how the promise of digital services has spurred their development to a considerable extent.

### **1.2.1 Taking the pressure off the healthcare system**

The healthcare sector needs to improve its information sharing. Inadequate data sharing diminishes the quality of care, leads to unnecessary mortality or complications, inconveniences patients and impairs the efficiency of care (Blumenthal, 2017; Vest, Kern, Silver, Kaushal, & HITEC investigators, 2014). In addition, the ageing of the population, staff shortages in healthcare and the use of more expensive healthcare technologies mean that government, health insurers and healthcare providers are looking for ways to take the pressure off the healthcare system. They are seeking solutions in ehealth and an upgrade of the digital healthcare infrastructure.

In 2011, the Dutch Senate blocked the introduction of a 'national electronic health record' (EHR), which was to form part of a mandatory connection to the National Health Data Switchboard. At that time, the Senate did not consider the protection and security of the data exchange sufficiently guaranteed, and it was also concerned about the accuracy and quality of the data that would be exchanged

through the National Health Data Switchboard. Since then, many other initiatives have been or are being developed that should improve the exchange of data within the healthcare sector, with due regard for privacy and security. Agreements about standardisation and uniform language are pivotal in that regard.

The patient has increasingly become the centre of attention in recent years. The ability to access and manage health data can be advantageous, leading to better care and allowing people to play a more active role in managing their health.

### **Participation, personalisation and prevention**

In 2017, the Norwegian Technology Committee noted that ‘digitalising our health’ can help us to achieve three Ps: participation, personalisation and prevention. At the same time, striving to accomplish the three Ps has also raised new, critical questions (Teknologirådet, 2017). Digital health data services help people to participate actively in their health or healthcare process. Analysing health data makes it possible to offer personalised healthcare and health advice. Combining and analysing large quantities of health data supports predictive medicine and thus the prevention of diseases. It is precisely these promises that lead us to embrace digital services, in the expectation that they can take the pressure off the healthcare system and improve public health. However, individual participation can also lead to a new type of inequality: personalisation is not attuned to individuals but rather to ‘people like us’, with the risk of inaccurate advice. In addition, the risk profiles defined with a view to prevention may in fact exclude people instead of giving them access to the necessary healthcare.

### **1.2.2 Rise of the health market**

Complementing the highly regulated medical domain is a growing market offering patients and consumers a wide range of health products to track and improve their health. These include the many apps that track weight, physical activity and food intake. The digitisation of health information and the heightened desire to share this data have given rise to new commercial parties dedicated to generating, reading, storing and managing the data generated by home medical devices, medical records and online consumer applications (health apps).

The domain of healthcare, which stresses ‘cure and care’, is expanding into the domains of health, wellness and lifestyle. Commercial parties are seen as ‘drivers’ of innovative services that contribute to digital health management. The Dutch government supports digital technologies in healthcare. In doing so, it is opening up the publicly funded and, in many cases, local healthcare domain to more private

and commercial initiatives from around the world. People are addressed as health-conscious consumers in this context, and not as patients.

### 1.2.3 Legislation that encourages digital sharing

A number of laws have been enacted in recent years that have a direct impact on digital health data services in Europe and the Netherlands.<sup>2</sup> They are particularly concerned with data protection and security.

#### Legal frameworks for digital health data services

- **Dutch Medical Treatment Contracts Act (WGBO):** underpins the provision of all healthcare and concerns the relationship between patient and healthcare practitioner.
- **Supplementary Provisions for the Processing of Personal Data in Healthcare Act (Wabvpz):** describes the rules governing the use of the citizen service number (BSN) in healthcare (Chapter II: Act on the Use of the Citizen Service Number in Healthcare), and the exchange of data within the healthcare sector (Chapter IIIa: Act providing for Patient Rights in Electronic Data Processing).
  - a. **Act on the Use of the Citizen Service Number in Healthcare:** introduces the citizen service number (BSN) as the patient identification number, making it possible for different healthcare practitioners and institutions to share data on a single person. There is no specific patient ID number in the Netherlands.
  - b. **Act providing for Patient Rights in Electronic Data Processing:** lays down the rights of individuals, specifically of patients. By July 2020, people will be able to access their data digitally and to specify the type of health data they want to share with each category of healthcare practitioner ('specified' consent).
- **General administrative regulation with regard to the electronic exchange of data between healthcare providers:** describes the specific functional, technical and organisational standards for data sharing in the healthcare sector.
- **General Data Protection Regulation (GDPR):** addresses the prudent handling of personal data, in the healthcare sector and beyond. It gives the

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<sup>2</sup> We listed the most important legal frameworks for accessing and sharing health data in our report *Responsible digital health management*. The present report adds two more items to that list: the proposed Digital Government Act and the Minister for Medical Care's Letter to Parliament on Electronic Data Exchange in the Healthcare Sector (Kamerstukken II 2018/2019 *Elektronische gegevensuitwisseling in de zorg*, 20 December 2018, Reference 1456422-184986-DICIO).

public the right to data portability (portability of personal data) and sets out the requirements for data protection or privacy by design.<sup>3</sup> Health information (health data) is considered a special category of personal data. Organisations that wish to use these data must first comply with special, stricter legal criteria.

- **GDPR Implementation Act (UAVG):** elaborates on the GDPR, among other things with regard to the processing of personal health data.
- **Digital Government Act bill:** with an intended effective date of 1 July 2019, the bill 'lays the foundations for further digitalisation, including rules and regulations governing digital government and, more specifically, the generic digital facilities of a government-wide infrastructure'.<sup>4</sup> The bill will, for example, make it possible to designate open standards that local and other authorities must uphold in their electronic transactions with other authorities, with the public and with businesses. It lays down rules on information security, assigns responsibilities for the management of digital public services, and regulates access to public services for members of the public and businesses. Personal identification and authentication are particularly important for the ongoing development of digital health data services.<sup>5</sup>
- **Letter to Parliament on Electronic Data Exchange in the Healthcare Sector** (20 December 2018). In this letter, the Minister for Medical Care, Bruno Bruins, states that he will take concrete steps towards making electronic data exchange in accordance with the appropriate information standards a statutory obligation. He will also ensure that all parties fulfil their role and achieve results.<sup>6</sup>

### 1.3 Parameters of the study

The various digital health data services used to give people more control over their health (and health data) have a number of different functionalities. They are designed to quantify, store, share and utilise the status of our health (and our health behaviour) digitally (see Figure 1). Our 'biological world' (physical and mental health) is thus increasingly being shadowed by a 'digital twin' (Kool, Timmer, & Van Est, 2017; Webster, 2002). Some services do nothing more than transfer this digital data, for example between doctor and patient. In other cases, such as health apps, the user collects the data and the service uses artificial intelligence (AI) to analyse

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3 This describes the process whereby organisations incorporate measures that enhance privacy and minimise personal data processing (data minimisation) while products and services are still under development (such as healthcare information systems).

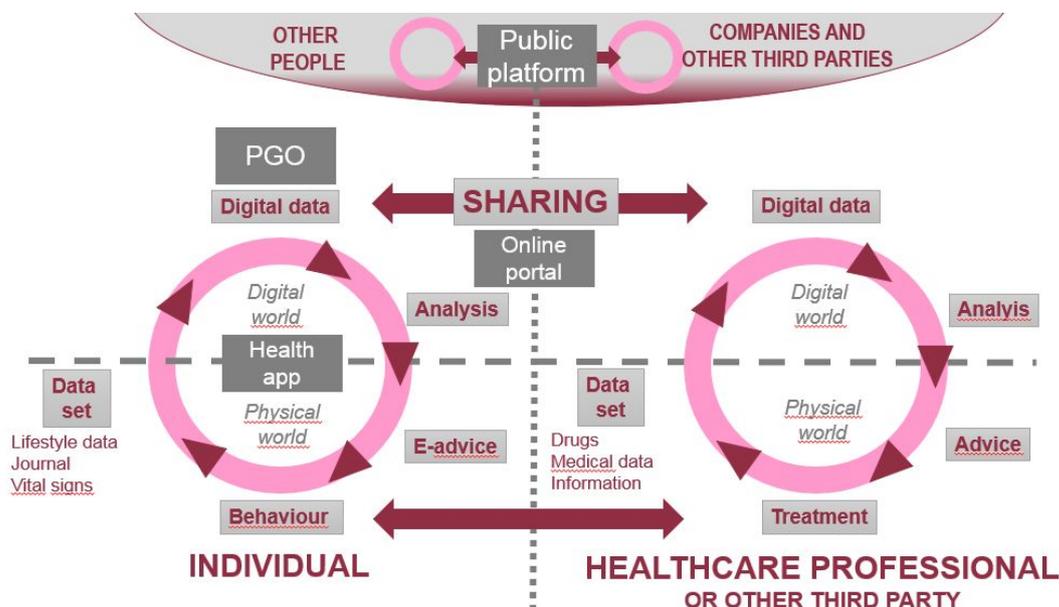
4 Kamerstukken II 2017-2018, 34 972 no. 2

5 The EU's eIDAS Regulation came into force on 29 September 2018. As of that date, all organisations, whether public or private, that deliver public digital services in an EU Member State must recognise electronic identification from all EU Member States. For more information on the Regulation, see <https://www.digitaleoverheid.nl/dossiers/eidas/> (in Dutch).

6 Kamerstukken II 2018/2019 *Elektronische gegevensuitwisseling in de zorg*, 20 December 2018, Reference 1456422-184986-DICIO.

and measure this information against standard values and then sends feedback to the user. In some cases, the feedback is fully automated (e-coaching); in others, it involves consultation with a healthcare practitioner (blended care). Users can then modify their behaviour in the physical world based on their feedback. Similarly, a healthcare practitioner can draw up a treatment plan based on patient data that has been collected, digitised and analysed. Thanks to this continuous process of collecting, sharing, combining, analysing, applying and advising (the 'data loop'), more data can lead to better understanding, better advice and, potentially, better health.

Figure 1 Double data loop for digital health data and advice



**Legend:** The steps in the data loop (pink circles) are shown in light grey rectangles and the digital data services are shown in dark grey rectangles. The horizontal line separates the physical world and the digital world and the vertical line the individual and the healthcare professional (or other third party). The arch at the top represents the world of other people and third parties with whom digital data are shared, without any physical interaction.

*PHE: Personal health environment, a data vault in which the user stores medical and self-collected data.*

*Online portal: online service for viewing, managing and/or sharing health data from practitioners' medical records.*

*Public platforms: patient platforms and data cooperatives.*

*Health app: tracking and feedback service aimed at behavioural change.*

The user is not always in control of the data in the loop. That is why our study distinguishes between three aspects of ‘personal health management’ (see Table 1).

Table 1 Three aspects of personal health management

Aspects	Digital health data services make it possible for users to:
Taking decisions	take decisions by explaining which decisions users can take themselves and which have been taken for them.
Controlling data	control their own health data by explaining how data are used and allowing users to share data.
Influencing health	influence their health as they see fit based on data, feedback on data and explanations.

## 1.4 Research questions, objective and method

In a previous study, *Responsible digital health management. More data, more control?*, the Rathenau Instituut investigated how legislation aims to give people more control over their healthcare process and health data (‘personal health management’). The present study focuses specifically on the extent to which the various digital health data services (online portals, health apps, PHEs and public platforms) allow people to control their health data and manage their health, and the impact of these services on Dutch healthcare practice and society at large.

### 1.4.1 Research questions and objective

**Main question:** To what extent does the use of digital health data services make it possible for people to control their health data and, consequently, manage their health?

**Subsidiary questions:**

1. What impact do digital health data services have on healthcare practice and on the Dutch healthcare system?
  - a. Which stakeholders, interests and responsibilities play a role and/or are changing?
  - b. How do the various digital services relate to one another and to stakeholders within the healthcare environment?

2. To what extent does using these different services allow people to take charge of their data by managing and sharing them and, consequently, to manage their health?
  - a. To what extent do the services help individuals decide how they wish to use the service?
  - b. To what extent do the services allow individuals to manage and share their health data with others?
  - c. To what extent can the services help individuals manage their health as they see fit based on their data (and related feedback) and findings?
3. What are the wider implications of using these services for society?

#### 1.4.2 Methods and structure of report

We began with an exploratory study of the various trends and developments in data sharing in the Dutch healthcare sector. This led to our selecting four case studies (exemplifying digital health data services): online portals, PHEs, health apps and public platforms. In this report, we start by addressing questions 1 and 2 for each of the cases (Chapters 2 to 5). The most important findings with regard to these two questions, and the social and ethical implications of using these digital services (question 3), follow from our overall analysis of the four case studies (Chapter 6). Chapter 6 ends with conclusions, which form the basis for potential actions described in Chapter 7. We consider these actions against the background of ongoing trends and developments, including in policy and legislation. A group of 19 professionals in the field helped us formulate these suggestions during a workshop (see Appendix A for the list of attendees).

The case studies regarding the four services are based on a study of the literature (both academic and policy analysis) and forty semi-structured interviews and conversations with experts and stakeholders involved in developing the various digital health data services (see Appendix A for a list of respondents). Research pertaining to the case studies took place from October 2017 to October 2018.

In each of the four case studies, we examined two or three specific services in more detail. It was by no means our intention to provide a complete picture of all possible existing digital health data services, but rather to assess the potential impact of these services, most of which are commercial, on Dutch society.

**Online portals:** various types of patient portals have emerged within the Dutch healthcare sector that allow patients to view, manage and/or share health data as

documented in practitioners' medical records. This report describes three online patient portals operating within the mental health and addiction care system (GGZ): Karify, Minddistrict, and Therapieland.

**Health apps:** smartphone applications focusing on healthcare, health and wellbeing. The apps use data that the user enters himself or herself or that the device (i.e. the smartphone) tracks. In this report we focus on three specific health apps: SamenGezond, MS Sherpa and the StressCoach app.

**Personal health environments (PHEs):** 'apps and websites used by patients and (healthcare) consumers to collect, manage and share all kinds of health data'.<sup>7</sup> PHEs provide access to health data in electronic health records (EHRs) and self-tracked health and/or lifestyle data within a single, secure online environment. The term PHEs has been in use since 2016; this report focuses specifically on the development of three such services: Philips VitalHealth's 'MyHealthJourney', Vital10 and Patients Know Best.

**Public platforms:** patients are setting up their own platforms, motivated by a desire to communicate with fellow sufferers but also to make their health data available to third parties for big data analysis. 'Self-trackers' and (privacy-aware) individuals increasingly participate in all sorts of platforms, for example. This report discusses two such platforms: the international Patients Like Me (PLM) platform and the Swiss MIDATA cooperative.

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7 Retrieved from <https://www.patientenfederatie.nl/themas/persoonlijke-gezondheidsomgeving/> in December 2017

## 2 Online portals: accessing data

Under the Supplementary Provisions for the Processing of Personal Data in Healthcare Act (Wabvpz), everyone in the Netherlands must be able to digitally access the data in their medical records as of 1 July 2020. Online portals are a form of digital health data service that gives people digital access to their data. Healthcare providers – including hospitals, general practices and mental health and addiction care services – are developing digital services of this kind to allow patients to view their own medical records and communicate with practitioners about them.

The mental health and addiction care sector uses online patient portals to improve the quality of care, reduce healthcare costs and give users more control over their treatment<sup>8</sup> (Rademakers, 2013). In this chapter, we examine how these online portals are incorporated into mental health and addiction care and to what extent they give patients<sup>9</sup> more control over their own data and health. Mental health and addiction care is an interesting sector because, according to the sector organisation, the Dutch Association of Mental Health and Addiction Care (GGZ Nederland), the Netherlands is pioneering the introduction and use of ehealth in this domain in Europe (GGZ Nederland, 2013; Van Raalte, 2015). For example, it is already using platforms to offer patients digital self-help resources. These platforms are now also increasingly being used to give patients access to their data and to support communication with patients. The integration of such portals has become mainstream in this area of healthcare practice. We investigated three online mental health and addiction care patient portals: Karify, Minddistrict, and Therapieland.

We conducted ten semi-structured interviews (six patients and four programme developers associated with two major providers of online patient portals in the Netherlands). We sought additional information in policy documents and the academic literature, on websites and in relevant social media.

We answer several of our subsidiary questions. Who is involved in seeing that online portals are used within mental health and addiction care, what interests are at stake, and who is responsible for what? How do patients use the online portals to take charge of their own treatment process and to manage their health? What

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8 Kamerstukken II 2017/2018 *Kamerbrief e-health en gegevensuitwisseling in de ggz*, 16 February 2018 Reference 1293405-173151-CZ

9 We are aware that in the mental health and addiction care sector, the customary term is 'client' and not 'patient'. For consistency's sake, however, we will refer in this report to 'patients'; where applicable, this refers to clients.

challenges do users, both healthcare professionals and patients, face? What benefits do stakeholders identify?

## 2.1 What do online portals do?

Online portals are designed to serve the healthcare sector and are linked to a healthcare institution. Originally, online or digital patient portals were not tailored to the individual patient but served as a general gateway to web-based healthcare information. They could be accessed by the general public (de Mul et al., 2013). In time, these patient portals evolved into web-based healthcare interfaces geared to individual patients. Patients can make or change appointments themselves, in many cases view their own medical data, and in some instances undertake certain treatment activities themselves after watching instructional videos or reading a text. They can also monitor their mood or physical status themselves by completing questionnaires.

### 2.1.1 A closer look at online portals

Karify, Therapieland and Minddistrict are providers of patient portals within the Dutch mental health and addiction care sector. Karify describes itself as a portal, Minddistrict calls itself a platform and Therapieland sees itself as the provider of a platform offering online programmes (see Table 2). In this report we will refer to them as online patient portals. It should be noted that commercial parties manage the patient portals that healthcare practitioners offer patients. In developing their portals, Karify and Minddistrict focused on the wishes and demands of healthcare professionals. Therapieland began as an online self-help platform but is now delivered to patients largely through their healthcare provider.

Online portals in the mental health and addiction care sector build on existing ehealth platforms but offer more mental health functionalities than do hospital portals. *'For several institutions, this was the gateway to setting up a portal. There are providers that offer an e-mental health platform and then turn it into a portal'* (Groothuis et al., 2017). Here, Groothuis et al. (2017) point out an obvious difference between the online portals developed by hospitals or general practices and the portals developed for mental health and addiction care.

Table 2 The three digital mental health and addiction care portals studied

Karify	Minddistrict	Therapieland
<p>'Karify is a portal that effectively facilitates the provision and exchange of information with users. Karify combines eHealth, online communication and access to medical and other data in a single portal'.<sup>10*</sup></p> <p>Founded in 2009 in cooperation with GGZ Centraal. Began operating officially in 2013. 'With more than 450 affiliated healthcare organisations, including 6 of the 10 largest mental health and addiction care institutions in the Netherlands, Karify eHealth is the market leader in mental health and addiction care'.<sup>11</sup></p>	<p>'Minddistrict is a secure, flexible and user-friendly ehealth platform with an extensive catalogue of online modules, diaries and questionnaires. Healthcare organisations use the platform and catalogue to treat or monitor their clients'.<sup>12</sup></p> <p>Founded in 2009 in cooperation with GGZ-Noord Holland. The company now claims to have 200,000 active users in seven countries.<sup>13</sup></p>	<p>Therapieland develops 'online programmes that support you and your client during treatment, so you can have better conversations with your client. Clients can work on their mental health problems at a time, place and pace of their own choosing'.<sup>14</sup></p> <p>Established in 2012 without having a direct affiliation with a mental health and addiction care provider. Now has about 123,000 active users.</p>

\* Most quotations in this report are originally written in Dutch. English translation has been conducted by a professional translation agency.

## 2.1.2 Online portal functionalities

Karify, Minddistrict and Therapieland all offer four main functionalities: a) information, b) communication, c) monitoring and d) intervention. In many cases it is possible to link apps to the portal to support faster and easier interaction between healthcare professional and user.

### Information

All three portals provide medical information assembled or verified by qualified healthcare professionals. Someone suffering from depression, for example, can look up information about their condition in an online library (in the case of Karify). Therapieland and Minddistrict offer information before or after the exercises or assignments that form part of a treatment module. They only provide information that is appropriate for the patient.

10 Retrieved from <https://www.karify.com/nl/clientenportaal/> in October 2018

11 Retrieved from <https://www.karify.com/nl/waarom-karify/> in October 2018

12 Retrieved from <https://www.minddistrict.com/nl-nl/over-minddistrict> in October 2018

13 idem

14 Retrieved from <https://www.therapieland.nl/zorgaanbieder/> in October 2018

Patients can also obtain information from their own medical records. This means that the online portal must be linked to the practitioner's medical record, the electronic health record or EHR. Creating this link is an extra step for the developer and means extra costs for the healthcare provider. Information obtained through the portal, such as completed exercises/assignments or journals or diaries filled in by the patient, can be integrated in the healthcare professional's EHR or into the Integrated Care Information System (ICIS) of the local healthcare institution. An EHR or ICIS sends the patient frequent and automatic requests for permission to share this information with his or her doctor. All three portals only allow patients to view their medical records if the healthcare provider offering the portal has also purchased the relevant link.

### **Communication**

Patient portals offer all sorts of facilities for digital communication, such as calling, video-calling and messaging with practitioners. Communication with other patients is an important functionality. Both Therapieland and Minddistrict have a group messaging feature. In the Therapieland programme, for example, users can join group chats on specific topics, such as 'Bullying and aggression at work' and 'Mindfulness'. The group chats are moderated by Therapieland staff. Minddistrict has a special app that allows users to message individually and in groups. Our interview with Karify revealed that they have deliberately chosen not to offer group messaging due to resistance from healthcare providers. Communication between patients would impose extra responsibilities on them and would be difficult to moderate (respondent 33).

### **Monitoring**

The portals also allow patients to monitor their mood, thoughts, behaviour, and physical condition. They do this by filling in questionnaires. Their responses are processed and visualisations are provided to facilitate tracking. The expectation is that the user will change his or her behaviour in response to the personal data recorded (see also under 'Intervention'). In addition, professionals can also track the client's status remotely (subject to his or her consent).

In mental health and addiction care, the Routine Outcome Measurement (or ROM) questionnaire is considered one of the most important monitoring instruments. ROM consists of self-reported feelings indicating how intensely the patient is experiencing his or her illness. Karify offers the option of integrating ROM data. Minddistrict and Therapieland do not offer a standard link to ROM but can certainly create one. Therapieland is in fact developing its own ROM portal. All three portals indicate that, at this stage, it would be difficult for them to integrate well-known apps such as Sleepcycle (which monitors sleep quality) and Moodgym (which monitors mood).

### **Intervention**

Finally, the portals offer patients psychotherapeutic interventions. As part of their ongoing treatment, patients also receive therapy online in the form of videos and exercises or assignments. Combining this with auxiliary, real-world therapy is known as 'blended care', an amalgamation of online and face-to-face therapy.

The digital versions of psychological or psychosocial interventions are a service in which *'you as a client are in control of your own mental wellbeing and decide for yourself what form your recovery process will take'*.<sup>15</sup> Cognitive behavioural therapy, in which the practitioner tries to interrupt the patient's negative spiral of sombre thoughts and feelings, is one of the most common interventions. Digital therapy offered by Therapieland consists of a series of videos, texts, figures and exercises, such as thought mapping. Subject to the user's consent, these data can also be viewed by the practitioner, who can then provide support.

### **Promises regarding participation, personalisation and prevention**

The heightened interest in data sharing and online interaction between healthcare practitioners and patients is an important incentive for patient participation (Allen et al., 2007, 2008; Leveille et al., 2009). Therapieland promotes the use of ehealth as follows: *'Clients are better prepared for appointments, they have greater self-reliance and they become co-owners of their treatment process.'*<sup>16</sup>

The care that patients receive is tailored to their personal needs. Minddistrict refers to 'personal routes' in this regard.<sup>17</sup> Patients play an active role in such personalisation, for example by sharing self-reported information from their journals. This means patients have input into their own records, both at the clinic (the medical records maintained by the healthcare professional) and on the online platform (de Mul et al., 2013). The wide range of monitoring tools, such as questionnaires, journals and dashboards, helps them to understand their own health and behavioural changes. These tools focus not only on mental health and addiction care but also on prevention and lifestyle. Karify, for example, also addresses occupational health. By using an online portal, patients are promised not only participation and personalisation, but also that such use will have a preventive effect.

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15 Retrieved from <https://www.therapieland.nl/zelfhulp/> in October 2018

16 Retrieved from <https://www.therapieland.nl/zorgaanbieder/> in October 2018

17 Retrieved from <https://www.minddistrict.com/nl-nl> in October 2018

## 2.2 Online portals in the context of mental health and addiction care

In this section we look at the stakeholders in online portals and their responsibilities when it comes to the development and practical use of these services.

### 2.2.1 Stakeholders, interests and responsibilities

The advent of online portals in the mental health and addiction care sector has brought new (commercial) players into the health market, working for (or together with) healthcare providers on digital services for both patients and practitioners.

#### **Developers aim to meet the demands of healthcare providers**

The developers of online portals see the providers of mental health and addiction care, both major institutions and small self-employed practitioners, as their main market. Karify and Minddistrict are international companies and also offer English and German versions of their portals. Therapieland focuses on the Dutch market. The developers say that it is important for their portal to meet the demands of healthcare providers and professionals (as well as observed needs of patients). Proper care or self-care is the starting point, but the viability of the portal depends on its making a profit. *'I can't say what our product will be like in a few years' time. ...It all depends on how ehealth services develop and whether can we offer it to people at a reasonable cost. That's how we innovate, by looking at what we have to hand and what the demand is'* (respondent 42<sup>18</sup>). Developers see opportunities in the trend towards participation and empowerment, not least because it puts bread on the table. It is less attractive for them to organise the service in a way that eliminates the need for healthcare providers and fully digitises self-help. According to one developer, self-help should be low threshold but developers should never try to compete with their own customers.

In her research into the use of ehealth in primary care, Huygens points out that its implementation is a complex process. It requires developers to furnish both patients and healthcare providers with information on the effective use of ehealth (Huygens, 2018). Developers confirm that offering the healthcare provider feedback contributes to the effective use of the portal in the healthcare process. Monitoring and evaluation of such use are evidently perceived as important, for example when it comes to developers offering healthcare providers and professionals feedback on

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18 All respondents' quotations are originally in Dutch. These Dutch quotations have been checked with the respondents. English translation has been conducted at a later stage and by a professional translation agency.

how, when and to whom they offer the portal. Such feedback is not always provided, however.

It is important to government (which finances many of the portals), healthcare institutions, healthcare professionals and patients to know whether the care provided through online portals is reliable. Developers, however, find it difficult to produce evidence that their modules and interventions are both effective and cost-effective, in line with current standards (randomised clinical trials). Nevertheless, all three portals claim that their work is evidence-based. Therapieland's website states: *'We know why ehealth is effective and have incorporated this knowledge into our evidence-based modules. We only employ qualified psychologists, from our trainers to our managing director. So we really do know what we are talking about and are confident that our modules meet clients' needs.'*<sup>19</sup> Minddistrict's 'Doctor eHealth' says this in a question and answer blog: *'E-health works, that's what the research shows. I cannot claim that every Minddistrict module has been proven effective. But every module is evidence-based.'*<sup>20</sup>

Previous research by the Rathenau Instituut shows that medical technology, such as a foot sole scanner for preventive research into foot abnormalities, requires more leeway for practical refinement and that its implementation should not depend on proven effectiveness or cost-effectiveness in line with traditional health technology assessment procedures (Asveld & Besters, 2009). However, the portal developers argue that not they but rather the healthcare professionals are responsible for placing validated (evidence-based) information on the platform or for providing blended care.

### **The healthcare professional – from guardian to coach**

Healthcare professionals find it challenging for patients to have online access to their own data, but the literature shows that they also see it as beneficial. While they have less control over the flow of information to the patient, they see the advantages of patient participation (Morton et al., 2017). Healthcare professionals are expected to coach patients who use online portals. A developer puts it this way: *'What we offer is a kind of toolbox of therapies that they can use to treat their clients. They still make their own assessment. We don't tell them what to do'* (respondent 42). The healthcare professional chooses which digital tools and therapies to use and for whom. Their duties also include supervising the patient's use.

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19 Retrieved from <https://www.therapieland.nl/over/team/> in October 2018

20 Retrieved from <https://www.minddistrict.com/nl-nl/blog/werkt-ehealth-wel-dokter-ehealth-geeft-antwoord> in October 2018

The use of digital portals requires new skills from professionals. More important than their digital skills is the ability to integrate digital consultations and information into face-to-face meetings.

One developer says: *'This means that healthcare professionals must be skilled, that they must have a good grasp of how to weave ehealth into therapy. As soon as they master that, they can start coaching'* (respondent 42). In some ways, blended care comes with responsibilities beyond those of the traditional therapeutic relationship. The basic idea is to empower the patient, with the professional being expected to offer guidance when necessary. In 2014, the Dutch Association of Mental Health and Addiction Care reported that practitioners were not always being educated and trained to provide blended care (GGZ Nederland, 2014).

Healthcare professionals sometimes experience tension between their responsibility to provide treatment and the needs of patients. One example is the use of group messaging on online portals. Patients need to be able to share their stories with peers, but allowing them to do so creates expectations when it comes to monitoring the quality of the information they share. Healthcare professionals feel responsible 24/7 when inaccurate or distressing information is shared. That is why Karify decided not to offer a group messaging service. Therapieland, on the other hand, does. Its representatives say that, legally speaking, group chats are regarded as a forum and not as a place for professionals to furnish medical data. Therapieland therefore only monitors communication between fellow patients to a limited extent.

### **The participating patient**

The literature shows that when help is available to people with mental health problems through an online portal, they have an easier time connecting with their healthcare practitioner (or fellow patients). This is considered acceptable within the treatment process (Van Raalte, 2015). Of course, patients can only use an online portal if they have access to a computer or have a smartphone or tablet. Online support, monitoring or access to data is not always possible. Both patients and developers say that people who are suffering an acute psychiatric illness require direct, face-to-face interventions.

Research shows that when patients have access to their own health data, they participate more in their healthcare process. Patients tend to see themselves as owners when they themselves monitor their perceived quality of life, for example. They also feel more responsible for the flow of information (Kipping et al., 2016). The online portals stipulate that after the end of treatment, the information stored in the e-health platform is no longer available to the healthcare professional. This means that patients are responsible for storing their data, including the login codes.

If they re-enter treatment, they must also check whether the old information is still relevant, according to a developer. Giving patients access to their own data requires them to see their role in the healthcare process in a new light because the online portals also have them managing their data.

### **Joint development and acceptance of online portals**

eHealth portals are only put to proper use when they have also been co-developed with users. These users are both healthcare providers/healthcare professionals and patients. In 2013, this was still a stumbling block: *'[A]s stakeholders, patients were frequently left out of the portal development process'* (de Mul et al., 2013, p. 45). The three portals we have studied indicate on their websites that they are seeking interaction with patients. *'Clients, expert patients and healthcare professionals are involved in the development process.'*<sup>21</sup> Karify *'develops on the basis of scientific insights and tests innovations for the end user before, during and after these become reality. Experiences of clients and therapists contribute this way to innovation processes and generate new research questions right away.'*<sup>22</sup> They find it more difficult to involve patients in content-related matters than in interacting with the service, i.e. its accessibility. All three portals have an interface reminiscent of well-known social media, making it easier for patients to access the programmes.

The degree to which online portals are accepted hinges on patient attributes and patient involvement during portal development, but also on the individual attributes of healthcare professionals and the culture and context in which the portals are being offered (Huygens, 2018, de Mul, 2013). Whether patients use the portal depends mainly on whether the healthcare professional is able to persuade them of its usefulness and importance, according to interviewees. Patients are more inclined to use the portal if they are offered an effective combination of online therapy and face-to-face contact. *'One practitioner will simply have higher patient acceptance rates and better adherence to treatment than another'* (respondent 53). The developers also measure and evaluate the acceptance rate for ehealth therapies offered through the online portals, for example by monitoring the questionnaires issued by the platform or by keeping track of the number of exercises or assignments completed. These figures indicate the level of acceptance of the ehealth therapy.

### **Government funding**

Government, patient organisations and healthcare providers all want to encourage the use and scaling up of online portals in mental health and addiction care (Bremmer & van Es, 2013). Information is needed about which form of ehealth is

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21 Retrieved from <https://www.minddistrict.com/nl-nl/ehealth-platform> in October 2018

22 Retrieved from <https://www.karify.com/research/> in October 2018

most suitable (for example in terms of outcomes), and to what extent it saves money (de Mul et al., 2013).

On 16 February 2018, the State Secretary for Health, Welfare and Sport sent a letter to the Dutch House of Representatives proposing to invest 50 million euros in the digital infrastructure for mental health and addiction care as a stimulus package. In consultation with the Dutch Association of Mental Health and Addiction Care, patient advocate the MIND Foundation and the National Association of Independent Psychologists and Psychotherapists (LVVP), the Ministry of Health, Welfare and Sport has implemented an Accelerated Patient and Professional Information Exchange Programme (VIPP) for the mental health and addiction care sector. On its website, the Dutch Association of Mental Health and Addiction Care describes how the funding is meant to contribute to *'providing patients with a better understanding of their health, uniformity in reporting, exchange of data, safer medication and the promotion of ehealth. This stimulus package will help patients to gain more control over their own care process, shorten waiting times and ease the administrative burden. It will also support cross-sector collaboration'*.<sup>23</sup>

The developers refer on their websites to the availability of these funds. For example, Minddistrict indicates that they can help mental health and addiction care institutions apply for funding under two of the three VIPP modules: patient & information and patient & ehealth. Karify and Therapieland also offer to assist healthcare providers in achieving their IT objectives with VIPP funding and meeting the relevant criteria.

### 2.2.2 Points of concern for integrating online portals

The process of integrating online portals into healthcare raises various points of concern and problems that we address briefly below.

#### **Lack of standardisation as a stumbling block**

It turns out to be difficult to actually transfer data, for example between a specific portal and the healthcare provider's EHR, or between the different portals, or even within the same portal when the data come from different healthcare providers. It is not always possible to transfer data between the EHR or other relevant healthcare information systems and information obtained through the portal in questionnaires. The developers are willing to create the links for a fee. Even so, if a patient used Karify at the Jellinek addiction clinic and is then treated at the Diaconessen Hospital and uses Therapieland there, it is not usually possible to transfer his or her data

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23 Retrieved from <https://www.vippgz.nl/> in September 2018

from the first portal to the second. There is no uniform language and the technical standards have yet to be harmonised.

### **The issue of ownership**

Healthcare providers, developers and patient representatives are discussing who ultimately owns which medical data in the healthcare sector and beyond. Here is what Karify has to say: *'Data are also transferred from the EHR to the online record in the portal. Healthcare practitioners obviously need to have these data available in their organisation to be able to offer quality patient care. But in truth this information simply belongs to the patient, and as such it has to be entered into the patient's medical record too'* (respondent 33). At Karify, then, the patient owns the data that the professional has submitted to the platform, even if they come from the medical record compiled by the doctor. Karify makes agreements about this with the healthcare professional or provider and with the user.

The ownership debate is a complex one. It not only affects patients but also the other stakeholders in the ehealth process, and there is no immediate indication of who 'owns' the data. Instead of ownership, then, it would be better to refer to control over data. Patients, healthcare practitioners and healthcare institutions all have different rights in that regard. Patients may access data and order their removal. Healthcare practitioners decide which data are entered into a medical record. The healthcare institution sees that the data are secure and owns the data carriers and systems. In reality, then, the point is not who owns a particular item of information but who controls access to that information and the way in which it is made accessible. Patients who use Therapieland also maintain their own record, allowing them to review what they have done so far. They can download their record and then choose whether or not to share it with others. *'If a practitioner invites you to our portal, you'll have access to your data for the rest of your life. That way, if certain problems should arise later, you can go back and review all the information, just like in a book. You also have the option of inviting your new therapist to review your record'* (respondent 42). While it is possible to give the new practitioner access to an existing record, linking that record to the new record remains difficult. Both Karify and Therapieland continue to give patients access to their data, even after the therapeutic relationship has ended.

### **Digital inclusion and personalisation as criteria**

All the portals we examined make an effort to reach a broad audience in terms of their language use, level of difficulty and design. For example, Karify takes low literacy into account and tries to lower the threshold to interventions and monitoring tools by working with visualisations whenever possible. Minddistrict offers online interventions that are optimised for smartphone use so that they can be accessed at the patient's convenience, provided he or she has an internet connection.

Developers point out that a portal does not need to be tailored precisely to individual patients, as long as it is accessible to a broad patient group. *‘Both the practitioner and the client can structure the treatment process. If a client is already familiar with certain concepts or has reached a more advanced level, they can skip parts and do other things. It’s important not to make the platform too rigid. That way there’s more personal control and it’s easier to align with the client’* (respondent 53). The disadvantage of broad accessibility, say developers, is that the platform is unappealing to high-educated patients. Portals do try to anticipate this, for example by offering in-depth information.

Online portals offer personalisation based on the choices made by practitioners and patients. Patients clearly differ in their needs, as the interviews reveal. One patient reported that she found the information and interventions offered through the portal too basic, given her level of knowledge. She felt a need for more in-depth information. Another patient said that the videos, the tone of voice, the examples and the exercises were just right for her. This shows that patients consider personalisation of online portals important but that, in reality, they cannot always be personalised.

## **2.3 Online portals and personal health management**

So far, our focus has been on the promises and obstacles that developers, healthcare professionals and patients have identified in the use of online portals. This section explores how online portals help patients to participate in their own healthcare process and to take charge of their health. The spectrum of disorders within mental health and addiction care is extremely broad and the complaints are of varying intensity. Patients also differ in terms of their educational and cultural background, age, and so on. Online portals try to equip this diverse population with digital tools.

### **2.3.1 Independence in decision-making**

#### **Activation and motivation as the goal**

The mental health and addiction care sector regards the capacity to manage one’s health as an important value. Patients, professionals and developers all support this idea. Our interviews with developers show that they mainly look at how they can motivate and activate users to take decisions that will support treatment. *‘Every day, we ask ourselves “Well, this information is all good and well, but what’s really going to help patients to get cracking themselves?” They won’t be able to in some phases of the process, and then they need a psychologist’s help. In my opinion,*

*personal health management means being able to take your own decisions'* (respondent 42). The online portals described in this report are already anticipating this by moving away from the image of the 'healthcare consumer' as a predominantly passive receptacle of information and services.

### **Skills are crucial**

One developer said, *'For me, personal health management means that people can get to work themselves, and that they've acquired the necessary skills. It doesn't work to have someone jump in just like that'* (respondent 42). Decision-making takes skill, and patients agree. Several patients reported that these skills can vary depending on the different functionalities of the online portal (information, communication, monitoring and intervention). For example, a patient may be skilled enough to read (or review) the information so that she is better able to understand what is being said in a face-to-face consultation, but she may not be able to monitor her mood and keep track of it in the system. Alternatively, a patient may be capable of monitoring or altering his behaviour simply by doing so but be less able to cope with feedback on behaviour because *'I don't understand what it's saying anyway'*. To take their own decisions, patients must have the skills necessary to handle the online portals, which is not always the case in real life.

### **Toolbox for professionals**

Even if patients do have the necessary decision-making skills, many decisions have already been taken out of their hands. Practitioners decide on the supply of information, the interventions, and in some cases the monitoring tools. One developer put it this way: *'Practitioners are given a "toolbox" of different modules'*. They can then choose which modules are most suitable to treat their patients.

### **Developer decides on supply information**

Developers also take decisions about what information is provided and how. *'People aren't keen on reading. It's much more effective to use multimedia. And to break it up in short, bite-sized chunks. ... We also work with animations and infographics that offer simple explanations. I don't mean infantile language, but explaining cognitive processes, psychological methods in simple terms'* (respondent 42). These decisions are not taken in consultation with individual patients. The portal developers do say that they have healthcare professionals write or check their information, and have consulted with specialists and expert patients.

Both Karify and Therapieland use analyses and self-learning algorithms to determine the 'appropriate' content for patients, for example in the self-help programmes they offer. Karify uses predictive algorithms to personalise information. It uses algorithms to determine which type of information is relevant, and at what level. Therapieland says that it does not build a client profile using algorithms;

instead, it develops programmes for different client profiles. For example, it has a CBT programme for Depression, but also a Sombreness programme. It is then up to the practitioner to find a good match between the patient's symptoms and the intensity of the programme. The patients decide how they want to receive the information (text, audio and/or animation), and the level at which it is presented.

### **Empowerment**

The decisions that patients can take themselves in online portals therefore seem limited. However, as the developers point out, healthcare professionals who use online portals empower patients to take their own decisions by reassuring them that they can manage their data through the portal. Whenever possible, patients are also given the freedom to decide for themselves whether to complete every section of an online module and how much time they will take. In addition, patients have greater control over data sharing, even with their own practitioner (see Section 2.3.2). What is less clear is the extent to which patients feel empowered by this. The academic literature shows that patients feel empowered by having access to their personal medical records in that they feel positive about using that record to access medical data in their practitioner's record. That also holds for the quality of the information in these records (Jilka et al., 2015).

### **2.3.2 Control over data Communicating about data**

Online portals allow healthcare professionals and patients to communicate more often by digital means about patient data. Respondents stated that these data include the information entered on questionnaires, but also feedback received from a healthcare practitioner or from the system, in the form of visualisations in the event of monitoring (respondent 33, respondent 42). The Karify website, for example, states the following: *'When you work with Karify, you have your own record in which you can save your medical information, for example a referral, a treatment plan or an x-ray. You decide whether to keep these medical data private or share them with your healthcare practitioner.'*<sup>24</sup>

Information about the type of data collected by the service itself can be found in the user agreements or privacy policies. It is not always clear what happens to data that are shared, for example through the messaging functions linked to the online portals, and how much control patients have over this. For example, the Minddistrict app collects data to be able to deliver, maintain and improve its services. *'We also use this information to provide personalised content to you, such as insights, tips and suggestions for relevant sessions.'*<sup>25</sup> The user data consist of 'emotion and intensity', 'description of situation', and 'pictures'. Karify's messaging app is not

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24 Retrieved from <https://www.karify.com/nl/vogelvlucht-client/dossier/> in January 2019

25 Retrieved from <https://www.minddistrict.com/nl-nl/privacybeleid-app> in October 2018

explicit about which data are recorded, but it does state that the information, whether in the form of texts or files, is highly secure and fully integrated into the Karify web application. Therapieland also has a messaging functionality. The user terms and conditions point out which data are managed by Therapieland. If patients want to delete these data, they can notify Therapieland and the relevant practitioners accordingly.

The online portals communicate more explicitly about data ownership than about the data they themselves collect. The Karify website, for example, states the following:

- You own your data. We do not publish or sell your data.
- All access to your information is transparent. If you share your data, then you know with whom they have been shared.
- Karify uses algorithms to predict which information is relevant to you. This happens without our employees having access to your data.<sup>26</sup>

Karify thereby explicitly gives the patient control over access to the data and the way in which the information is made accessible (see also Section 2.2.2 on ownership).

### **Access to and sharing of data**

In all three cases, it is not always possible for patients to consult the medical record created for them by the professional through the online portal. Linking to a patient's medical record or to the self-reported ROM questionnaires requires customisation. Healthcare providers must pay extra for this functionality. Research by M&I/Partners (2017) supports the finding that patients have only limited access to their own medical records. *'Access to data mainly means access to personal data, the care plan and reporting. That is less the case for medication and test results'* (Groothuis et al., 2017).

It is even more difficult for patients to add data collected through self-tracking apps. Patients can communicate their home health monitoring data through online messaging or in face-to-face appointments, but they cannot link apps directly to the online portal. Full integration of the messaging app into the web application, as described in the previous section, therefore says something about the level of data security, but not about the extent to which data collected through 'external' apps can actually be linked to a patient's online record.

It is not only data sharing with healthcare professionals that is an important feature of the online portals but also data sharing with third parties. Therapieland, for

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26 Retrieved from <https://www.karify.com/nl/gebruikers/> in October 2018

example, allows family members, friends and/or informal caregivers to access part of the patient's online portal. *'People can also talk to members of their social circle [such as a partner, neighbour, or acquaintance]. These people can be invited to participate in their own programme...to learn all kinds of things about the patient's problems'* (respondent 53). Therapieland does not give third parties access to the patient's medical record, in other words, but does give them access to the patient's clinical picture, but only when the patient extends the invitation.

### **2.3.3 Influencing healthy behaviour and health**

Users of an online portal have limited choice when it comes to the design of the information or the level at which it is pitched, but they are given tools to control data sharing. This section discusses whether patients are given enough support to improve their mental health.

#### **Patients like prompt feedback, but firm agreements needed**

Some patients like being able to share their feelings and thoughts directly with the practitioner through the online messaging feature. One patient felt she benefited from being able to quickly communicate feedback on her assignments to her psychologist using the secure app function. A precondition for online communication is that patients should not have to wait too long for feedback from their practitioner and that specific pointers for behavioural change exist.

Digital communication is different for each patient. It can cause patients who have trouble expressing their emotions to feel alienated from their practitioner and a lack of empathy on his or her part. *'Sometimes it's difficult to explain something, and when they try to help you put it into words, they actually waltz right over your story'* (respondent 36). The number and timing of communication sessions are also crucial to whether or not digital communication is accepted. *'You don't really interact, for the simple reason that you don't get an immediate answer. You might be having a hard time and feeling like you want the world to end and take you with it, but you won't get an answer straight away. I find that difficult about working online'* (respondent 36). These patients felt that face-to-face contact was more appropriate to their own health process in helping them to change their behaviour. On the other hand, a patient who used the messaging feature as a diary, found that it became an important part of the conversation during face-to-face sessions. In this instance, the patient found that the feature made it easier to communicate about problems.

Each patient experiences digital communication differently, and the practitioner and the patient will therefore need to make firm agreements about how the online portal will be used and when patients can expect feedback.

### **Monitoring doesn't always work**

The mental health and addiction care sector often uses lifestyle and behaviour tracking, generally in the form of questionnaires and visualisations, to help patients attain perceived better health. Using an app that tracks when she experienced psychosis and why helped one patient gain more insight into her dissociations.<sup>27</sup> Notifications and monitoring questions allowed the patient to monitor and review her own feelings. *'It helps to get a message and ask yourself what your feelings are now, and what you're doing. To simply stop and think for a minute'* (respondent 41). For this patient, reflecting on her physical well-being was not always a positive experience. *'One question was: are you in pain? And I thought, no, I'm not in pain. Why would I be in pain? Then I reflected on my body and thought, well I do feel a little pain somewhere. It's not a ten on a scale of one to ten, but I still thought, well, it's good to reflect on my body and my feelings'* (respondent 41). This shows us how continuous monitoring of behaviour forces the patient to reflect constantly on her condition, whereas she would also like to turn her thoughts to other matters.

Another patient found it confrontational to have her data visualised in the form of a rating. *'Every day I had to rate how lousy I felt, and it wasn't very nice to have to fill in a very low score every time. ... I found it confrontational to have to think about it day after day. I had to fill in a score and state what had been positive and what had been negative about the day. It's awful to try to come up with something positive when there's nothing there. And it's awful to come up with something negative too'* (respondent 43). Reviewing all the scores made the patient feel as if there had been no improvement. This shows that visualisations and self-reported health data do not always result in a (perceived) improvement in healthy behaviour.

### **Interventions not always personalised**

Online portals offer patients the therapeutic modules prescribed by the healthcare practitioner. One patient felt that the treatment offered her was in line with her experience of the world and the way she wished to interact. *'For example, I was very anxious about going to the supermarket. And someone in the video had the same problem. She explained how she had improved. So I tried it at once and I have to say that I soon saw results'* (respondent 35). She had to experiment with

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27 Patients experiencing dissociation feel disconnected from themselves. They lose all sense of time, their thoughts and feelings are murky, and their memory of events may be distorted. Psychiatry defines dissociation as a disruption of normally integrated functions of consciousness, memory, identity, or perception of one's surroundings. Another definition (by Hilgard) describes dissociation as the phenomenon of diminished or interrupted continuity of personal experiences and behaviours. See (in Dutch): <https://hulp.gids.nl/informatie/ziektebeelden/dissociatieve-stoornissen/>

new forms of social interaction that made her feel better informed and self-confident. The programme also allowed the patient to work at her own pace. If she felt good about the progress she had made, she could immediately proceed to the next exercise. User flexibility is thus built right into the technology.

Other patients said that they had trouble accepting the interventions and how they were trying to influence their behaviour. They considered the information made available during the online interventions to be basic and too simple. One patient had tried similar therapies before and did not see any added value in the online module. She was looking for more depth than was offered online. Another patient reported that the online therapy made her feel isolated and lonely – there she was, alone in her room, staring at her computer screen.

In these cases, behavioural change can only be stimulated by adapting the interventions to the patient's needs. This has also been confirmed by research such as Archer et al.'s 2011 study of the use of personal medical records.

### **Examining your digital self**

The interviews also show that digital home health monitoring gives patients the opportunity to reflect continuously and more objectively on their mental or physical state so that they learn to change their behaviour. One patient found it less confrontational to check and update her weight later, on the website, than when she was standing on the scale. Digital monitoring thus allows patients to view mental and physical phenomena with more detachment, which means that they respond less emotionally to these phenomena. One patient told her practitioner certain things through the messenger feature that she would not have told him otherwise. People who are motivated and for whom the technology is a good cognitive and environmental fit can successfully change their behaviour using an online portal.

When people who are reflecting on their own physical or mental state feel detached from their digitally observed physical or mental state, they may also be less willing to take the necessary steps to change their behaviour. The extent to which a person regards a quantified representation of phenomena as a true representation of his real-world self can differ. Precisely because of their condition, patients may be unwilling to track and quantify their disorder or illness, may not see the data generated as 'theirs' or not identify with the visualised data, and therefore not be motivated to take action in response to their online data.

According to the meta-review by Jilka et al. (2015), having online access to one's own data does not automatically lead to a statistically significant change in behaviour or clinical outcome. The authors believe having online access should be evaluated in practical settings and the implementation improved.

## 2.4 Online portals summarised

This report takes a closer look at three online portals in the mental health and addiction care sector.

The developers of the portals state that they work in consultation with healthcare professionals and patients. Thanks to this co-creation, the portals are better suited to the needs of patients and healthcare professionals, a prerequisite for their acceptance and use. The co-creators are in the process of reassessing one another's responsibilities with respect to the provision of proper healthcare, patient participation in healthcare and the secure exchange of digital health data. Practitioners are becoming more like coaches and patients are more active and communicate more frequently with practitioners. Patients also play an active role in collecting and managing their own data.

All three online portals offer different functionalities, including messaging, online questionnaires and e-consultations. The services inform users about what happens to their data and the online portals tell patients which of their data have been recorded and with whom they can share these data. Having access to their data and communicating with professionals about this information gives patients a sense of control.

The amount of data being recorded on patients is increasing. It is not always clear whether, how and by whom these data can be used. The portals do not always provide a link to the healthcare professional's medical record on the patient. That depends on the healthcare provider's willingness to pay for the link. It is not always technically or organisationally possible for patients to enter self-tracked and other data themselves.

Before the online portals are ready to reach a broad mental health and addiction care audience, developers must therefore come up with customised solutions that make it technically possible for data to circulate from the professional to the patient and vice versa, especially when patients switch healthcare practitioners. Such links once again raise privacy issues: with whom is the patient sharing which data?

The interviews showed that some patients who worked with online portals experienced an improvement in mental health, but others did not. When patients are motivated, and the online portal is well suited to their needs and capabilities, it helps them to manage the treatment process in a way that would not be possible otherwise. Developers of all three portals say that they are working to build the portals in 'co-creation' with healthcare professionals and patients. Thanks to such

co-creation, the portals are better suited to the needs of patients and healthcare professionals, a prerequisite for their acceptance and use.

The online portals in mental health and addiction care show how blended care and close coordination between practitioners and patients can help some patients feel more in control of their health process. The developers are still figuring out what works and for which patients. They will need to do more research to ascertain whether online portals are an effective tool for behavioural change and to evaluate their practical use. Within the relatively confined setting of mental health and addiction care, further efforts can be made to develop evidence-based interventions, with sound data quality and meaningful analysis as important criteria. The portals are working to ensure proper privacy and security in data sharing, but they will explicitly need to support patients in making sound decisions about data sharing with third parties. This is a particularly sensitive matter when data are shared (inadvertently) beyond the familiar healthcare domain.

### 3 Health apps: using data

We use our smartphones to store and transfer vast amounts of personal data. Thanks to mobile health apps, more and more of these data concern our healthcare and our health. The apps help us to track our lifestyle, physical activity or state of wellbeing throughout the day (Research2Guidance, 2017; Sama et al., 2014) and do everything from counting steps to tracking calories burned and monitoring sleep quality. Sensors integrated into smartphones or paired wearables allow the apps to also track vital signs. In many cases, the app has an e-coach service that offers 'personal' feedback (more or less), for example whether the wearer has reached his or her goal or suggestions for changing behaviour.

In addition, there are specific health apps for patients, also called medical apps (Boulos, et al., 2014). Patients can, for example, use the app to keep a journal that records symptoms and medicinal drug use. Once again, an important component is tracking vital signs. The data help patients understand their condition better, and in some instances they can also share these data with their healthcare practitioner. In this case, e-coaching supports the treatment or coaching provided by the healthcare practitioner.

Health apps are examples of e-coaches.<sup>28</sup> The Rathenau Instituut has studied this phenomenon before. In the report *Sincere support. The rise of the e-coach*, it viewed health apps within the context of other data-sharing services, such as the now upcoming PHE, and examined the extent to which such apps allow people to control their health data and consequently better manage their health (Kool, Timmer & Van Est, 2014).

This report describes three apps as examples: StressCoach, SamenGezond and MS Sherpa. Using semi-structured interviews with one developer, one developer/researcher, one researcher and four managers (communication/marketing/programme) employed by the providers, complemented by policy and research publications, website information and the findings of the Rathenau Instituut's working visit to digital healthcare technology companies and hospitals in California in November 2017, we answer various subsidiary questions. Who is involved in developing and using the health apps, what interests are at stake, and who is responsible for what? To what extent do health apps allow people to take charge of their health? What problems do users encounter? What are the

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28 Smart tools for quantification and analysis are combined with cognition, psychology, and coaching expertise to encourage certain behaviour or the desired change in behaviour. The e-coaches derived from this combination feature three processes: 1. Data are collected from sensors or other digital sources. 2. The data are analysed and the coaching strategy is determined. 3. Persuasive, motivating feedback is provided (Purpura et al. 2011).

benefits according to the stakeholders? We draw attention to various points of concern regarding the real-life use of health apps and what that use entails for personal health management.

### 3.1 What are health apps and what do they do?

As we noted above, there are health apps for general use and health apps for patients, including apps specifically for chronic patients.

#### **Health apps for general use**

Health apps are software applications for smartphones, tablets and PCs that allow users to self-report or have sensors record all kinds of lifestyle behaviour and health data. They are a popular feature on smartphones. Sometimes the smartphone tracks and records health data on its own, and sometimes it is connected to another device, such as a smart watch or other wearable with sensors that count steps or measure the wearer's heart rate, for example. Health apps store the data locally (on the smartphone, tablet or PC). A copy of the data is stored 'in the cloud', for example in online databases managed by the app's supplier. Many apps focus on physical health, but there are also apps that allow users to keep track of their mental wellbeing.

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#### **Enough choice and who uses them?**

Research2Guidance (Research2Guidance, 2017) reports that a total of 325,000 health apps were on the market in 2017 and that 78,000 new apps were added in that year. The apps can be downloaded for free or for a fee. People often start using them voluntarily, without a healthcare practitioner's involvement. The number of app developers is growing and app use remains high, but there has been a dip in the number of new apps being downloaded. Only 2% of health apps have more than 500,000 active users each month.

Market research in the Netherlands in 2016 revealed that a third of Dutch people use apps, wearables or wireless devices to monitor their health or physical activity. According to that survey, half of the consumers had never used these digital applications before (Multiscope, 2016). A world-wide survey showed that *'a smaller percentage of Dutch people monitor health*

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*or activity: 13%. That puts the Netherlands at the bottom of the global rankings. At 46%, China is at the top' (GFK, 2016).*

According to the most recent national eHealth Monitor Survey, 34% of healthcare users tracked their physical activity digitally in 2018. In 2014 that figure stood at only 12%. Applications that require more effort on the part of healthcare users, for example in which they measure and update their health data themselves, are less popular (Wouters et al., 2018).

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### **Medical apps**

Specific patient health apps allow users to record data themselves, for example medicinal drugs used, perceived anxiety or fatigue. It is also possible to collect biometric data, such as heart rate or blood glucose levels, using a smartphone or a linked sensor. A sensor can also be attached to a drug applicator (for example an asthma inhaler). These types of apps can then be used to better manage a specific, chronic disorder, such as asthma or type two diabetes mellitus. Patients can use the app to share data with their doctor, for example for quick advice about drug dosage or behaviour modification (Boulos et al., 2014).

In Chapter 2, we discussed the digital patient portals within the mental health and addiction care sector that focus on digital access and use of data to support a specific treatment process. The medical apps discussed in this chapter are forms of technology for patients, their informal carers and/or their healthcare practitioners that use (continuously) collected data to help the patient better manage living with a chronic disease.

### 3.1.1 A closer look at health apps

The three health apps that we studied were developed or are under development in the Netherlands. They are: StressCoach app, which allows users to pursue a specific health goal; SamenGezond app, which combines all kinds of health and health behaviour data to come up with a daily personal fitness score ; and MS Sherpa app, a medical app.

Table 3 Health apps studied

	StressCoach app	SamenGezond app	MS Sherpa app
Description	<p>Helps users to quantify and monitor their stress levels and mental resilience and provides personal coaching based on the readings. A better understanding of stress levels can also have a preventive effect.</p> <p>Sources:  <a href="http://www.stresscoachapp.com/">http://www.stresscoachapp.com/</a>  <a href="https://www.tno.nl/en/tno-insights/articles/tackling-work-related-stress-with-the-stresscoach-app/">https://www.tno.nl/en/tno-insights/articles/tackling-work-related-stress-with-the-stresscoach-app/</a></p>	<p>Helps users to improve health by making them aware of their current behaviour and helping them to change their lifestyle behaviour. The app calculates a daily personal fitness score based on the user's physical and mental state, amount of daily exercise, nutrition and other choices that affect health. An automated online coach offers tips for improving health and achieving goals.</p> <p>Source:  <a href="https://samengezond.menzis.nl/">https://samengezond.menzis.nl/</a></p>	<p>Helps people with multiple sclerosis (MS) and their physicians understand gradual changes in the patient's condition based on medical data, cognitive and gait tests, and monitoring of eye movement activity.</p> <p>In time, self-learning algorithms may be used to predict the course of the disease and to discover links between the disorder and lifestyle choices, allowing patients to manage their disease better.</p> <p>Source:  <a href="https://www.mssherpa.nl/">https://www.mssherpa.nl/</a></p>
Primary users	Private individuals or employees who want to manage their stress	Private individuals: Menzis clients (84%), clients of other insurers (16%)	Patients with multiple sclerosis (MS)
	StressCoach app	SamenGezond app	MS Sherpa app
Status	Developed by The Performance Experts in	Offered by health insurer Menzis to its own clients and	Developed by Orikami in

	<p>partnership with TNO to build a reliable app that is both validated and can guarantee user privacy. The app can be tested on request.</p>	<p>to non-Menzis clients since October 2017. The app is part of the older SamenGezond platform, which has about 365,000 participants. It was developed by the Swiss digital health firm dacadoo and has been downloaded more than 153,000 times.</p> <p>The University of Groningen (RUG) is currently testing the long-term effectiveness of SamenGezond.</p>	<p>collaboration with patients, the local patient organisation, MS4 Research Institute, Netherlands MS Fund, the MS centre at VU Amsterdam Medical Centre and Radboud University Nijmegen. For now, only being tested at university hospitals.</p>
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The apps differ in terms of the context in which they are used (in conjunction with a healthcare practitioner or outside healthcare practice) or their purpose (specific purpose, broader purpose of general fitness, or to better manage the course of a chronic illness). They are similar in that they all offer a certain degree of coaching, although the type of coaching differs (e-coaching alone or the option of getting personal coaching). The developers of the MS Sherpa app furthermore aim to use algorithms eventually to predict the course of the disease based on behaviour or circumstances, although the emphasis at the moment is on monitoring the course of the disease.

### 3.1.2 Health app functionalities

Whereas the online portals (see Chapter 2) provide general information about illness and treatment and have online communication with the healthcare provider or service desk as important key features, the three health apps that we have investigated focus primarily on monitoring (using sensor and other data) and intervention. The software compares the user's values against standard values and in so doing, gets to 'know' the user. It then offers the user 'personal' advice about changing his or her behaviour. It is in fact more appropriate to refer to 'motivation' than 'intervention', given the non-committal nature of e-coaching. The predictive nature of the MS Sherpa app is also an important feature. At the end of this section, we briefly describe the promises that each of the apps makes with regard to participation, personalisation and prevention.

#### Monitoring

StressCoach collects stress-related data from users in several ways: by measuring their heart rate (users place a finger on their smartphone heart rate sensor for about 70 seconds) and by asking them questions about their mood and how much energy

they have. After analysing the readings and answers and comparing them with personal standard values, the app gives the user information about how various circumstances will affect them during the day at the stress levels they are experiencing.

SamenGezond tracks individual fitness, recorded as a fitness score (a number between 0 and 1000). The app calculates the fitness score based on various completed questionnaires and sensor readings. The purpose of the fitness score is to make users aware of their health (and health behaviour). The fitness score is composed of three parts: the user's physical and mental state and daily amount of exercise, nutrition, and other health-related choices. The app can be linked to other apps such as Fitbit and Runkeeper.

The MS Sherpa app, which is still in the testing phase, links the patient's medical data to information that they themselves gather about their lifestyle behaviour, level of fatigue, mood, level of concentration, and stress levels. Biometric tests are added that users carry out themselves using their mobile phones, such as a two-minute gait test, a cognition test and a fatigue test (based on eye movements). The app syncs to a Fitbit to track heartbeat and activity. Regular testing gives the MS patient a much better idea of how certain behaviours affect the course of the disease.

### **Prediction**

Ultimately, MS Sherpa wants to use algorithms to analyse stand-out patterns in the relationship between behaviour/medicinal drugs and symptoms and what this means for the individual patient. The software is capable of learning (artificial intelligence) and can predict the course of the disease. Users can take its predictions into account when planning activities. Although the developers have this predictive function as their aim, the app's most important function at the moment is to monitor the course of the disease.

### **Motivation and intervention**

The monitored data in the health apps help users to understand their own behaviour and how close they are to achieving a certain health target. Monitoring alone may already inspire some users to change their behaviour; that is the idea behind weight-loss programmes, for example. The health apps that we have investigated all offer feedback, functioning as an e-coach. StressCoach takes the personality of the user into account during set-up, since not everyone is equally prone to stress. After analysis and interpretation based on standard values for degree of overstimulation, standard feedback texts encouraging behavioural changes appear on the user's screen. Users can also share their stress values with a real-life coach to get his or her personal advice.

SamenGezond challenges users to set goals, for example eating healthier, taking ten thousand steps a day or drinking more water. They can also get others to join them in the challenge. The e-coach asks questions, offers practical lifestyle tips and motivates users to achieve their goals. They can share goals they have accomplished (for example a photograph of a healthy meal they prepared themselves) and receive SamenGezond points as a reward. Users (whether or not insured with Menzis) can trade in the points for products in an online shop, such as a scale.

MS Sherpa helps patients discover links between their condition and lifestyle behaviour, including activity and rest. This gives them a framework for changing their behaviour voluntarily, for example taking timely breaks. Trends in their test results give physicians a quick impression of whether their medication is effective, and treatment can then be adjusted accordingly.

### **Participation, personalisation and prevention**

We see that health apps can help users to track progress towards a specific personal goal ('exercise more' or 'reduce stress'), to adopt healthier lifestyle habits ('improve fitness score'), or to analyse their state of health at first hand and share the data with their healthcare practitioner. In all three cases, users participate in improving their health (StressCoach and SamenGezond) and their treatment programme (MS Sherpa). All three apps also offer a certain degree of personalisation: users set personal targets in the apps based on their initial situation. For example, the StressCoach app provides as much personalised advice as possible. The website states the following: '*Stress is a personal measure. That's why the app compares several different readings with a baseline value that it measures in the morning. That way you'll always measure your own, individual stress value.*' The MS Sherpa app predicts future symptoms related to the user's behaviour, based on his or her own data. Users may be able to prevent deterioration or further complaints by adapting their lifestyle or behaviour in good time. The StressCoach app website says this about prevention: '*Avoid complaints and always stay one step ahead of stress*'. In addition to individual health benefits, the apps are expected to deliver social benefits as well. Developers and providers argue that these applications can make healthcare more efficient and effective and less expensive (see Section 2.2.1).

## **3.2 Health apps in a broader context**

In addition to the three health apps that we have studied in-depth, this section also discusses health apps in a broader context based on the academic literature, the Rathenau Instituut's working visit to Silicon Valley in November 2017, and our

publication *Sincere support. The rise of the e-coach* (Kool et al., 2014). The latter report concluded that users of e-coaching now have a whole network of different parties to contend with, each of which has its own commercial or other interests. The user's interests are not always automatically top priority. Section 3.2.1 describes stakeholders and their interests based on our empirical research, the academic literature and online information. Section 3.2.2 then addresses how health apps are used for personal health management, both within and outside the healthcare sector.

### 3.2.1 Stakeholders, interests and responsibilities

#### **Health app developers: revenue, but with a mission**

Traditional healthcare sector parties, such as hospitals, pharmacists and insurers, are a minority among health app publishers. More than half of all health app developers are technology companies or app developers active in other market segments (Research2Guidance, 2017). The app developers (providers) claim that both economic and social interests underpin the widespread use of their apps, for example the need to cut the cost of healthcare by improving drug compliance or by preventing diseases. Although there are echoes of the 'make the world a better place' rhetoric of Silicon Valley tech companies, the health app sector is in fact becoming just a mainstream money-making industry. Even so, it is difficult for technology firms to achieve success. A working visit by Rathenau Instituut researchers to the digital health domain on the US West Coast in November 2017 taught us the following: '*California technology firms no longer dream of instant success with health apps. The future is interoperability: better cooperation, communication and information sharing. Silicon Valley is developing appropriate digital healthcare technologies in cooperation with healthcare practitioners.*'<sup>29</sup>

StressCoach, by The Performance Experts, was developed in cooperation with researchers at the Netherlands Organisation for Applied Scientific Research (TNO) who have expertise in such areas as sensor technology, signal processing, data-streaming, mathematics and privacy. The product is in line with TNO's mission to develop ehealth products for disease prevention. In addition to its social purpose, the company is obviously also interested in running a healthy business. The StressCoach app must be commercialised as quickly as possible because costs have been incurred and must be recouped. The research institute that is collaborating with them, in this case TNO, would like to do more testing and, for example, more research into the app's reliability and validity. There is tension

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29 Retrieved from <https://www.rathenau.nl/nl/maakbare-levens/california-blues-gebarsten-bubbel-en-toekomstmuziek> in September 2018

between the partners: the partner that is going to commercialise the app wants to go to market, whereas the research partner wants to keep testing the app.

One respondent explained that this immediately gives rise to another interest on the part of developers and researchers, namely access to the collected data with a view to improving the app. Of course, they aim to do this with the users' explicit consent, after providing them with information about their purposes. To collect data from patients, for example to optimise the MS Sherpa app, the developers offer hospitals a subscription that registers patients to use the app, with trends in their own health data automatically ending up in their EHR. This is revealing in that it shows that data collected through apps are of interest to third parties; in the case of the MS Sherpa app, they are of interest to pharmaceutical companies that market drugs to manage MS.

The present study has also shown that developers often produce an app on behalf of an insurance company, a firm or a government agency that wants to coach employees on healthy behaviour, or on behalf of a healthcare institution that wants to support patients in their treatment. These app providers (which are not necessarily the app developers) may have other interests at stake, as described in more detail below.

### **Healthcare: lower costs and easier coaching**

In a broader sense, the healthcare sector sees e-coaching mainly as a way to lower costs by supporting treatment. Such support means that patients have less need to visit or speak to a doctor in person and will adhere more closely to their treatment plan, and that treatment is more cost-effective. That is why hospitals offer medical apps as part of a treatment programme, for example. A study by Agnihotri et al. (2018) shows that there has not been enough research to ascertain whether an investment in a particular app actually has the desired effect.

An enormous number of health apps can be downloaded for free and people almost always use them voluntarily. They almost never consult their GP or other practitioner about using these apps, although a doctor may of course recommend an app to track a patient's physical activity or to help him or her lose weight. In contrast, the MS Sherpa coach is an example of a health app developed in cooperation with the healthcare sector that shares data with the patient's neurologist so that he or she can track the effectiveness of patient's drug treatment. This case study shows that app development in cooperation with and within the healthcare sector is important for both patients and healthcare professionals because monitoring and coaching become easier and are underpinned by data.

### Providers of health apps: insurers, government and employers

Insurer websites draw customers' attention to existing health apps or propose that they use a specially developed app in exchange for certain benefits. For example, app users can take advantage of special offers in a web shop or receive a discount on supplementary insurance. After all, healthy customers are expected to claim fewer healthcare expenses. Health insurer Achmea has the Actify platform and Menzis the SamenGezond platform. Both platforms deliver an app that uses an online coach (a chatbot) to encourage people to live healthier lives. The SamenGezond app was developed by the firm *dacadoo*. In an interview with *SmartHealth*, dacadoo COO Marcel Heuer said: *'I get that this is a sensitive issue, but being rewarded for a proven healthier lifestyle has benefits for both parties.'*<sup>30</sup> The SamenGezond app's spokespersons are also at pains to stress the importance of the app for individuals, its users, who can improve their health. They also mention social considerations, including the reduction of rising healthcare costs. *'We see ourselves as a civil society organisation that plays a significant role in a system based on solidarity. Our responsibility therefore extends far beyond financial services,'* one spokesman explained. That is why the app is also available to people who are not insured with Menzis.

The Eetmeter app<sup>31</sup> is an example of a lifestyle app provided by a government-subsidised institution, the Netherlands Nutrition Centre. Government's interest lies mainly in reducing healthcare costs by means of primary or secondary prevention of lifestyle-related diseases. In the case of the Menzis SamenGezond app, cooperation is being sought with municipal authorities, making it possible to supplement medical data with lifestyle and health data. Consideration is being given to cooperation between district social welfare teams and healthcare providers and to providing long-term support for healthy behaviour at local level.

Employers also have a stake in a healthy workforce, because sickness absenteeism costs money. That was the idea behind the development of the StressCoach. In an interview with *TNO Insights* in 2017, Henk-Jan Zwolle, Director of Innovation at The Performance Experts, said: *'Look, over a million people in the Netherlands suffer from work-related stress. That can lead to a burn-out. If you can help to prevent serious stress by offering people personal advice every day, then you can significantly cut the cost of sickness absenteeism. Two years ago, with this in mind, we came up with the idea of the StressCoach app. The app is very effective. It is currently undergoing further testing, by hundreds of people with desk jobs at various companies.'*<sup>32</sup>

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30 Retrieved from <https://www.smarthealth.nl/2015/08/03/smarthealth-europe-dacadoo-zwitzerland/> in October 2018

31 Retrieved from <https://mijn.voedingscentrum.nl/nl/eetmeter/> in October 2018

32 Retrieved from <https://www.tno.nl/en/tno-insights/articles/tackling-work-related-stress-with-the-stresscoach-app/> in October 2018

### **What consumers or patients want**

People increasingly use health apps to help themselves develop healthy habits without involving a healthcare practitioner – although once the app is installed, they tend not to make much active use of it (see box on page 46). People say that they use health apps to avoid illness and to feel fit. Research shows that the users of these types of apps are mostly young people who are well-educated, in good health and in a higher income bracket (Carroll et al., 2017; Ernsting et al., 2017).

The 2018 national eHealth Monitor survey shows that one in ten people with a chronic condition tracks or measures health data digitally using a mobile app (Wouters et al., 2018). Forty percent say they do not wish to do this. Specific medical apps such as MS Sherpa mainly meet the needs of patients who want to exercise more influence on the course of their illness or the symptoms they experience. The demand for such apps and their actual use have not been studied widely.

The report *Sincere support. The rise of the e-coach* (Kool et al., 2014) concluded that e-coach users find it extremely important for apps to do what they promise (data collection is of good quality and advice is reliable) and for their privacy to be guaranteed. What standards underpin the e-coach's recommendations, for example? Do the sensors actually track movement correctly? Does the e-coach do its work with 'integrity' and are data kept confidential?

### **Encouragement by government**

The Ministry of Health, Welfare and Sport promotes the use of ehealth in all sorts of ways. In 2014, the then Minister of Health, Welfare and Sport, Edith Schippers, identified three objectives, one of which was that 75% of chronically ill and vulnerable elderly people who were willing and able could monitor their health themselves, combined with remote data monitoring by a healthcare practitioner, within the next five years. In the spring of 2018, the Dutch Minister for Medical Care Bruno Bruins concluded an agreement with overarching organisations in the medical-specialist care sector, patient organisations and health insurers. A major part of that agreement concerned the use of ehealth. After all, government has a vested interest in reducing the workload in the healthcare sector and the cost of healthcare, and ehealth is expected to help achieve this reduction.

## **3.2.2 Points of concern for integrating health apps**

The previous section shows that there are many interests at stake. Economic or social interests prevail for health app developers and providers, but users' interests do remain central to the company's or institution's mission. All stakeholders have

certain responsibilities. Below we list some key points of concern when integrating health apps into healthcare practice and beyond.

### **Reliability and quality of data and advice**

As early as 2014, the Rathenau Instituut recommended that product developers and government should anticipate stricter privacy protection under the upcoming GDPR (Kool et al., 2014). App providers that work with healthcare providers devote considerable attention to secure data use and the same trend can also be seen among other app developers. Under the GDPR, privacy guarantees have almost become a *standard component* of apps but in fact privacy is by no means always guaranteed. In 2018, for example, the news magazine *de Correspondent* reported that anyone who had the fitness app operated by the Finnish company Polar could track down the names and addresses of thousands of military personnel and secret agents.

The developers interviewed for this study appear to be well aware of privacy protection, but also of the importance of reliable sensor readings and good advice. For example, in the case of the StressCoach app, a multidisciplinary research team works with the developers on validated quantification methods and analyses, and user data and sensor readings are secure and only visible to the user. On 1 September 2018, the University of Groningen launched a six-year study into the long-term effectiveness of SamenGezond. A spokesperson says that SamenGezond participants explicitly consent to share their data with the university and it is entirely transparent which data are being shared. Users can cease participating in the study at any time without further notice. In the year ahead, MS Sherpa will be working in several hospitals to determine whether patients and healthcare professionals can manage the disease better using the app. The developers have adopted a step-by-step approach, with one of the new developments being a method for quantifying the extreme fatigue that often occurs in MS patients.

In 2014, the Rathenau Instituut stated that consumer organisations and app developers should agree on quality criteria (industry quality marks) for e-coaches. An update is provided in the box 'Sincere support in 2018'. Section 3.3.3 examines the quality of the advice that apps provide for influencing health.

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### Sincere support in 2018

There is still no industry quality mark for health apps. However, the GGD AppStore<sup>33</sup> offers a list of dependable and effective health apps that have been assessed on user friendliness, reliability, underlying principles and privacy. One striking point is that as long as the app's provider is transparent about the commercial objectives of its data use, for example, app privacy is considered 'satisfactory'. The GGD AppStore does report such commercial objectives, for example by stating: *'Users should be aware that the app tracks and stores large amounts of personal data and uses these for commercial purposes. For an explanation, see the privacy terms. The app also requires access to a considerable quantity of data on the device itself, such as the address book and location data'*.

The KNMG Medical App checker *'provides parameters for assessing the quality of medical apps and aims to encourage responsible use by doctors and patients. The Medical App Checker consists of three checks. The first check offers parameters for a targeted search for a suitable medical app for use by patients, doctors or informal carers. The second check helps to assess the reliability and quality of a medical app before downloading. The third check helps to assess personal data protection after the app has been downloaded'*.<sup>34</sup>

Another attempt to separate the wheat from the chaff is the National eHealth Living Lab (NeLL), whose founders include Niels Chavannes, Professor of e-health applications at Leiden University Medical Centre (LUMC). The lab tests digital health products such as apps, sensors, wearables and robots for reliability. The significance of this is even clearer if we consider that people will be expected to link more and more apps to their personal health environment (PHE) in the future, which will contain not only lifestyle but also medical data. You will read more about the PHE in Chapter 4.

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33 Retrieved from <http://ggdappstore.nl> in January 2018

34 Retrieved from <https://www.knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/medische-app-checker-handreiking-bij-het-beoordelen-van-medische-apps.htm> in January 2019

### **Transparency of the revenue model**

The app user is only one of a whole network of stakeholders. There is the health insurer that rewards a healthy lifestyle by offering (a discount on) online self-help programmes (such as the e-learning module Beter Slapen) or reduced insurance premiums, and that may be partnered with the municipal authorities in this domain. There is the developer of an app that helps users manage a chronic disease, and the pharmaceutical company that would be very happy to have such data to further development of the drugs that users require. Fitness apps Runkeeper and Strava garnered negative publicity because they had resold their users' data to third parties. As early as 2014, the Rathenau Instituut called on government to make transparency about revenue models mandatory (Kool et al., 2014). The present study once again shows the lack of such transparency. Users should be able to see what happens to their information and who is earning money from it.

## **3.3 Health apps and personal health management**

### **3.3.1 Independence in decision-making**

It is up to every individual to decide whether or not to use apps that monitor health, and by no means everyone opts to use them. The ability to take independent decisions depends on the situation in which the apps are offered. That situation also plays a role in the steps that need to be taken when using the apps.

#### **Voluntary nature of e-coaching depends on context**

People generally use health apps such as those listed in the Apple App Store voluntarily, sometimes at the instigation of family, friends or a doctor. However, the context in which the app is made available, does determine whether that decision can be taken independently. How independent is this decision, for example, if an insurer offers an app in exchange for a discount on an insurance premium or for loyalty points? What about a stress management app that's been recommended by an employer's HR department? Or an app to manage a chronic disease that an enthusiastic doctor at the hospital is testing and asks his patients to use? As our interviews reveal, the developers, publishers and end-providers certainly have the user's interests at heart (healthier behaviour, better stress or disease management), but it would nevertheless not be easy for a policyholder, an employee or a patient to refuse the e-coaching service in these three examples.

#### **Independent decision-making within the parameters of the technology**

Once a person has started to use an app, he or she will have to take a conscious decision to share the data it collects with the e-coach for purposes of analysis and

feedback. After all, without data sharing there can be no feedback. The decision may depend on the revenue model or privacy terms. It must be clear to the user exactly which data are being collected and whether further analyses are being carried out (by third parties) and for what purpose. However, since so many apps do not live up to the quality standards of initiatives like the GGD AppStore, such transparency is often lacking.

There is limited choice when it comes to the type of tracking that can take place. For example, like many other health apps, the MS Sherpa app and the StressCoach app need users to fill in questionnaires and permit tracking of various vital signs so that algorithms can monitor or even predict trends in fatigue and stress levels. The more complete the dataset is, the more accurate the feedback or prediction. In that sense, the user has very little to say about what will or will not be quantified.

The apps in these case studies could all be customised (to a limited extent) to suit the user's personal attributes, personality and habits and to set personal targets. Although users are at liberty to set their own targets, they are not told how realistic these targets are in their own situation. The advice given by e-coaches is 'personalised' (for example to account for a user being less sensitive to stress than the average person), but it turns out that they leave relatively little freedom of choice: users can decide whether or not to follow the advice; other options are not usually available. The extent to which users are at liberty to follow some or all of the advice or to ignore it entirely therefore depends on their own knowledge and understanding.

### **3.3.2 Control over data**

Health app users must therefore first decide whether or not to use the app. If they do, the immediate implication is that they will be sharing data for analysis purposes and then receive advice. But to what extent do users control their data? We explore this aspect below.

#### **Data for users, and others**

First of all, it is difficult for users to see their own data. Trends (such as the fitness score or stress levels over a certain period) are often summarised and made available, but users never see the underlying (raw) data on a specific vital sign or behaviour that produced the composite score. SamenGezond does explain the fitness score and why it changes in the lifestyle, physical or mental categories.

Second, it is difficult if not impossible to download your data or to input that data into a PHE (see Chapter 4) or medical record (see Chapter 2) for further analysis, making it hard for users to take charge of their health based on data from multiple sources.

Third, the user has little or no control over how data are shared with parties other than the e-coaching provider. It is in the service provider's interest for the developer to utilise data collected by users to improve the service. It is also in the developer's interest, because – as we found in the interviews – such data can lay the groundwork for another app for another type of customer. However, data are usually shared with the user's permission, especially in the case of apps that process vast amounts of medical data. Having a transparent revenue model, listed as a point of concern in Section 3.2.2, gives users some sense of control. However, things are less straightforward when data are shared with parties beyond the provider and developer. Can a pharmaceutical company gain access to a completely anonymised dataset of all the users of a medical app? Will researchers eventually be allowed to use that dataset in pursuit of greater scientific understanding? In an interview with Dutch newspaper *NRC* on 21 December 2018, Mark van Houdenhoven, CEO of specialist hospital Sint Maartenskliniek and professor of Economic Management in Healthcare at Radboud University, had this to say: *'Medical data must be made available in a secure manner to drive innovation in healthcare. We shouldn't concentrate data exclusively with suppliers, because it's not a good idea to allow one party to have a monopoly on healthcare data'*.<sup>35</sup> Chapter 5, which discusses public data platforms, looks more closely at this topic.

### **Algorithms intangible**

Algorithms play an important role in producing personal fitness scores or values that indicate health and wellbeing. The e-coach also bases its advice on such algorithms. The software sometimes 'learns' from user behaviour and takes that behaviour into account in its future advice. Users cannot tell which individual data are or are not used or how they are weighted, and so in that sense they are unverifiable.

### **3.3.3 Influencing healthy behaviour and health**

We have seen that health apps that track personal behaviour, quantify aspects of health and help users achieve targets differ widely in their features. As the present

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35 Retrieved from <https://www.nrc.nl/nieuws/2018/12/21/delen-van-patientendata-innovatief-en-gevaarlijk-a3126787> in December 2018

study shows, it remains unclear to what extent apps give users tools with which to change their health (or their health-related behaviour).

### **Apps developed for specific purposes more likely to support personal health management**

Overall, the vast majority of apps (about 75%) are general apps that provide information about healthy lifestyle or that help users monitor and adapt their lifestyle behaviour (take exercise, count calories). Apps that monitor aspects of wellbeing (sleep quality, stress, mood) are less common (about 25%) (Sama et al., 2014). We do not know how many special apps for disease management have been developed in collaboration with specialists and patients. Our interviews indicate that medical apps developed in close cooperation with healthcare professionals and patients do provide a firmer grip on health. Apps based on self-learning software that can also make predictions about the course of a user's illness or state of wellbeing in the near future function as extra health management tools. As the MS Sherpa app shows, this outcome can also be attributed to the dialogue that takes place between healthcare professionals and patients using the app. At the same time, the data and the advice can also serve commercial interests, for example those of the pharmaceutical industry.

### **Easier to manage personal health digitally?**

People have naturally been using pen and paper to track their eating habits or progress towards a weight loss target for a long time and doing so can motivate them to change their behaviour. Apps make this process easier and can help users visualise their progress – but are they really more effective than an old-fashioned journal? Digital tools are advantageous when they combine multiple data into a single score. Even so, do we really need to digitise our health information and share the data with an app provider to gain control over our health (and health data) and lifestyle behaviour?

The scientific underpinnings of the advice and behavioural therapy provided in apps available to all leave much to be desired. The relevant software rarely incorporates the latest research findings concerning risk prediction or behavioural change. Nevertheless, controlled trials show that app-based e-coaching can be an effective tool for improving users' physical and mental health (Rathbone & Prescott, 2017; Scott et al., 2018).

### **Standards unclear but users still want to comply**

We already mentioned in Section 3.3.2 ('Algorithms intangible') that users have little understanding of the algorithms responsible for analysing and evaluating their data. Healthy lifestyle e-coaches, for example, may tell us that there is a certain health risk associated with our behaviour or the status of our vital signs, but it is often unclear which standards they are using and how valid they are.

Digital self-help is turning healthy behaviour into a baseline standard from which we are not permitted to deviate. There are people who take the dog out for an extra walk in the evening so that they can meet their goal of '10,000 steps', but there is in fact no scientific evidence that a 10,000-steps-a-day regime leads to good physical health.<sup>36</sup>

### 3.4 Health apps summarised

The many health apps now available to consumers offer them all sorts of ways to monitor their health, set personal targets and adopt healthier behaviour. Medical apps tend to be developed for specific patient target groups in consultation with patients and doctors. They can support treatment and help patients to better manage their disease and/or health process. In both cases, it is the user who is responsible.

Of the three health apps that we examined, two were developed as e-coaches for lifestyle change (StressCoach and SamenGezond) and one within the context of healthcare. The StressCoach app was developed in collaboration with TNO and is now being tested in workplace environments; the SamenGezond app is offered by a health insurer but its users are not restricted to clients; and the MS Sherpa app is undergoing further development in consultation with researchers and healthcare professionals, the aim being to incorporate self-learning algorithms at some point.

Our study shows that the context in which an app is offered determines whether a person feels free to use or refuse the app. It is difficult for users to personalise apps because the technological parameters do not allow this. Users have little control over the individual source data, which are not easily accessible.

The advice offered by the StressCoach and MS Sherpa apps is based on research evidence; the scientific underpinnings of the SamenGezond app are less clear but it mainly focuses on monitoring. The MS Sherpa app is a good example of how the evidence underpinning the monitoring and advisory functions and the app's ongoing development is being accumulated step-by-step and in cooperation with practitioners. Nevertheless, in all three cases the underlying health standards and the quality of the data analyses remain obscure to users. The GGD AppStore, the KNMG Medical App checker and NeLL are attempting to evaluate the quality and reliability of the measurements and e-advice of all sorts of consumer apps. As yet, it is not clear who will enforce their findings.

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36 Retrieved from <https://www.theguardian.com/lifeandstyle/2018/sep/03/watch-your-step-why-the-10000-daily-goal-is-built-on-bad-science> in October 2018

All three apps that we have examined are concerned about data privacy. The introduction of the GDPR has led to better privacy arrangements. The service providers must act responsibly in this regard, but users also need to take a good look at the privacy terms associated with an app. That calls for terms and conditions that are easy to read and understand. Yet, when apps are linked to other services, such as online portals (see Chapter 2) or public platforms (see Chapter 5), it is less clear where the data are being sent and how they are being analysed. They may end up in the hands of commercial parties. It is crucial to exercise caution when sharing data generated by the apps.

Our study shows that the developers and providers of the above three apps understand the need to explain their revenue model, but that is not the case for many consumer apps. There is no national ‘watchdog’ for non-transparent business models or data abuse, and the data are much less secure outside the medical domain, potentially leading to exclusion or discrimination based on profiling.

Broadly speaking, our impression is that the many apps now available could result in a healthy lifestyle becoming the baseline standard, with digital support. Healthcare must, however, be guaranteed for those who are unable or unwilling to meet this standard. The ‘human rights in the robot age’ suggested in a previous publication by the Rathenau Instituut – namely the right to not be measured, analysed or coached, and the right to meaningful human contact – also apply in the case of e-coaching by health apps.

## 4 Personal health environments: managing data

In this chapter we look at the rise of personal health environments (PHEs) in the Netherlands. From 1 January 2020, Dutch patients must be able to communicate securely with the information systems of healthcare providers through their PHEs, so that they can collect and manage their own health data in a single location. PHEs are thus an alternative to the mandatory connection to the National Health Data Switchboard (also known as the 'national electronic health record') whose introduction was blocked by the Dutch Senate in 2011. PHEs put patients at the centre of personal health data collection and sharing. They are a collection point for different types of health-related information, for example about treatments, test results or self-tracked data using apps and wearables, stored in a kind of personal data vault. PHEs are meant to ensure that people can control their own health data, from cradle to grave.

In its report *Responsible digital health management. More data, more control?* (Niezen & Verhoef, 2018), the Rathenau Instituut described the MedMij Programme, set up to develop a set of rules (a Trust Framework) for the secure transfer of health data until the end of December 2017.<sup>37</sup> In 2011, the Dutch Senate rejected a bill introducing a national electronic health record because it did not adequately guarantee the protection and security of data (and data transfer). The MedMij Programme provides for a set of agreements that do offer adequate guarantees, based in part on new legislation, i.e. the Processing of Personal Data in Healthcare (Additional Provisions) Act (Wabpvz). However, as that study showed, data transfer is complicated (technically speaking) and requires not only a system of central agreements (such as the MedMij system), but also decentralised arrangements and partnerships that enable data to be transferred between individuals' PHEs and professional medical records and that also connect with apps. It further became clear that the developer of the PHE was mainly concerned with chronic patients. The question then is to what extent PHEs will meet the needs of healthy individuals or groups of (vulnerable) people (Niezen & Verhoef, 2018).

This chapter provides a brief update of the MedMij rules and agreements. In particular, we investigate how PHEs are used in the real world and describe three

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37 The MedMij Programme is laying down rules that will give patients a complete overview of their personal health data – a personal health environment or PHE – where they can access, manage and share their health information, regardless of where it is stored, digitally and securely with a healthcare provider whenever and wherever they like. See: <https://www.medmij.nl/>

PHEs (under development): Philips VitalHealth's 'MyHealthJourney' (referred to here as 'Philips PHE'), Patients Know Best (PKB) and Vital10. To follow the discussion about and new developments in these PHEs, we made use of academic literature, policy texts, relevant social media and websites, newsletters issued by relevant initiatives, the findings of the workshop 'Digital Health Management for Citizens' in May 2018, and semi-structured interviews with PHE developers and stakeholders involved in the MedMij system.

What do these digital health data services offer? Which parties are involved in developing and using them? What responsibilities do private individuals, healthcare practitioners and PHE developers bear when it comes to sharing data and the insights gained into their own health? What are the benefits according to the stakeholders? We then discuss points of concern associated with real-world data sharing and personal health management.

## 4.1 What are personal health environments for?

A PHE concentrates personal health information that is distributed across multiple locations in a single, central environment, such as an app or website. This allows the user to manage and share his or her health data securely and reliably.<sup>38</sup> The use of PHEs puts patients at the centre of their own healthcare process (Bierma & Heldoorn, 2013).

PHEs are developed by commercial parties. They must ensure that the PHE can also be linked to the EHRs/medical records maintained by the various medical and diagnostic centres and pharmacies, as well as to data that people record or enter themselves, for example using a wearable or an app. Most of these personal data vaults are still under development, some are already in use (such as PKB), while others are expected to be launched early 2019.

A PHE differs from the online portals described in Chapter 2 in five fundamental respects.

1. It collects digital information that is scattered across the records of different healthcare practitioners, from nutritionist to medical specialist to dentist. *'Not only can you view this data, but you can also manage, share and add information to it.'*

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38 Personal health environments (PHEs) are apps and websites used by patients and (healthcare) consumers to collect, manage and share all kinds of health data. A PHE is a lifelong online tool that allows patients to manage their own health data, from treatment to medication, test results and vaccinations. Retrieved from <https://www.patiëntenfederatie.nl/themas/persoonlijke-gezondheidsomgeving/> in May 2018

2. It is not tied to any particular healthcare institution and people can therefore take decisions for themselves.
3. It ensures that everyone has their data to hand at all times and can access that information whenever and wherever they want. People, and not medical professionals, are therefore responsible for their own PHE. The latter are responsible for and obliged to keep a medical record within the institution where they work.<sup>39</sup>
4. It is also the collection point for self-generated health data: a journal, a mood monitor, a running app, a step counter, etc. These data can also be securely and reliably shared with a healthcare provider through the MedMij system, as they may be important for treatment (respondent 15).
5. Once data have been entered into a PHE, users can make good use of them. For example, having a comprehensive list of one's medication makes it possible to check an app for interactions when a new drug is prescribed. Users not only have access to their own data, but can use these data for the benefit of their own health (respondent 15).

PHEs can eliminate duplicate diagnostics or missed diagnoses, for example. Developers and government expect people who have a PHE to participate actively in their own healthcare, and to work proactively on being healthy and avoiding disease, among other things by generating their own health data and by taking decisions about their own healthcare process and health based on these data.

#### **4.1.1 A closer look at PHEs**

Philips VitalHealth's 'MyHealthJourney' (Philips PHE), Vital10 and Patients Know Best (PKB) are three examples of PHEs (under development). As we saw with the online portals in Chapter 2 and the health apps in Chapter 3, different developers accentuate different factors and use different words to describe their PHEs (see Table 4).

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39 Retrieved from <https://www.patientenfederatie.nl/themas/persoonlijke-gezondheidsomgeving/> in May 2018

Table 4 Personal health environments investigated

	Philips VitalHealth PHE	Vital10	Patients Know Best (PKB)
Description	<p>A <b>digital tool</b> that gives you a comprehensive <b>overview</b> of your medical and personal data <b>in a secure environment</b>. You can:</p> <ul style="list-style-type: none"> <li>- upload your own medical data from different healthcare providers.</li> <li>- monitor your own health by linking to smart devices.</li> <li>- decide for yourself which information you want to share with which healthcare provider.</li> <li>- enrol in self-care programmes in which you receive personalised advice and information..<sup>40</sup></li> </ul>	<p>Provides people with an <b>environment</b> in which health-related products and services can be accessed at a discount and encourages them to <b>self-manage</b> their health while also receiving <b>remote guidance</b>. Vital10 helps you to:</p> <ul style="list-style-type: none"> <li>- check and where necessary improve your score on the ten most important health risk factors, considerably reducing the chance of becoming ill.</li> <li>- get healthy and stay healthy.</li> <li>- achieve your health targets thanks to continuous coaching by our e-coaches and e-physicians..<sup>41</sup></li> </ul>	<p>A <b>digital platform</b> that enables patients to <b>manage their own healthcare</b>, a platform that also gives healthcare practitioners a complete overview of everything that matters for the care they deliver to you. Your PC, tablet or smartphone gives you access to all the medical data held by your GP, hospital, pharmacist, social support team and other healthcare practitioners. But you can also add information yourself, either manually or by connecting to an app or wearable device that monitors your vital signs..<sup>42</sup></p>
Main target group	The public and patients	Recovering and/or chronic (heart) patients and health-conscious adults	Chronic and other patients
Status of service	Service is not yet available. Philips VitalHealth has been active in the market for quite some time and PHE functionalities are now being added on and actively tested in the PROVES Programme	Yes, mainly in the BENEFIT research programme. According to Vital10's own report, there are currently 5000 users.	Yes, PKB is in use internationally as a digital health data service and has more than 1.5 million users. There are no user figures for the Netherlands.

The three PHEs are in differing stages of development. Philips PHE is not commercially available yet. Vital10 is currently being offered to people with a higher risk of cardiometabolic disorders (including cardiovascular diseases and diabetes)

40 Based on <https://www.digitalezorggids.nl/product/myhealthjourney>, retrieved 3 October 2018

41 Based on <https://www.vital10.nl/>, retrieved 3 October 2018

42 Based on <https://www.digitalezorggids.nl/product/patients-know-best-pkb>, retrieved 3 October 2018

and to people who use anticoagulants. The service is linked to the Personal Health Check offered by ehealth research institute NIPED<sup>43</sup> and is part of the BENEFIT research programme, funded by the Netherlands Organisation for Health Research and Development (ZonMw) and the Dutch Heart Foundation. This means that Vital10 is being implemented, evaluated and developed as a public-private partnership and has also been registered for MedMij certification. PKB is already in use as a patient platform, for example in the regional rheumatoid arthritis centre RZWN, and thus connects the various healthcare institutions involved in rheumatoid care.<sup>44</sup>

At the time we selected the three PHEs for our study (winter 2017), we looked at the extent to which the digital health data services aimed to make the PHE accessible to a broad public. This means that 'conscious consumers' are the target group and that the PHE does not specifically target a group such as the long-term or chronically ill or a regional population. In October 2018, the three PHEs that we have studied were not classified as such on a healthcare review website set up by the Dutch Patient Federation, the 'Digital Healthcare Guide',<sup>45</sup> although it does refer to Philips PHE and PKB as a 'digital healthcare service'. On its website comparing PHEs, M&I/Partners, an IT consultancy for healthcare and government, refers to all three services as PHEs,<sup>46</sup> but it also uses that label for the three online portals examined in Chapter 2. Although the definition of a PHE provided above is clear, it is in fact far from transparent which developers do or do not offer a PHE as a service. The underlying criteria have not been well defined. Communication with MedMij shows that the selection criteria for the Digital Healthcare Guide are: users can choose their own PHE and create an account for themselves; the PHE is not a service offered by (and operated under the responsibility of) a healthcare provider; and the PHE does not ask for a person's citizen service number (BSN).<sup>47</sup>

At the end of 2017, the PHEs we selected were aiming to develop a PHE for a broad target group, but in reality all three are affiliated to existing healthcare chains. Vital10, for example, is a 'health management service' that can be offered in addition to secondary and primary care and across the public health sector, and that links the public and private worlds (Kraaijenhagen, 2018). It can give a broad

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43 Retrieved from <http://www.persoonlijkegezondheidscheck.nl> in January 2019

44 Retrieved from <http://www.carepoint.nl/laatste-nieuws/carepoint-nederland-b-v-verwelkomt-met-trots-reumazorg-zuid-west-nederland-als-nieuwe-relatie/> in October 2018

45 The Digital Healthcare Guide listed 13 PHEs in March 2018, including PKB. Of these 13, only six are still on the current list (8 October 2018). Of the original list, one PHE has now gone into liquidation (Patient1) and the other six PHEs have been replaced by other software suppliers, i.e. CarenZorgt, Drimpy, Halza, Med2Mob, Quli, and Samen1Plan.

46 Retrieved from <https://www.pgovergelijker.nl/overzicht.html> in October 2018

47 When a healthcare provider offers a PHE for which it is itself responsible, however, it may use citizen service numbers because, legally speaking, it falls within the citizen service number domain. According to MedMij, PHEs are public domain services and should therefore not require users to provide their citizen service number.

target group a better understanding of their health status by quantifying and monitoring ten risk factors. According to its developer, Vital10's most important focus at present is cardiovascular patients during and after cardiac rehabilitation.

#### 4.1.2 PHE functionalities

As with the other digital health data services we have examined, i.e. the online portals and health apps, PHEs offer various functionalities that can be categorised as: information, communication, monitoring, and intervention.

##### Information

The three PHEs indicate that making users' health status and health data transparent is an important part of empowering them to participate actively in their own healthcare or health process. The purpose of the information feature is to provide information about conditions, for example in the form of a medical encyclopaedia, a daily dashboard (Philips PHE & Vital10) or a library (PKB & Vital10), to furnish access to the various healthcare providers' medical records (Philips PHE, Vital10 & PKB), or to chart the user's health status (Vital10 & Philips PHE).

Not only can users receive relevant information themselves, they can also send it to their healthcare providers. The process of receiving and sending information in this way is what the services refer to as 'controlling' one's health data. It is the functionality that the PHE developers are most eager to promote. All three promote themselves by claiming that users are in control, for example because they let individuals decide who has access to their data and because users can administer their own health data records. PKB, for example claims to be the '*world's first patient-controlled medical records system*'.<sup>48</sup>

##### Communication

All three PHEs offer secure messaging services and the option of initiating an online consultation. Philips PHE and PKB will soon also offer the option of linking video conferencing or messaging for telecare interventions to the service. PKB's PHE is aiming to support shared-decision making and informed consent through the platform.

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48 Retrieved from <https://www.skipt.nl/actueel/id30981-medisch-facebook-maakt-opwachting-in-nederland.html> in February 2018

### **Monitoring**

Vital10 emphasises the possibility of monitoring and improving one's health. The service offers guided self-care, as it were. *'Vital10 helps you check and where necessary improve your score on the ten most important health risk factors, considerably reducing the chance of becoming ill.'*<sup>49</sup> By taking an integrated and structured approach to manageable risk factors and setting health targets, Vital10 helps users track their health status and the progress they are making. PHEs such as Philips PHE and Vital10 also aim to work preventively and attract people who are not ill by helping them to monitor general lifestyle factors such as sleep and food consumption. PKB also offers monitoring but lets the physician and patient decide what they wish to monitor.

### **Intervention**

The developers indicate that they are reluctant to offer interventions of their own through the PHEs. Philips PHE in particular indicates that both the healthcare provider, the insurer or third parties are better placed to develop these services. Its PHE offers them a platform for co-creating such interventions and a channel, making it easy to scale up from monitoring to intervention. Philips PHE offers specific tools for collaborating with healthcare providers on developing 'healthcare programmes', for example. Vital10 has a 'remote coaching' option that links the service to other digital devices such as activity trackers (e.g. Fitbit, Apple Watch or Polar Fitness) and heart rate monitors. The idea is that the service will help users achieve their own health goals *'by having continuous guidance from our e-coaches and e-doctors'*. PKB also does not offer its own interventions, but the care plan is an essential element of its PHE. *'A plan describes your medical condition, monitors its progress and makes suggestions about possible actions to be taken'* (PKB, test account, October 2018).

### **Promises regarding participation, personalisation and prevention**

All three PHEs aim to take a personalised approach to meeting users' needs. The developers expect that users will become active in their own health process as a result. The treatment plan (PKB) referred to above, or, as Philips puts it, the 'individual care plan', ensures integration of a patient's multiple self-care programmes and interactions with healthcare practitioners throughout his or her lifetime. PHEs also make it possible to modulate the intensity of the healthcare practitioners' guidance. They create a personalised health programme in which patients themselves can choose the content and self-management tasks or let themselves be advised by healthcare practitioners or e-coaches in that regard (Vital10). A PHE provides the basic structure, i.e. a platform that supports data sharing as well as relevant programmes that help users avoid illness, maintain a

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49 Retrieved from <https://www.vital10.nl/home-2/> in September 2018

healthy lifestyle or manage a chronic condition and support them during periods of illness.

## 4.2 PHEs in context

The section above discussed the promise that PHEs would give people control over their health data and thus allow them to better manage their health and the approach that they take to it. It should be noted that at this stage it is almost impossible to examine the actual use of PHEs in real life. There are no MedMij-certified PHEs yet (as of 30 November 2018) and PHEs that already have users are mostly embedded in research projects.

Section 4.1 described what PHEs do in general and, more specifically, what the three PHEs examined in this study have to offer. This section describes the interests and responsibilities surrounding PHEs, based on empirical research, policy texts, academic literature and online information (Section 4.2.1). This description helps us to identify points of concern associated with PHEs and with their acceptance and use by the public and healthcare professionals (Section 4.2.2).

### 4.2.1 Stakeholders, interests and responsibilities

The three PHEs are all commercial initiatives that have emerged in different ways, and they also serve differing interests.

Philips, a company that has focused on the health market since the 2000s,<sup>50</sup> has developed its 'MyHealthJourney' PHE by launching an internal venture initiative and acquiring the firm of VitalHealth. The PHE is now being marketed as part of Philips VitalHealth and will be added on to the company's 'Engage' product.<sup>51</sup> Philips previously developed various predecessors of its PHE, such as the eCareManager<sup>52</sup> and eCareCoordinator, services aimed at patients and healthcare professionals within healthcare organisations.<sup>53</sup> Like its predecessors, Philips PHE

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50 In 2009, healthcare products and services accounted for 33% of Philips' sales; in 2014, Philips officially prioritised 'health and health care'.

51 Retrieved from <https://www.vitalhealthsoftware.nl/oplossingen/vitalhealth-engage> in January 2019

52 eCareManager is a software platform that facilitates applications for hospital patients. It is designed to ensure that a patient's data are stored in a central location and are transferred with the patient when he or she moves to another unit or ward.

53 eCareCoordinator is a telehealth software platform that allows general practitioners or other healthcare professionals to connect with their patient populations. Linking medical home monitoring devices and self-

will, in the first instance, be embedded into the healthcare setting through the HealthSuite<sup>54</sup> and offer consumers/patients additional services. Philips PHE wants to connect with healthcare providers because HealthSuite can be integrated directly with other services, such as the eCareManager, eCareCoordinator and e-Vita, recently acquired from VitalHealth.<sup>55</sup>

Vital10 is a Dutch health platform that healthcare providers Pinedo and Kraaijenhagen developed in 2016, building on their earlier initiatives, i.e. the online thrombosis service Trombovitaal (2007) and the cardiovascular rehabilitation platform Cardiovitaal (2013).<sup>56</sup> Vital10 is one of the initiators of the BENEFIT Programme ([www.benefitforall.nl](http://www.benefitforall.nl)), a large-scale research project funded by the Dutch Heart Foundation and ZonMW. The Vital10 platform plays a key role in this project, its purpose being to motivate and activate participants by rewarding healthy behaviour. Various hospitals and general practices are involved in the project and offer their patients the Vital10 service under the BENEFIT Programme to support them in changing their behaviour and adopting a healthy lifestyle. Leiden University is heading the research programme and working with academic centres and other public knowledge institutions to study data use, data management and data sharing, factors that will make the programme's implementation successful, and individual lifestyle change.<sup>57</sup> Because they are integrated into healthcare and the associated research programme is subsidised, the PHE and Vital 10's services are covered under health insurance. The aim is to continue developing Vital10 both within and outside the healthcare context.

The third PHE, PKB, is based on an existing concept, the 'personal health record', which was developed and tested in the United Kingdom. In June 2017, the Dutch firm of Carepoint became a sales partner for Patients Know Best in the Netherlands and Germany.<sup>58</sup> PKB has more than six million users in the United Kingdom; 1.2 million of these are active users. This means that Carepoint can build on a tried-and-tested concept and adapt it to the Dutch situation where necessary. It is doing this in cooperation with regional rheumatoid arthritis centre RZWN and other partners.

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reporting in the cloud gives healthcare professionals relevant information about patient populations at their fingertips, says Philips

54 HealthSuite is an open cloud-based platform in which clinical and other data from various devices and sources are collected, correlated and analyzed with each other - <https://www.philips.nl/healthcare/innovatie/healthsuite-digital-platform/>

55 Retrieved from <https://www.vitalhealthsoftware.nl/oplossingen/evita-zelfmanagement-in-de-zorg> in November 2018

56 Retrieved from <https://www.vital10.nl/nieuws/> in November 2018

57 Retrieved from <http://benefitforall.nl/benefit-project/> in November 2018

58 Retrieved from <https://www.skipt.nl/actueel/id30981-medisch-facebook-maakt-opwachting-in-nederland.html> in February 2018

Table 5 Parties involved in PHEs

Parties involved	Philips VitalHealth PHE	Vital10	PKB
Commercial parties	ForCare – acquired by Philips. Providers of lifestyle apps, fitness trackers, etc. Providers of healthcare programmes and content	Siemens Healthineers KPN <sup>59</sup> Providers of lifestyle apps, fitness trackers, etc.	Carepoint supplies hospitals with software for such critical units as OR, IC and A&E and for recordkeeping.
Healthcare providers	not in public domain	Various hospitals (including Tergooi Hospital) and general practices	Reumazorg Zuidwest Nederland (RZWN) Radboud Hospital Nijmegen (under the name CMyLife) <sup>60</sup>
Medical insurers	not in public domain	Achmea CZ	Unknown

Parties involved	Philips VitalHealth PHE	Vital10	PKB
Patient associations	Which ones are unknown, but the predecessor of Philips PHE was tested by patients	Cardiovascular Group Individual experiential experts/patients <sup>61</sup>	Hematon for CMyLife (PKB is the underlying platform)
Research institutes	Unknown	LUMC Leiden University	PKB is being used for research purposes through the RZWN
Other stakeholders	Cooperates with MedMij and VZVZ in the PROVES Programme, <sup>62</sup> which has funding to support development activities	Receives funding from the Dutch Heart Foundation and ZonMW	Unknown, is not receiving funding

Each of the many parties involved in the development and use of PHEs has its own interests and responsibilities (see also Table 5). PHEs are based on the idea of

59 Retrieved from <https://www.skipr.nl/actueel/id32684-kpn-en-vital10-werken-samen-in-hartzorg-op-afstand.html> in November 2018

60 Retrieved from <http://www.carepoint.nl/pgo/> in February 2018

61 We all BENEFIT: The Ecosystem for Healthy Living (2017). From a popular summary of the research project in Dutch.

62 Retrieved from <https://www.linkedin.com/pulse/journey-personal-health-henk-van-houten/> in December 2018

empowering patients, placing them at the centre of healthcare and giving them access to and allowing them to control their health data. The result is a change in the traditional doctor-patient relationship. At the same time, new parties, the developers, become part of that relationship.

### **Patient manages and generates data**

Patients and consumers can upload and download data themselves and take steps in their own health process based on these data. They decide when to trust or mistrust the data or when to involve a healthcare professional. *'In principle, patients are responsible for the devices they use, ranging from a free step counter app on their smartphone to the most advanced Fitbit, Apple Watch or Polar fitness tracker. Some hospitals are planning to make certain devices available free of charge or at a discount.'*<sup>63</sup> This shows that patients are given more responsibility when it comes to managing and sharing data.

People can decide, whether or not in consultation with their healthcare professional or family, which healthcare professionals will have access to which data, including data patients have recorded themselves. One respondent says that *'it's challenging for users, who must be able to maintain an overview, and it's a responsibility too. Is my doctor asking me for access to something that's none of his business?'* (respondent 39). Because individuals need to take a proactive approach, their relationship with healthcare professionals will also change.

### **Healthcare professionals have mixed feelings**

On the one hand, healthcare professionals look forward to the arrival of health data services that will improve data sharing and encourage more participation by patients. With more data becoming available, they can make more informed decisions about treatments and healthcare processes. Data can also be used to study how to improve the quality of care (Federatie Medisch Specialisten, 2017). *'Maybe only 30% will be able to use such an environment for self-management and remote supervision. Even so, this will relieve the burden on the healthcare system, leaving more time for people who can't manage on their own. So it really isn't necessary for everyone to be on board, as long as it's available to everyone who wants it and it takes some of the pressure off the healthcare system'* (respondent 31). PHEs make it possible to organise healthcare more efficiently and to free up time for people who are incapable of participating in their own health process.

On the other hand, healthcare professionals worry about being held liable for using or not using data provided by patients or other parties through the PHE. There is little information available in this regard, and much confusion.<sup>64</sup> Healthcare

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63 Retrieved from <https://www.vital10.nl/artikel-smarthealth-vital10-benefit/> in November 2018

64 Retrieved from <https://www.medmij.nl/veelgestelde-vragen-zorgaanbieders/> in September 2018

professionals also anticipate having to work harder to access the PHE data, and GPs, for example, are afraid that they will suddenly have more people in their waiting room who are puzzled by the results of their hospital blood test. One developer says that, in his experience, these fears are unfounded. He says that the service has helped to reduce the number of visits and calls to doctors and saves time (respondent 27). Nevertheless, it is clear that healthcare providers will also be held responsible for explaining test results, for example, or for offering services themselves.

Healthcare professionals' concerns are intensified because they do not see how using a PHE benefits them directly. In fact, they are expected to do more while not feeling any immediate relief or receiving any financial compensation. *'We ensure that people do not have to show up for face-to-face appointments if they are feeling good. That means we make less money, of course, but I felt it was important to offer patients the service, so we started experimenting and our patients are very happy with it'* (respondent 31). Anxiety regarding liability and the lack of financial compensation may make healthcare professionals less motivated to work with PHEs.

### **Developers share and delegate responsibility**

PHE developers are responsible for three aspects: the accuracy of the data, reliable and secure data processing and sharing, and the quality of any interventions offered.

The liability of PHE providers is explained in user agreements. Philips PHE has not yet placed a user agreement online, unlike Vital10 and PKB. Vital10 says the following: *'You and any Partners are responsible for the accuracy and verification of this information and data and for checking the appropriateness of the (medical) advice and (medical) treatments for your situation'*.<sup>65</sup> Vital10 also states that it is the user who is responsible for ascertaining the accuracy of information and any (medical) interventions offered. This 'user' refers to both the healthcare professional and the patient. PKB also makes patients responsible for any information that they enter themselves.

Privacy notices or privacy policies explain how developers process personal data. Vital10 explicitly takes responsibility for personal data and associates this with its aim of providing the best possible remote care. It explains which data are collected and with whom they are shared and for what purpose. For example, Vital10 shares data with Zorgdoc to log and retrieve the names of the drugs the patient is taking. PKB uses the same approach and emphasises the importance of having the user's

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65 Retrieved from <https://www.vital10.nl/algemene-voorwaarden-deelnemers/> in November 2018

consent to share data. *'Once you have given PKB permission and decided who has access to your data, PKB will use software to search through databases to display your information. You decide how this information will be used. For example if we tell you about a trial, you might decide to participate in it. Your information will not be passed on until you have told us that you want it to be.'*

All three PHEs also coordinate with other commercial parties, such as health app providers. Secure environments can be set up for this purpose, making it impossible to use the link to access a medical record, for example (respondent 48). *'Our company has a responsibility to think about which apps we will integrate with. ...In principle, we only want to integrate with secure apps, but there's a lot of pressure to link to popular apps'* (respondent 39). This differs from the views of the other developers: *'We don't want to position ourselves as an inspection authority for apps and wearables, but we do explicitly show the source of the data'* (respondent 27). This makes clear that the various developers also have different ways of interpreting the responsibility to ensure a secure connection with apps furnished by other (commercial) parties.

As the interviews demonstrate, the issue of who is responsible for interventions offered through a PHE is a touchy one. Developers explicitly state that it is the programme developer who is responsible for the quality of the programme, i.e. the digital intervention. That is generally not the same party that has developed the PHE, but rather the healthcare organisation or a third party, such as an app provider. Philips PHE and Vital10 differ in their approach in this respect. Philips PHE has opted for a step-up / step-down programme linked to HealthSuite in which the Philips PHE represents the lowest level at which people take responsibility for monitoring their own health. As soon as a healthcare professional gets involved, monitoring is scaled up to another HealthSuite service, and the healthcare professional shares responsibility or assumes full responsibility. At Vital10, healthcare professionals are closely involved from the start: *'We are responsible for the PHE and the relevant hospital actually issues a sort of membership to the individual. All the data in the hospital information system belong to the hospital, and the hospital is responsible. All the data that the individual collects in his own system [the Vital10 portal] belongs to the individual, but we bear the responsibility'* (respondent 31).

### **The MedMij Programme**

Although the MedMij Programme is not a stakeholder, it does represent parties that are important in the development of PHEs and their views on reliable and secure data exchange in healthcare. The MedMij Programme, headed by the Dutch Patient Federation, Nictiz centre of expertise for eHealth and the Dutch Ministry of Health, Welfare and Sport, developed a system that lays down the most important

agreements on the organisational and technical parameters within which PHEs must be developed, the financial infrastructure that must form the backbone for this, and further matters. The system ensures the standardised and secure exchange of information (source: Medmij.nl). More about the MedMij Programme can be found in Appendix C, including a description of how PHEs are being tested in so-called controlled go-lives. The system has been transferred from the MedMij Programme to the MedMij Foundation. The MedMij Foundation was established in January 2019 and certifies the PHE suppliers and the healthcare information systems of healthcare providers to which the PHEs are linked in accordance with the rules of the system. MedMij also monitors compliance with this quality mark.<sup>66</sup>

### Creating a market for PHEs

The Rathenau Instituut's previous report, *Responsible digital health management* (Niezen & Verhoef, 2018), observes that the MedMij model is a market model that reflects the political decision not to set up a national infrastructure. As it turns out, it is not that easy to get this market off the ground and that is why government is offering financial incentives as an extra stimulus. In addition to the earlier MedMij funding and the VIPP schemes,<sup>67</sup> the Ministry of Health, Welfare and Sport has now taken steps to drive the actual development of PHEs in accordance with the MedMij Trust Framework.

Among the financial incentives supporting this market are the following:

1. Administration of MedMij €4.1 million (as of May 2018)
2. The various schemes under the 'Accelerated Patient and Professional Information Exchange Programme' (VIPP):
  - a. VIPP: €105 million for the 2017-2019 period<sup>68</sup>
  - b. Follow-up VIPP within the Framework Agreement on medical-specialist care: an annual €25 million for the 2020-2022 period
  - c. VIPP for mental health and addiction care: €25.7 million.<sup>69</sup>
  - d. VIPP Care: €30 million.<sup>70</sup>

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66 Retrieved from <https://www.medmij.nl/artikel/ronald-gorter-voorzitter-stichting-medmij-theo-hooghiemstra-expert-bestuurder/>, and [https://afsprakenstelsel.medmij.nl/display/PUBLIC/Inrichting in January 2019](https://afsprakenstelsel.medmij.nl/display/PUBLIC/Inrichting+in+January+2019)

67 The VIPP schemes have broader objectives than promoting PHEs, but they do make a significant contribution to this aim. For example, one of the stated objectives of VIPP is the following: On 31 December 2019, every healthcare institution will have a secure patient portal and/or a link to a Personal Health Environment in which the healthcare institution can upload standardised medical data for the patient'; see: <https://www.vipp-programma.nl/over-vipp/doelstellingen>.

68 See Rijksbegroting 2019 XVI Volksgezondheid, Welzijn en Sport.

69 Idem plus extra funding, see: <https://www.vippggz.nl/action/news/item/504/VWS%20stelt%20extra%20geld%20ter%20beschikking%20voor%20VIPP%20GGZ.html?showDate=1&showImage=0&showRelatedItems=1>

70 Idem

- e. VIPP for Independent Clinics in the Netherlands: €32.5 million.<sup>71</sup>
- 3. OPEN Programme (accessibility of patient data in primary care in the Netherlands): €75 million.<sup>72</sup>
- 4. Financial Incentive Scheme for PHE suppliers 2018-2021: €4 million.<sup>73</sup>
- 5. The Ministry of Health, Welfare and Sport is also expected to announce in the first quarter of 2019 that for the 2019-2021 period it will offer PHEs financial compensation for each demonstrable active user (in other words, mutual use by both the individual and the healthcare practitioner).

The financial incentive for PHEs aims to create a market for them that allows people to take charge of their health data and thus to be actively involved in their health. According to a report by Gupta Strategists that was commissioned by MedMij, it is likely that the majority of Dutch people will be using a PHE within ten years. It should be noted that this is contingent on there being PHEs that meet people's needs and requirements and that 'communicate' quickly and easily. While Gupta Strategists ideally sees a market for approximately nine PHE suppliers, at least 25 are currently seeking to call themselves a MedMij-certified PHE (Gupta Strategists, 2017).

#### 4.2.2 Points of concern for integrating PHEs

In our previous report *Responsible digital health management*, we noted that there are still a number of technical, organisational, legal and financial obstacles to overcome before PHEs can be broadly implemented in healthcare practice, and before data sharing within the healthcare sector, online access and specified consent for sharing data with third parties can be streamlined.<sup>74</sup> Our empirical research into the three PHEs confirms this and makes clear that there are still hurdles to be taken between policymaking and the actual development and implementation of PHEs in healthcare settings.

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71 Retrieved from <https://www.zkn.nl/nieuws/vws-stelt-subsidie-beschikbaar-aan-uw-kliniek-voor-ontsluiten-digitale-informatie/342> in January 2019

72 Retrieved from <https://www.open-eerstelij.nl/> in January 2019

73 Suppliers could apply for this grant, called the 'Incentive funding grant scheme for PHE suppliers 2018-2021', in August 2018. It was published in the Government Gazette on 12 July 2018. The scheme made a total of €4 million available. A total of 61 suppliers applied, with the first 25 suppliers that submitted their application on 1 August 2018 actually receiving a grant of €160,000. Within an hour, all the grant money had been distributed.

74 As from July 2020, individuals will be able to state digitally which healthcare providers are permitted to make which types of data available to certain occupational groups. Specified consent is a further interpretation of specific consent. Specific consent is laid down in the Dutch General Data Protection Regulation implementation act and entails that it must be clear for patients for which processing, of which data, for what purpose the healthcare provider requests permission. With specified consent, as laid down in the Act Supplementary Provisions for the Processing of Personal Data in Healthcare the patient must also be given the opportunity to specify or distinguish which data can be provided to which healthcare provider or categories of healthcare providers. It is important to note that patients will not be obliged to consent to their medical data being shared electronically with other healthcare practitioners.

### Proper identification is a strict requirement

The main technical obstacle, according to both Philips PHE and PKB, is the absence of a good method of identification and authentication. DigiD, the Dutch government's system for electronic identity (eID) authentication, is not advanced enough to permit 'automatic' data sharing between patients and healthcare practitioners. Each and every session involving a particular medical record or app requires a login, and that is not at all user-friendly. According to Philips PHE and PKB, having a properly functioning system of identification and authentication is a strict requirement for user-friendliness. As a participant in the PROVES Programme, Philips PHE is actively seeking alternatives, but it is also looking forward to advances in eID. Progress in the healthcare sector depends on broader progress being made in digitalising public services. PKB claims to have a two-pronged strategy: 1) PKB in compliance with the MedMij System, 2) PKB in compliance with the MedMij System but without the obstructive aspects of MedMij, including a user-friendly login and more focus on the professional.

### MedMij plug unfinished

To ensure the successful implementation of PHEs under the MedMij Programme, the developers must first solve the biggest technical issue: to create a 'plug' to MedMij from the healthcare providers' own healthcare information systems (XIS). XIS suppliers are lagging behind PHE developers in building the required gateways and standards (respondent 16). The involvement of Chipsoft's Zorgplatform in the PROVES Programme is important to MedMij: *'...because this potentially means that patients can receive health information from more than 65% of Dutch hospitals in their PHE'*.<sup>75</sup> According to reports from MedMij, it recently became clear that these plugs are also technically possible within the PROVES test environment.<sup>76</sup>

In an article in *ICT&Health*, Ruud Kluivers of Liferay Benelux is less optimistic than, for example, the Dutch Minister for Medical Care Bruno Bruins recently was with regard to the timely implementation of PHEs. According to Kluivers, the existing systems and even new apps are still generating too many data silos, making it impossible to access data from them. We cannot continue linking systems indefinitely (via APIs), Kluivers says, because that would be detrimental to user-friendliness (Kluivers, 2018).

In addition to technical challenges, there are also organisational issues. How do you schedule the necessary appointments when patients relay their home health monitoring outcomes to their doctors through a PHE? How can data from different healthcare practitioners be combined and presented to healthcare consumers when

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75 Retrieved from <https://www.medmij.nl/artikel/chipsoft-doet-mee-aan-praktijkproef-medmij/> in September 2018

76 Retrieved from <https://www.medmij.nl/artikel/chipsoft-reinier-de-graaf-en-pgos-boeken-samen-medmij-succes/> in January 2019

there is no uniform language and when healthcare is organised differently from one region to the next?

### **Regional approach preferable**

Discussions with Philips PHE, Vital10 and PKB reveal that the current approach is seemingly not to immediately link all healthcare providers in the Netherlands to the system, but to start with a number of healthcare providers and suppliers within a single region. The developers say that they prefer the regional approach because it makes both the technical hurdles, such as those mentioned above, and the organisational hurdles, which require extensive consultation and changes to healthcare practices, manageable. One of the developers we spoke to also says that *'[t]he institutions we are talking to all have their own policy preferences. Trying to cater for all PHEs would be detrimental to the quality of the service'* (respondent 27). PHE developers are considering how they can connect technically at three levels: at the national level with the National Health Data Switchboard; at the regional level with the RSOs (regional cooperative organisations)<sup>77</sup>; and with the organisations that supply healthcare information systems to healthcare providers. The test environments facilitated by the MedMij Support Programme also show that a regional approach is preferable (respondent 16).

### **Legal frameworks incentivise but do not protect the public**

Legislation (the GDPR, the Processing of Personal Data in Healthcare (Additional Provisions) Act or Wabvpz, and the Medical Treatment Contracts Act or WGBO) offer important incentives for the emergence of PHEs.<sup>78</sup> The Dutch government believes that PHEs represent a key technical remedy for complying with the rules governing data portability within the healthcare sector, online access and specified consent. However, there is less concern about data sharing outside the healthcare sector, which is also facilitated by the arrival of PHEs. There are still no *'proper safeguards to protect individuals against abuse, such as the unauthorised access to or sale of health data'* (Hooghiemstra, 2018, p. 169). This means that the PHE developers have the power to ensure that control over the data rests with the public.

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77 An RSO is a regional cooperative organisation that is mandated by regional healthcare providers to coordinate communication and data sharing and in doing so enhances cooperation in healthcare. Source: RSO Nederland, retrieved from <https://www.rsonl.nl/> in December 2018

78 PHEs make the GDPR and the individual's right to access and share data (data portability) technically possible. The WABVPZ, which came into effect on 1 July 2017, complements the GDPR (data portability) and the WGBO. Under this act, citizens must be able to view their record online by 1 July 2020. They must also be able to give specified consent as to which data may be viewed by which healthcare providers. The 'General administrative regulation with regard to the electronic exchange of data between healthcare providers' is an addendum to the WABVPZ and concerns the use of the citizen service number (BSN) and the Dutch NEN standards that apply to information security (NEN 7510). These laws and regulatory schemes have accelerated the introduction of personal health environments.

### Questionable sustainability of PHE revenue models

The Financial Incentive Scheme meant to support the development of MedMij-certified PHEs by 1 November 2019 has overcome an important technical and organisational hurdle.<sup>79</sup> According to the developers, however, there are other obstacles to the ongoing development of PHEs, such as the search for a sustainable revenue model. They say that the revenue model for a PHE that can be accessed by a broad public is unprofitable in the start-up phase. Rheumatoid arthritis and other chronic patients are more likely to use a PHE than conscious consumers. One PHE that is clearly seeking out 'ordinary' consumers is Drimpy.<sup>80</sup> Drimpy is currently offering consumers a free account or a premium account for €2/month. The Drimpy platform is based on an international research project that receives EU funding.<sup>81</sup>

Each of the three PHEs investigated in this report is taking its own approach to the health market. The people at Philips believe that we should be building on the reports by Gupta Strategists (Gupta Strategists, 2017), which place government funding at the centre and see development in co-creation with healthcare practitioners as an important factor. After all, the developer says, *'It would be a shame if access to the PHE was limited to "premium payers"'* (respondent 39). If financial barriers prevent universal access to a PHE, the result would be unequal access to care, according to this developer. That is why healthcare insurers should reserve a budget for PHEs, something confirmed by the participants in our workshop *Digital Health Management for the Public* (Rathenau Instituut, The Hague, 30 May 2018).

Vital10 positions itself as a personal health portal that offers discounted access to (third-party) products and services. In that respect, it is the very core of the BENEFIT Programme, which is attempting to build an ecosystem for healthy living. The research programme finances users' connection to the BENEFIT Programme (a grant of €2,499,426). After the research phase, BENEFIT must continue on its own. The cooperating developers, researchers and physicians want the health insurers of participating cardiovascular patients to cover the cost of the programme. Because financing of this kind is not sufficiently future-proof, as it depends too heavily on insurance coverage, Vital10 works with other parties through a reward system. Users can earn points and receive discounts on various products marketed by affiliated parties. *'Under this model, you charge a commission on the discounts to keep the portal up and running'* (respondent 31). But Professor Evers, BENEFIT's project coordinator, hopes that eventually, people will be prepared to pay out of pocket to

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79 Retrieved from <https://www.skipt.nl/actueel/id35234-vws-trekt-4-miljoen-uit-voor-doorontwikkeling-pgo.html> in August 2018

80 Retrieved from <https://www.drimpy.com/> in November 2018

81 Retrieved from <https://www.ManyMy.eu> in November 2018

join the programme. She draws parallels with paying for a fitness club membership. *'BENEFIT not only gives them customised fitness exercises but also provides dietary and lifestyle tips and monitors important vital functions.'* While the programme currently focuses on cardiovascular patients, it could one day be helpful for people with high blood pressure or who have or are at risk of diabetes.<sup>82</sup> *'For now, any broader scaling-up is hampered by the absence of insurance coverage for implementation outside existing healthcare chains'* (respondent 31).

PKB aligns itself as much as possible with regional trends and online environments. The larger the number of connected users in a region, the cheaper PKB is for the healthcare providers that offer the PHE to their patients. The founder of UK-based PKB, Al-Ubaydli, identifies the system's comprehensive functionality for patients and healthcare practitioners as an important aspect of the revenue model. At the same time, Al-Ubaydli advocates *'structural financing by government and health insurers. After all, they have the biggest financial stake. Subsidies should be limited.'*<sup>83</sup> PKB sales partner Carepoint also operates on the basis of a regional approach, with patients being channelled through healthcare providers. The consent form says that *'PKB is paid by organisations such as your hospital, healthcare service or local practice. PKB will continue to serve you, the patient, even if we no longer have a contract with the organisation through which you originally registered'*. In a presentation, Carepoint claims that for every euro spent on PKB, the payer saves €5.<sup>84</sup> Because all data are stored at PKB, record continuity can be guaranteed. According to PKB, that is why it is important to sell its service to regional healthcare cooperatives and not to individual healthcare providers.

### **Trust in the service as a success factor**

Because developers regard the service (and not the data) as the most important product, they see trust as a critical factor for successful implementation. Consequently, all of the PHE suppliers are deeply concerned about data protection and data security, end-to-end encryption, privacy by default and (cyber)security as components of trust. In addition, most developers also provide access to a log history and require consent from users to share data. This underscores the importance of trust and shows that trust can be earned not only by guaranteeing proper data security and data protection, but also by presenting data in a comprehensible manner, by ensuring that the service is user-friendly, and by clarifying what happens to the user's information and where that information is stored.

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82 Retrieved from <https://www.vital10.nl/artikel-smarthealth-vital10-benefit/> in November 2018

83 Retrieved from <https://www.ictmagazine.nl/uitgelicht/arts-en-patient-ontwikkelden-pgo-en-dat-werd-een-succes/> in October 2018

84 Carepoint presentation, 15 May 2018, Eindhoven, RZCC Meet-up

### **International services**

Promoting the use of PHEs also means opening the door wide to international parties. Evidence for this can be found in the applications for the MedMij Financial Incentive Scheme submitted by health data services not based in the Netherlands. PKB and Philips PHE also have an international dimension. In addition, changes in legislation and regulatory schemes mean that health insurers across Europe are increasingly covering treatment abroad. Sound information sharing at European level is a key issue on the EU policy agenda. Some respondents expect that the involvement of international, and in some cases, large-scale parties will challenge the long-term sustainability of the MedMij agreements in a sector that is rapidly globalising (respondents 25 & 39).

## **4.3 PHEs and personal health management**

This section analyses how PHEs help people manage their health, especially when it comes to sharing their data.

### **4.3.1 Independence in decision-making**

Personal health management largely concerns decisions that people take about their health. It is up to individuals to decide whether or not to use a PHE; they are not obliged to do so.

#### **PHEs usually offered by healthcare professionals**

Ideally, it should be up to patients to choose which PHE they will use to communicate with their healthcare practitioners and to share health data. However, during the development phase, most PHE providers opt to approach users through their healthcare providers. Once a PHE is embedded within a regional system, it is obvious that healthcare professionals will recommend it to their patients in the region. In other words, the healthcare professional plays a crucial role in the PHE proposition. This point is confirmed by PKB founder Al-Ubaydli, who says that one of the key success factors is to limit a patient's choice to two or three PHEs, *'so that the healthcare provider can focus and offer real added value... Only then will a doctor encourage patients to use a PHE'*.<sup>85</sup> Of course, there are also developers who choose to make their PHE broadly accessible, in other words to offer it directly to users.

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85 Retrieved from <https://www.ictmagazine.nl/uitgelicht/arts-en-patient-ontwikkelden-pgo-en-dat-werd-een-succes/> in October 2018

### **Certification**

Available sources such as the Digital Healthcare Guide and M&I/Partners' comparison website do not list the same PHEs; there is, as yet, no comprehensive, authoritative overview, in other words. Moreover, not all suppliers of PHEs (under development) report that their aim is to offer a PHE in the near future. In other words, there is also no list of PHEs that are being developed in accordance with the MedMij agreements and that are official MedMij candidates. By way of explanation, MedMij says that some suppliers do not want to reveal their progress to their competitors. However, for people to be able to choose between different PHEs, they will need a proper overview of the existing services and the functionalities that they offer. As soon as MedMij starts certifying PHEs, the Digital Healthcare Guide intends to publish a consumer guide (respondent 15).

MedMij will in fact be certifying the first set of PHEs soon, and MedMij's Financial Incentive Scheme has been instrumental in driving this forward. Certification will help the public to identify reliable PHEs, particularly in terms of data security and data protection. As more than 50 applications have been submitted for the Financial Incentive Scheme, 25 of which have been accepted, we are likely to see a considerable number of PHEs, especially since major market parties that did not qualify for the Financial Incentive Scheme, such as Nedap Healthcare, continue to target the PHE market.<sup>86</sup> Certification will not say anything about the quality of the service or any advice it may provide. It will also not identify the most suitable target groups for a PHE. This is notable, given that some PHEs have been developed specifically for chronic patients.

### **PHE developer selects complementary app connections**

People not only choose a PHE but also the healthcare programmes and apps they want to connect to it. The experience of Zelfzorg Ondersteund, a support platform for personal health management, shows that offering a database as a service, as a data management environment, is a good start but that the real added value of a health data service lies in the perceived ease of communicating, getting repeat prescriptions filled and integrating disease-specific modules, for example (respondent 17). Not all health apps are connected to the PHEs that we studied, but users can ask the developer to create the necessary connection. PKB connects to some 100 apps and devices, ranging from Apple Health to YOO.<sup>87</sup> In selecting apps, Vital10 looks at '*which apps store the data in the Netherlands/Europe and not, for example, in the USA*' (respondent 31), as this makes it easier to comply with the GDPR. According to its developer, Philips PHE takes informed decisions about which apps it may or may not integrate, based on such factors as being able

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86 Retrieved from [https://www.telegraaf.nl/financieel/2399735/zorgapp-van-nedap-wil-de-grootste-woorden?utm\\_source=google&utm\\_medium=organic](https://www.telegraaf.nl/financieel/2399735/zorgapp-van-nedap-wil-de-grootste-woorden?utm_source=google&utm_medium=organic) in October 2018

87 Retrieved from <http://www.carepoint.nl/pgo/> in February 2018

to guarantee satisfactory service and data portability. *'Fitbit, Nokia, Jawbone and MyFitnessPal all unlock data in different ways, and I'm only mentioning a few. There's no standard. [...] And all the different integrations are costly and take time. You also have to be able to guarantee and maintain the service itself. It's not easy. It takes a lot of effort'* (respondent 39). When health apps switch APIs<sup>88</sup> – the socket that the various programmes can 'plug' into – without warning the PHE suppliers, customers will complain about system malfunctions.

### Personalising options

The design of the user interface also partly determines which options are available to PHE users. The various PHEs use algorithms to meet users' needs. The algorithms identify 'good suggestions'. That is the case with the Philips PHE user interface, which adapts to the user's personal healthcare plan by pre-selecting the programmes the user is offered (respondent 39). Vital10 also says that using algorithms to analyse data makes it possible to offer personal advice. *'Algorithms structure, integrate and interpret all the data on the Vital10 server, after which the PHE offers the user personal feedback with customised advice.'*<sup>89</sup>

At the same time, all three PHEs stress the importance of talking to healthcare practitioners and family members about using the service and any additional apps and programmes, especially when it comes to selecting appropriate apps and sharing data (see also the following section). Users are not entirely independent in their decision making, then; their decisions depend on the underlying algorithms of the service and on their own network of healthcare practitioners and family members.

### 4.3.2 Control over data

PHEs' main promise to patients is that they themselves will be in charge of their data. *'The health consumer is the only constant throughout the health continuum, having the right and motivation to own a copy of the data, and providing consent to use the data.'* (presentation by Philips)<sup>90</sup> According to PHE suppliers, by storing data themselves, people avoid the risk of losing 'important' data about their own health. Medical data are generally deleted from systems after fifteen years. *'Even stored data and images of yourself as an embryo in the womb can be useful.'* They may turn out to be crucial later (respondent 39). The implication is that people are regarded as data brokers when it comes to their own health.

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88 An application programming interface (API) is a set of definitions that allows computer software to communicate with another program or component (usually in the form of libraries).

89 Pinedo & Kraaijenhaagen (2017), presentation at stakeholder meeting in Amstelveen

**Removing data**

PHEs allow us to collect data in a single digital environment, but it is not as easy to remove data, as our interviews revealed. The PHEs that we investigated offer limited support for people who want to delete inaccurate data from their records or who do not wish to be 'pursued' by certain information in their ongoing healthcare processes. Only data that they have added themselves, such as home health monitoring data, can be edited or hidden. Data entered into the various medical records remain the responsibility of the relevant healthcare practitioners (as established in the WGBO) and cannot be edited or hidden. To make any changes to such data, the individual must submit an official request to the relevant healthcare practitioner or healthcare institution. So far, the PHEs have no official functionality for requesting such changes.

**The data we collect is pre-programmed**

The type of PHE that we choose (see Section 4.3.1) largely determines the type of data we can share as individuals. The data categories are often pre-programmed within the PHE. For example, in PKB data are divided into four components: general health (e.g. diabetes), sexual health (e.g. sexually transmitted diseases), mental health (e.g. depression), and social wellbeing (e.g. going to an activity centre). Vital10's data selection is determined mainly by the ten manageable and quantifiable risk factors that are central to this digital portal.

**The user decides who sees what**

The PHE's user decides with whom to share which data. He or she decides which type of data to share with which category of healthcare practitioner and which family members. See, for example, PKB (Figure 2).

Figure 2 Sharing data from PKB

**Welkom Bea de Bruin**

Bericht verzenden 

Professional uitnodigen 

Start een consult 

	Normaal	Mild	Matig	Ernstig
Hoesten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Kortademigheid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Opslaan



Gebeurtenissen en berichten →



Gezondheid ▼



Behandelingen ▼



Logboek ▼



Bestanden →



Apparaten →



Delen ▼

An access log – a digital logging mechanism required by NEN 7513 – shows who has viewed the record, when they have viewed it, which data they have viewed, and what permissions they have. An orthopaedic doctor would view other data than an oncological nurse, for example.

### Difficult to arrange push messages to healthcare practitioners

The healthcare sector is adopting a growing number of standards for sharing health data and for giving patients online access to their own medical records, as the Nictiz list reveals.<sup>90</sup> There are also standards laying down a uniform language and specifying which data must be entered at which location and under what name (Van Gool et al. 2018). How PHEs share data with physicians is much less clear, however. The question is to what extent data that users have collected or recorded themselves can easily be shared with the systems of healthcare professionals. It turns out that this can often be difficult to do, even under the MedMij agreements.

90 Retrieved from <https://www.nictiz.nl/overzicht-standaarden/> in December 2018

**No data sharing without consent**

Our study has not revealed any indications that PHE suppliers are selling data. Yet, a study by Zang et al. (2015), shows that some health apps and other services may have data sharing with third parties as their core business. What we do see is that many PHE suppliers choose to cooperate with researchers during the development process. After users issue 'informed consent', their data are passed on for research purposes. In many cases, the aim of such cooperation is to improve the quality of care, but also to make the PHE more responsive to the needs of users. It is a legal requirement to provide feedback on these data, but it was not always clear in our study whether and how that occurred.

**Open door for third parties**

The fact that individuals can now access and provide access to their own health data through a PHE is also interesting to third parties such as local authorities and commercial services. Because private persons are not subject to a professional duty to maintain medical confidentiality, they can choose to share their data with third parties. The user agreements explicitly state that they themselves are responsible for deciding with whom they will share their data. The Rathenau Instituut has noted that several different factors – i.e. the creation of networks between systems, the ability to 'hook up' apps and platforms to PHEs, and the ease with which data can be downloaded from a person's own medical record – have opened the door to data sharing both within and outside the healthcare sector.

According to suppliers, responsible decision-making about data sharing requires consultation between patients and their medical professionals, but the healthcare sector has made very few arrangements in this respect. Who should start the conversation? When? What should the patient and professional discuss? These are questions to which we have few answers as yet, and each healthcare context will require a different approach. Neonatology, geriatric care and oncology all raise their own concerns and questions. At the same time, the expectation is that PHEs will focus explicitly on *non-patients (as yet)* and *former* patients, making consultation with healthcare professionals harder by definition. People who are not under a healthcare practitioner's care but who want control over their data will have to arrange a consultation in some other way. This study shows that while PHEs do make individuals aware of their responsibilities with regard to data sharing, they do little to support responsible decision-making by individuals.

### 4.3.3 Influencing healthy behaviour and health

PHEs are primarily data management tools or personal data vaults. In this section we ask to what extent PHEs also give users the tools they need to improve their health and adopt healthy habits.

#### Encouraging healthy behaviour

The starting point for most PHEs is a distinct need on the part of a patient group, usually chronic patients. For example, the PHE supplier Curavista markets a burden of disease calculator for COPD patients. Chronic patients are a logical target group because they often invest considerable time and energy in their own care and therefore need a tool that keeps track of the course of their illness, the drugs they are taking and their appointments with healthcare practitioners. Better disease management for chronic patients has many positive implications for the healthcare system. This study has shown, however, that the real aim of PHEs is to use data to promote healthy behaviour and sickness prevention, although there are, as yet, virtually no PHEs that are useful to everyone, regardless of illness or age.

PHEs try to motivate healthier behaviour through a bonus system or insurance points, for example based on meal match recipes. Good behaviour is encouraged and rewarded. Once people have begun using a PHE, developers also try to retain them as users by awarding them points for turning up for appointments or for achieving weight loss or activity targets. Users can cash in these points to purchase products at reduced prices from affiliated partners, such as a fitness club offering a discount on membership.

#### Quantified health

PHEs take quantifiable parameters as a basis for assessing a user's healthy (or unhealthy) behaviour or health status. Blood pressure, blood count, weight, BMI, lung capacity, heart rate, etc. are all converted into figures, graphs and indicators, giving users an idea of how healthy they are. PHEs also use journals or questionnaires to reveal how users interpret this information and how they themselves rate the quality of their lives. For example, they may ask a user *'How much pain are you experiencing, on a scale of 0 to 10?'*

Research shows that this approach can help improve people's health and encourage healthy behaviour (Morton et al., 2017). At the same time, authors such as Lupton (2013) and Prainsack (2017) also point out that quantifying the human concept of disease and health in this way makes us more likely to be preoccupied with our illness or with the possibility of becoming sick. Whereas most PHEs operate on the premise that prevention is better than cure, the fact of the matter is that using PHEs could lead to medicalisation. People may be more inclined to

consult a healthcare practitioner if they believe they have a higher risk of a disease or condition based on measurements of their vital signs. They may, for example, want to discuss the outcome of their latest cardio workout at the gym, especially if it deviates from the norm.

We have noted yet another trend: indicators that used to lead to a person being admitted to a medical care process are now referred to as 'lifestyle issues'. Lucivero and Prainsack (2015) call this 'lifestylisation', *'in which treatments are not only personalised to the person's genetic makeup but also to the individual's lifestyle'*. People with health problems are expected to work on various quantifiable lifestyle factors in their own environment. 'Lifestyle medicine' is one of the outcomes. The healthy self is a quantified self.

### **Prevention and profiling**

Our analysis of the information surveyed in this study shows that PHEs generally operate according to the principle that 'an ounce of prevention is worth a tonne of cure'. All three services use data collected from their users to personalise the information, interpretations and other products that they offer. The developers of Philips PHE believe that health forecasting and population research will be possible in the longer term. Not only does profiling users make it possible to personalise the service, but combining the data of all users can also improve health forecasting at regional and national level.

Not all health forecasts can be explained by the use of self-learning algorithms (machine learning). We hope that PHE developers will ask themselves some critical questions, for example: Is my dataset biased? How do I avoid bias? How do I avoid bad decisions or the exclusion of certain population groups? As this study shows, however, so far no one is monitoring the use of artificial intelligence within and through PHEs.

Many PHE developers, government officials and healthcare professionals see tremendous potential in giving researchers access to anonymised health data. PHEs ask their users to participate in research, with developers telling them that their participation is important not for their own health but for the health of us all. The PHEs clarify their participation in research in their user agreements and on their websites. The outcomes can help the developers make the PHE and the advice it offers more reliable. Participation in research is also an expression of solidarity with others because it contributes to better public health and better treatments.

## 4.4 PHEs summarised

PHEs are meant to form the backbone of a secure, user-friendly system within the healthcare sector that allows healthcare professionals to share data, provides users (both patients and non-patients) with online access and makes it possible for them to grant specified consent to share their healthcare data within and outside the sector. Individuals will, in time, store all their health data in their personal data vault. In our 2018 report, we pointed out some technical and organisational hurdles that needed to be overcome before the system could be put to widespread use. Our present study of three PHEs confirms this earlier conclusion.

Of the three PHEs that we have studied, PKB is already in use and Vital10 and Philips PHE are being used in research and in test environments. All three PHEs prefer to operate regionally and to approach users through their healthcare providers. They differ in character and in their target groups: Philips PHE has the broadest target group (the healthcare consumer) but approaches them through their healthcare providers, whereas Vital10 has the most specific target group: chronic cardiovascular patients. PHEs in fact seem to be most effective among such specific target groups. This report concludes that we should encourage the use of PHEs among specific target groups at regional level. Step-by-step progress, with due consideration for data protection and data quality, will help build the public's trust in these services. As with the other services covered earlier in this report, one point of concern is the accidental or unwitting sharing of highly sensitive data with insurers, authorities, banks or other commercial parties, which could have a far-reaching impact on a user's private life, for example his or her ability to take out a mortgage or qualify for a benefit.

The number of PHEs is expected to be in excess of market capacity and demand among healthcare providers. An independent list of available and certified PHEs and their functionalities will allow users and healthcare providers to make an informed choice between them. No such list exists as yet. Both healthcare providers and the public must be able to base their decision on sound information.

## 5 Public platforms: collective data management

The public has itself also started to organise services and infrastructures for storing and sharing health data. This chapter describes initiatives in which private individuals are actively involved in developing such services. We discuss two examples from abroad: the Patients Like Me (PLM) network and the MIDATA data cooperative. The third example is a Dutch initiative that is still under development: Holland Health Data Cooperation (HHDC). All three fit in with a trend in which people do their own research, consult one another and wish to share their data securely in pursuit of a common purpose.

Over the past few years, digitalisation has given people new ways to collect data about their own health in the interests of research ('citizen science'). The Quantified Self movement can be regarded as an extreme form of citizen science (Haklay, 2013). Participants in this movement collect data about their own bodies and their daily activity and carry out small (N=1) research projects. The data that they collect about themselves are also valuable to others, giving rise to the Quantified Us movement (Ajana, 2017). Researchers, for example, can make good use of such shared individual data.

The rise of social media has made it possible for patients to seek one another out and share stories on special digital patient networks, such as Patients Like Me (PLM), or on social media designed for a completely different purpose, such as Facebook. There is also the 'data commons' movement, which views personal data not as personal property but as a public good. This philosophy has led to 'data cooperatives' such as MIDATA.

Who is involved in digital patient networks and data cooperatives, and what interests are at stake? What is the connection between these platforms and trends in accessing and sharing medical data? What practical issues have arisen? How is responsibility apportioned between private individuals, patients and healthcare practitioners? What are the benefits according to stakeholders? We have based our answers on academic literature, websites, blogs, relevant social media and interviews. We also list various points of concern regarding the real-life use of public platforms and what that use entails for personal health management.

## 5.1 Public data-sharing initiatives and what they do

The PLM network and MIDATA cooperative are both health data sharing services established by the public. Both promise that members will be better able to manage their health. In this section we describe how the two services are organised, how they function and what they promise. See also Table 6.

Table 6 Public platforms investigated

	Patients Like Me	MIDATA
Description	<p>Commercial service that allows patients to store and organise their own data (hospital admissions, laboratory results, symptoms and treatments) and to learn from the experience of other patients. Using the 'DigitalMe' feature, members can have free blood tests every few months to check RNA, DNA, proteins, antibodies, the microbiome and metabolites in order to build a 'digital version' of themselves. The data are sold to third parties, such as pharmaceutical companies.</p> <p><a href="https://www.patientslikeme.com/">https://www.patientslikeme.com/</a></p>	<p>Service for storing and sharing health data provided by the Swiss data cooperative MIDATA.coop. The data cooperative provides access through the MIDATA portal to various third-party apps; these parties then use the data for their own purposes. Some apps use visualisation tools to explain the data to the user. Apps can also put users in touch with other parties. Members can contribute to research into new treatments.</p> <p>If a research group wants to access MIDATA data, the cooperative's board and ethics committee first reviews the quality and ethical aspects of the application. The board and committee are appointed by the members of the cooperative (sometimes indirectly).</p> <p><a href="https://www.midata.coop/">https://www.midata.coop/</a></p>
Primary users	Patients who have a range of chronic disorders.	Swiss citizens, some of them chronic patients, who are interested in wellbeing and health.
Status of service	Used by ALS patients since 2004. Since 2011, it has functioned as a large, international platform with 600,000 members who have a variety of different chronic conditions.	So far only available to residents of Switzerland. There are plans to expand the service internationally.

### 5.1.1 A closer look at PLM and MIDATA

#### Patients Like Me

Patients Like Me is, briefly, a large-scale service based on a commercial revenue model. In exchange for their data, people are better able to manage their health because the service organises their information for them and because they can learn from the experience of others. PLM describes itself as '*a health information sharing website for patients*'.<sup>91</sup> This description also makes certain promises: patients should be able to find detailed information about every drug, supplement or device used to treat patients 'like them' to explore effective remedies, connect easily with others who have the same condition, and learn from patients 'like them'.

PLM was set up in the United States in 2004 by Jamie and Ben Heywood, who were seeking more information about Amyotrophic Lateral Sclerosis (ALS) after their brother Stephen was diagnosed with the condition. In 2011, they made their website accessible to any patient living with any condition.<sup>92</sup> By now, PLM has grown into a huge international network of 600,000 members living with a wide variety of conditions, with approximately 1500 public profiles from the Netherlands. PLM has become a commercial enterprise, a '*for-profit company with a not-just-for-profit attitude*'. It has a patients-only Team of Advisors that collaborates with the company on new research and product development and advocates on behalf of patients to industry and PLM's partners.<sup>93</sup>

#### MIDATA

MIDATA says it focuses on empowering people to manage their health and control their personal data. It is a data-sharing service run by the **Swiss data cooperative** MIDATA.coop. The cooperative was founded in 2015 by members of the Swiss 'Data and Health' association, whose purpose was to discuss the scientific, ethical, social, legal and political dimensions of using personal health data in healthcare and research (Mòdol, 2018). The MIDATA website lists the cooperative's values:<sup>94</sup> 'citizen owned', 'nonprofit', 'regional', 'transparent', and 'secure'. 'Transparent' refers to the fact that MIDATA's governance principles are public and that members are informed and can participate in decision-making processes. In addition, the code used to build the platform is open source (Riso et al., 2017). People resident in Switzerland can create an account to use the platform free of charge. Members of the cooperative pay a small membership fee. According to the

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91 Retrieved from <https://support.patientslikeme.com/hc/en-us/articles/201186434-What-is-PatientsLikeMe-> on 25 July 2018

92 Retrieved from <https://catalyst.nejm.org/survey-snapshot-patient-networks-important-outcomes/> in July 2018

93 Retrieved from <https://news.patientslikeme.com/press-release/patientslikeme-names-2018-team-advisors> in July 2018

94 Retrieved from <https://www.midata.coop/> in July 2018

initiators' website, the MIDATA 'ecosystem' enables users to '*gather all your different health relevant and other personal data... in one secure place*'. The user controls the purposes for which his or her data will be used (Riso et al., 2017). '*You can decide...to share data with friends or physicians or to participate in research by providing access to subsets of your data. In that way you contribute to the development of new treatments for OUR HEALTH.*'<sup>95</sup>

So far, the MIDATA platform is only available to residents of Switzerland. However, the cooperative also wants to help people in other regions establish their own national/regional not-for-profit cooperatives (sister cooperatives),<sup>96</sup> based on the notion that people and patients in different countries have similar needs (Blasimme, Vayena, & Hafen, 2018). MIDATA has a modular infrastructure, which makes it possible to add on new components. A network associated with the data-sharing service would be interesting for large-scale, international research projects, for example (Hafen, Kossmann, & Brand, 2014). However, setting up such a network would involve a considerable challenge in terms of interoperability and governance both at regional and network level (Mòdol, 2018). At the moment, the network has yet to be created.

Residents of the Netherlands cannot make use of platforms such as MIDATA yet. However, a Dutch data cooperative (Holland Health Data Cooperative, HHDC) has been established by the nonprofit MD/OG in collaboration with the City of Rotterdam, Medical Delta, the IJsselwijs Foundation and TNO Netherlands Organisation for Applied Scientific Research, which endorses the same principles as MIDATA.<sup>97</sup> The HHDC advocates the collective use of data and wants to work with the MIDATA infrastructure in the future. Its 'MyOwnResearch' project, a citizen science initiative aimed at patients suffering combined fatigue and abdominal complaints, recently received funding from the SGF, the association of cooperating health funds in the Netherlands.<sup>98</sup> As far as we know, it is not yet possible for non-patients to join the cooperative.

## 5.1.2 Public platform functionalities

### Patients Like Me

After registering on the PLM website, patients can accurately track their hospital admissions, laboratory results, symptoms and treatments in their personal profile.

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95 Retrieved from <https://www.midata.coop/> in August 2018

96 'MIDATA.coop enables citizens to securely store, manage and control access to their personal data by helping them to establish and own national/regional not-for-profit MIDATA cooperatives.' Retrieved from <https://www.midata.coop/#about> in August 2018

97 Retrieved from <http://hhdc.nl/> in July 2018

98 Retrieved from <http://sgfbetergezond.nl/> in July 2018

Members can choose what they want to track. They can also create a DailyMe to *'see how your status changes over time and which factors are affecting it'* (monitoring). Members use an emoticon to indicate how they feel that day and can provide context in a text box. They can gather information by reviewing other members' data, which are tracked collectively. For example, they can look at what other patients with their symptoms have reported about the side effects of certain drugs or the effects of specific nutrition on their condition. The site also provides information on clinical trials that patients can join. PLM is a community, like a social media network, and the DailyMe feature allows members to communicate with others. In addition to their own data, they can peruse the data of the entire community.

Since 2018, members can also sign up for a new service: DigitalMe. In addition to self-reporting their data on the PLM website, participants in DigitalMe have free blood tests every few months. Researchers combine the patient's data on PLM with the blood data on RNA, DNA, proteins, antibodies, microbiome and metabolites to create a 'digital version' of the patient.<sup>99</sup> According to PLM, DigitalMe participants can contribute to our knowledge of illness, health and ageing in this way, and also to developing the technology that makes it possible to acquire this knowledge. PLM admits that the research will not provide any direct benefit to participants because it will take time for its scientists to analyse the data to determine their impact. PLM does promise to share whatever it learns with the community.

## MIDATA

Account holders can go through the MIDATA portal to access various third-party apps that utilise their data (Mòdol, 2018). Some apps visualise the data for the user using such tools such as timelines or graphs (monitoring); one example is MIMOTI, an app that motivates patients who have had gastric bypass surgery to achieve a healthy bodyweight. Apps can also put patients in touch with other parties. For example, the MIWADO app facilitates secure communication between patient and doctor.<sup>100</sup> Members of MIDATA can also contribute to research into new treatments.

## Promises regarding participation, personalisation and prevention

It is clear that both public platforms are based on patient participation, but both are also closely linked to improving the healthcare system and disease prevention. PLM is very clear about its intentions in that regard. According to the PLM website, the

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99 Retrieved from [https://join.patientslikeme.com/research/digitalme/home?utm\\_source=homepage&utm\\_medium=site\\_link&utm\\_campaign=plm\\_homepage\\_link](https://join.patientslikeme.com/research/digitalme/home?utm_source=homepage&utm_medium=site_link&utm_campaign=plm_homepage_link) in July 2018

100 Retrieved from <https://static1.squarespace.com/static/58f60c8086e6c010d4ae9a34/t/595c8a5f099c0165c82a72e3/1499236965606/MIDATA.coop.pdf> in July 2018

heart of the PatientsLikeMe vision is *'the kind of information sharing that will impact the lives of patients like you and transform healthcare by putting patients back at the center of the system'*.<sup>101</sup> To achieve this, the company has an 'Openness Philosophy'<sup>102</sup>: it believes that by sharing real-world data, patients can help speed up the pace of research and fix a broken healthcare system. PLM takes a stand against the inaccessibility of most healthcare data due to privacy regulations or proprietary tactics.

This vision is also reflected in the way it encourages patients to participate in the DigitalMe service, in which they are given the chance to *'advance personalized health'*.<sup>103</sup> PLM believes that *'the Internet can democratize patient data'*.<sup>104</sup>

## 5.2 Public platforms in context

We have described the aims and functionalities of the two public platforms above. In addition to the individual benefits of using health data, the platforms also highlight the 'democratisation' of data for research as an important value. The remainder of this section deals with the various stakeholder interests and responsibilities and how use of these data platforms fits in with other trends and developments related to medical data in our healthcare system.

### 5.2.1 Stakeholders, interests and responsibilities

#### Platform owners and their revenue models

PLM earns money by offering commercial research services. The data collected on the site and through the DigitalMe<sup>105</sup> programme is 'de-identified' and sold to PLM's 'partners'. The partners are research institutes, patient associations, insurance companies and major pharmaceuticals such as Pfizer and Genentech. These organisations use the data PLM sells them to support their research & development or the sale of products, ranging from drugs and medical devices to insurance.

MIDATA is a non-profit organisation and does not solicit corporate investment. At present, MIDATA and the Dutch initiative Holland Health Data Cooperation (HHDC) are staying afloat thanks to subsidies, but to guarantee their long-term financial

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101 Retrieved from <https://support.patientslikeme.com/hc/en-us/articles/201186434-What-is-PatientsLikeMe> in July 2018

102 Retrieved from <https://www.patientslikeme.com/about/openness> in July 2018

103 Retrieved from <https://www.patientslikeme.com/> in July 2018

104 Retrieved from <https://www.patientslikeme.com/about/openness> in July 2018

105 Retrieved from [https://www.patientslikeme.com/digitalme/consent\\_document](https://www.patientslikeme.com/digitalme/consent_document) in July 2018

stability, external parties must be prepared to pay for non-exclusive access to the available data. A critical mass of users is needed to obtain sufficient data, and the question is whether the benefits of joining the cooperative are enough to attract healthy people (Blasimme et al., 2018). MIDATA must also compete to some degree with other platforms such as PLM, which have much larger financial resources at their disposal. A respondent affiliated with HHDC says in that regard: *'Yes, money is a major barrier right now. We will have to work very hard to keep things moving under our own steam. The future holds promise and that's what we're banking on, but at a certain point the game's up. We think that government ought to step in. And then be able to withdraw again'* (respondent 26).

The aim is for MIDATA users to own MIDATA as a cooperative. Currently, the Swiss initiative is being financed through funds and private loans (Riso et al., 2017). In the future, MIDATA intends to finance itself entirely from membership fees and contributions by research centres seeking to access its data (Riso et al., 2017). The cooperative as a whole can benefit economically from the service that MIDATA can deliver to researchers and companies that want access to members' data. Individual members do not themselves derive any income from this, and it is up to the cooperative to decide whether such revenue should be used to improve the platform itself or to support research projects. These decisions are taken during general assemblies based on the principle of one-member-one-vote.

### **Platform users and their personal goals**

PLM says that its members value participation in a patient network primarily because it gives them access to information and a shared patient experience, e.g. emotional support and the opportunity to express one's feelings and to be part of a community. Others have also noted that the digitalisation of healthcare is leading patients to rely increasingly on the experience of other, like-minded patients (Sillence, Hardy, & Briggs, 2013). Patients are therefore becoming more important as experiential experts. Platform users also feel a greater sense of control over their illness (Isupova, 2011; McCosker & Darcy, 2013; Mazanderani et al., 2013; Wicks et al., 2012; Yli-Uotila et al., 2013, in Lupton, 2014). A survey among PLM members showed that such control comes from their knowing the impact of a condition (which helps them live with it), what treatments are available, what side effects are associated with a treatment, and what factors are important when deciding on treatment (Wicks et al., 2018). Part of the control also lies in their being able to put research topics on the agenda themselves (see the following heading, 'Researchers: platform members and third parties').

Sharing stories online can also have an adverse effect on patients, however, and some researchers are concerned about the highly emotional content that patients may come across, or the sense of isolation that patients may feel if they believe that

only other experiential experts understand what they are going through. There is also the question of how trustworthy the information and advice of other patients actually is (Sillence et al., 2013).

Using the MIDATA platform, individuals can store all their personal data in different locations, thereby taking on a new role as a 'data aggregator' (Blasimme et al., 2018), i.e. someone who links and collects data. MIDATA is merely a tool in that case, a type of health data vault that can be connected to other vaults on request. The data in this vault are well protected but that does not mean that they are only stored in this vault – after all, they have been collected and copied from a variety of other locations. One respondent (respondent 24) involved in another public platform had this to say: *'We're not making something out of nothing because the data are already there. They're already stored somewhere that's less secure. So we're offering access, we're offering a more secure environment, more choice and health benefits.'* In other words, having control over one's data does not mean that patients want only to protect their data, but rather that they want to be able to access the data themselves and decide how to use those data. *'Organisations that handle data are reluctant to do this and work with cumbersome protocols in that regard. These can be relaxed because the responsibility is shared,'* according to respondent 26.

Self-determination and self-care are therefore important values for MIDATA users. However, members who actively participate in determining the policy on access for research purposes take on much more work as well as new responsibilities. According to Mòdol (2018), it is therefore important to study how to encourage such participation.

The kind of **active participation** sought by MIDATA is not for everyone. Account holders can be offered various options when it comes to decision-making about data, for example giving another person, such as their GP, automatic authorisation in such cases. The account holder must, however, actually decide to do this, as one respondent explains: *'The default is that you, as the account holder, decide, and if your decision is that you want someone else to arrange everything on your behalf, then that's fine, but you have to stand by that decision'* (respondent 26). According to this respondent, the pioneers in this domain will also induce other, less active individuals to take control: *I think the pioneers will raise one corner of the tablecloth and then you'll see the rest joining in. That's the underlying idea.'*

### **Researchers: platform members and third parties**

At PLM, the idea is that patients themselves can take up a new role as 'researchers', assigning them all kinds of new responsibilities. Members update their own data, for example. They also interpret and learn from data visualisations

on their own profile and those of others. They can choose which data they would like to visualise, including aggregate data from across the website. Members are not given further assistance in this respect.

The data that patients gather collectively on PLM opens up opportunities for new types of research. There are several examples of patient-led research studies on PLM, including a study of the influence of lithium on the progression of ALS (O'Connor, 2013). The lion's share of the research is carried out by PLM's partners, however.

According to the DigitalMe informed consent form,<sup>106</sup> every PLM research partner has access to members' donated data. It is not always clear precisely how these data are used. PLM's website does provide access to the results of research conducted in cooperation with non-commercial partners.<sup>107</sup> It is, for example, striking how much space the website devotes to the patient-led study of the effects of lithium. Yet so far, it has very little to say about the results of PLM's partnerships with commercial parties. For example, in 2015 AstraZeneca announced that it was entering into a five-year partnership with PLM,<sup>108</sup> but the outcomes of this partnership are not on PLM's website.

The promise inherent in collecting vast amounts of data day after day is enormous, but in reality many of the studies are based on specific questionnaires distributed among the platform's members. Little use is made of external expertise. The validity of the type of research that makes PLM possible has also been questioned. Critics believe that data provided by self-selected patients who are self-reporting on the effects of their treatment do not meet the criteria for sound medical research (Van Dijck & Poell, 2016).

Another PLM priority is how to make the best possible use of big data, in part through artificial intelligence. In 2015, iCarbonX, a company specialising in DNA research, biotechnology and self-learning systems, acquired a minority stake in PLM. The aim of the partnership is to explore how machine learning can be deployed to make better use of the available data.<sup>109</sup> According to one respondent involved in another public platform, individual DNA data in hospitals could ultimately be used to develop highly targeted diagnoses and personalised treatment: *'DNA is increasingly being used in diagnostics. It will be very convenient someday when we all have our DNA data and hospitals can work with them to arrive at the best*

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106 Retrieved from [https://www.patientslikeme.com/digitalme/consent\\_document](https://www.patientslikeme.com/digitalme/consent_document) in July 2018

107 Retrieved from <https://news.patientslikeme.com/research> in July 2018

108 Retrieved from <https://www.astrazeneca.com/media-centre/press-releases/2015/astrazeneca-patientslikeme-research-oncology-diabetes-lupus-respiratory-disease-13042015.html#!> in July 2018

109 Retrieved from <https://www.smarthealth.nl/2017/01/18/patientslikeme-icarbonx-dna-machine-learning/> in July 2018

*possible treatment. I see that as an extremely positive prospect, but we're not there yet* (respondent 24).

The idea behind MIDATA is not only to give individuals more control over their data but also to allow associations of patients to aggregate their data and in doing so encourage research into rare diseases (Blasimme et al., 2018). The promise of MIDATA is that members can contribute in this way to new treatments benefiting 'our health'. The individual gains more control, but the idea is that all patients will benefit.

Blasimme et al. (2018) argue that this will give patients a more active role in improving evidence-based medicine and they specifically address the role of patients as data aggregators. This is also changing what we mean by 'evidence' in evidence-based medicine. Data collection is no longer an activity reserved for the healthcare sector but is undertaken by individuals themselves in their everyday lives. The expectation is that aggregating such N=1 datasets could make a substantial contribution to research.

Respondent 26 says that this will require us to change our thinking about how research is conducted. In the medical world, for example, the efficacy of a medicine is only regarded as proven if it has been demonstrated in a clinical trial. Initiatives such as MIDATA are based on another paradigm, in which research is premised on the fact that patients differ and the real world is complex.<sup>110</sup> In this paradigm, doctors and researchers are less inclined to adhere to existing protocols and patients are encouraged to adopt a more experimental attitude.

### **Platform developers**

PLM's developers work hard to turn patients' experience into useful research data, and the underlying practices are not easily understood by those outside the organisation. Tempini studied these practices by working with PLM (2015) for six months. He describes how difficult it is to strike the right balance between operating an attractive, context-rich system that works for a wide variety of patients and collecting valuable, specific research data. If a patient is experiencing symptoms that have yet to be entered into the database, he is given the option of proposing a new symptom. PLM staff then assess these symptoms manually (Tempini, 2015).

The question is to what extent the wealth of patients' experience *is* used to full advantage in the research that the website can currently support. Research at PLM into patient perspectives on neuromyelitis optical spectrum disorders (Eaneff et al.,

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<sup>110</sup> For example, several of these arguments were raised during the BeyondRCT-2 conference in Amsterdam, held 25-26 September 2018. For an executive summary of the conference proceedings, see <https://www.beyondrct.net/>. Retrieved in December 2018

2017), for example, only provides numerical outcomes on patient-reported symptoms. This information can be useful, but it has very little to do with patient ‘perspectives’.

MIDATA uses a ‘flat’ database, with data being stored with minimal metadata on the MIDATA servers managed by a Swiss cloud provider.<sup>111</sup> It is up to app developers to define and interpret the data. On the one hand, this means that developers can themselves decide how to do this for their specific app. On the other hand, there are no standards to adhere to, making it difficult to link data between different apps (Mòdol 2018). A further issue is whether members understand the way in which developers interpret the data.

### **Healthcare sector, including healthcare research**

PLM not only mediates between patients; the platform also serves to connect other parties in the healthcare sector (Tempini, 2015). Unlike the Dutch healthcare system, where the doctor is the gatekeeper, PLM is now creating a new relationship between patients and the medical world. That relationship is based on information sharing. It is not a one-to-one relationship, such as between a patient and a GP, but rather a relationship between large groups of patients and the broader research and healthcare community. In the short term, information moves in one direction only, to PLM’s partners, with the promise that this information will, in the longer term, benefit patients. Nevertheless, nothing has been set down in writing as of yet.

The role of the physician also changes in this context. A doctor can offer patients support and coaching as they conduct their own tests. Using MIDATA, doctors can also better understand the effects of treatment. According to respondent 26, giving patients more control will also ease the burden on doctors and allow them to diverge more from protocols, so they have more freedom to explore what works for which patient.

## **5.2.2 Points of concern for integrating public platforms**

Section 5.2.1 identified the main stakeholders and their interests and discussed how public platforms are actually being used and what this means for the allocation of responsibilities and relationships in healthcare. This section addresses points of concern when integrating public platforms for data sharing into our healthcare and research system.

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111 Retrieved from [https://www.ti.bfh.ch/fileadmin/x\\_forschung/forschung.ti.bfh.ch/0\\_Zentral\\_InfrastrukturGeraete/Medical\\_Informatics\\_I4MI/Projektbeschreibung/MIDATA\\_Patientenzentrierte\\_Verwaltung\\_Gesundheitsdaten.pdf](https://www.ti.bfh.ch/fileadmin/x_forschung/forschung.ti.bfh.ch/0_Zentral_InfrastrukturGeraete/Medical_Informatics_I4MI/Projektbeschreibung/MIDATA_Patientenzentrierte_Verwaltung_Gesundheitsdaten.pdf) in July 2018

### **Infringing privacy and profiling**

PLM, MIDATA and other such initiatives are designed as platforms for sharing information and encouraging research into rare diseases and other conditions. The initiators believe that their members and fellow sufferers benefit and that is why they are willing to share their data. To join these communities, you must share certain data.

How this impacts privacy is a point of concern. On PLM's website, for example, its developers state the following: '*Being open about one's health is not for everyone, and we strive, with full transparency, to outline the benefits and risks of being part of this sharing site...*'<sup>112</sup> PLM's Privacy Policy,<sup>113</sup> a simplified version of which is available on the site, states for example that members '*should consider that the more information that is entered, the more likely it is that a Member could be located or identified.*' The website also lists potential risks: '*For example, it is possible that employers, insurance companies, or others may discriminate based on health information*'<sup>114</sup> (i.e. profiling).

The data platforms are working on this. PLM is setting a good example by allowing members to choose between differing privacy levels. 'Restricted data', data that could reasonably be used to identify the member that entered them, is 'de-identified' *before* it is used by PLM's research partners. The platform uses a special consent management functionality for this purpose. After the account holder has granted consent, the data are de-identified, aggregated and exported for the specific data analysis requested (Mòdol, 2018). For other data, there are two privacy settings: 'members only' and 'public'. This only concerns the visibility of data on a member's profile, and not which data are shared with which PLM partners.

MIDATA stores data securely, so that they are virtually unidentifiable and encrypted using multi-level encryption (Mòdol, 2018). It is crucial that the members of a data cooperative trust the platform's data management. A respondent affiliated with HHDC listed the questions that worry its members: '*Are my data being managed properly? How do I know they aren't being tampered with? Do I understand what's being done with them?*'

The foregoing shows that the site's users are expected to familiarise themselves with the platform's privacy policy, but that the platform owners themselves are also taking steps to ensure greater privacy.

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112 Retrieved from [https://www.patientslikeme.com/about/privacy\\_full](https://www.patientslikeme.com/about/privacy_full) in January 2018

113 Retrieved from <https://www.patientslikeme.com/about/privacy> in January 2018

114 Retrieved from [https://www.patientslikeme.com/about/privacy\\_full](https://www.patientslikeme.com/about/privacy_full) in January 2018

### **Balancing collective and individual interests**

The public platforms discussed above focus on sharing data for the benefit of fellow patients and research. Members endorse the goal of supporting medical research, for example research into the condition that they themselves are suffering, by sharing their data, and as long the quality is good, such a vast amount of data could lead to more valuable research. This is how people contribute to 'data solidarity', as referred to by the Minister for Medical Care, Bruno Bruins, in his Letter to Parliament in November 2018, entitled 'Let data work for health'.<sup>115</sup> But the user's individual interests naturally also count. Those interests are multifaceted and range from having control over one's data to receiving a return on investment.

After joining PLM, for example, members in fact no longer have any control over their data. They can naturally decide to close their account or withdraw their data whenever they wish. Their data will then no longer be visible on the site and will not be included in future analyses. They cannot, however, withdraw data that have already been used in research.

Respondent 26 provided examples of return on investment issues: *'Am I getting enough in exchange for the data I'm providing? Will I only get a sort of comparison with the Dutch average? Or will I get a share of the profit earned on the product that you've developed using my data?'* The same respondent also feels that differences between patients should be taken into account: *'Every piece of the puzzle counts, every opinion, every bit of data, every context is valuable in and of itself.'*

The above reveals the importance of governance for maintaining the right balance between individual and collective interests in such platforms.

### **Data solidarity and research quality hand-in-hand**

Public platforms allow patients to play a more active role in improving evidence-based medicine. People can themselves support research by contributing their N=1 data set in everyday life ('evidence').

Researchers gain access to more data and can test new technology on biological samples provided by members. All this ultimately makes big data analysis possible. Another topic of study, for example by PLM, is how to make the most of artificial intelligence. Data quality, representativeness and, consequently, the validity of the research made possible by the data is an ongoing issue. If a research group wants to access MIDATA data, for example, the cooperative's board and ethics committee first review the quality and ethical aspects of the application. The board and committee are appointed by the members of the cooperative (sometimes indirectly)

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<sup>115</sup> Kamerstukken II 2018/2019 *Kamerbrief Data laten werken voor gezondheid*, 15 November 2018, Reference 1440757-183490-DICIO

(Blasimme et al., 2018). Researchers and healthcare parties have yet to draw up guidelines governing the proper use of data from public platforms for research purposes.

Complete data solidarity depends on other parties also sharing their data and the results of research. In his Letter to Parliament of November 2018, Minister Bruins says the following:<sup>116</sup> *‘In addition to data made available by the public, it is important to look at access to data held by manufacturers of information systems or healthcare devices. In many cases, they are not sharing these data even though it would benefit society for them to do so. I think that we should consider how data can be made available for the greater good, provided that the purposes of data analyses – in line with the GDPR – are well defined and clearly deliver added value for the health of others’.*

## 5.3 Public platforms and personal health management

To what extent do these two examples of public platforms contribute to personal health management? This section offers an analysis based on interviews, the literature and other information.

### 5.3.1 Independence in decision-making

#### **Free to choose platform, limited options**

With regard to the use of data platforms, ‘personal health management’ is, first and foremost, about choice. It is up to people themselves to decide to use these health data services. So far, both PLM and MIDATA are supplementary to existing health care systems in that they offer people extra tools to improve their health but do not deprive non-members of regular healthcare services.

However, it is reasonable to ask to what extent people who want a better grip on their health really have a choice when it comes to choosing a public platform for data sharing in a free market. Larger commercial organisations such as PLM have better access to financial resources, allowing them to spend more on technical expertise. As a result, their websites are more visible online and they can offer more, or more professional, services (Lupton, 2014). A company such as PLM is more visible than MIDATA and will therefore attract more users. It is difficult for small public platforms to compete with large healthcare and commercial parties without a sound revenue model (Purtova, 2017). So far, MIDATA has mainly

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<sup>116</sup> Kamerstukken II 2018/2019 *Kamerbrief Data laten werken voor gezondheid*, 15 November 2018, Reference 1440757-183490-DICIO

attracted people who are already participating in a research project. In addition, only Swiss citizens can join the MIDATA cooperative. Although the Netherlands has the HHDC, the platform has yet to obtain the funding it needs to function as a genuine data cooperative.

### **Influence on interface, but little diversity**

Members of both PLM and MIDATA can influence the interface they are given to work with. For example, PLM allows members to add symptoms themselves and choose which factors they want to track. MIDATA allows account holders to choose which apps they want to use and which aspects of their health they would like to focus on. It is impossible to say whether these choices are actually useful for users. They are made responsible and they base their decisions on their own sense of what is good for them.

In spite of that, as developers work on these platforms, they make all kinds of decisions that are beyond the user's control. Ultimately, these decisions influence the users' health decisions. For example, the complex categorisation of diseases, symptoms and treatments on the PLM platform is by no means spontaneous. The choices made in this regard influence the conclusions that can be drawn (Tempini, 2015). The developers of MIDATA apps also take decisions about what kind of data will be collected and how it will be categorised. For example, the cooperative examines whether research is ethical and of good quality, but this does not automatically mean that it has taken the patient's perspective into account in assembling the data set, or that the research ultimately reflects patients' everyday routines or wishes, or that the research answers questions that are relevant to patients.

### **Transparency sometimes lacking**

PLM is studying the use of self-learning algorithms to analyse the data collected on its site. How will the lessons it learns influence what members see on the website? How do PLM's partners use algorithms? PLM claims that transparency and openness are important company values, but it is not always transparent about everything, and the question is to what extent openness is even possible when self-learning algorithms are involved (Janssen & Kuk, 2016).

### **User locked into a (shifting) revenue model**

As described above, when it comes to citizen science and digital patient networks, individual and commercial interests are intertwined. PLM qualifies as a public movement because it was founded by two specific individuals and because patients still have an advisory role. However, nowadays it is also a commercial enterprise that earns money off its members' data. Other websites (such as CureTogether and Healthunlocked) also had their origins in a public interest or ideal but are now taking

an increasingly commercial approach or have been acquired by a commercial enterprise. Public platforms only survive if they have a viable revenue model, i.e. by commercialising.

But commercialisation may cause these platforms to shift their focus. For example, Barrett et al. (2016) describe how value creation at Healthunlocked evolved over time. What started as a service that appraised healthcare services developed into a network that connected patients with other parties in healthcare, and then into a monitor that tracked what patients posted on the website. It has now become a patient profiling service that helps pharmaceutical companies find suitable candidates for trials, for example. PLM no longer aims to connect ALS patients, but to narrow the gap between patient experience and industry.

An evolution of this kind can conflict with the original values to which a public platform first committed itself (Barrett et al., 2016). In addition, private individuals cannot use the network without agreeing to share their data with third parties.

### **5.3.2 Control over data**

We must then consider to what extent people really 'have control over their data' through these platforms, i.e. the extent to which they can control what these services do with their data.

#### **Sharing data with commercial parties, or preferably not**

One important principle of both services is that people should have the opportunity to share their data with researchers. However, the two platforms take very different approaches in that regard. PLM members transfer all their data and relinquish control: the patient's intimate experience becomes the commercial property of companies in PLM's network. Patients are not compensated financially for their data because PLM is valuable to them in another way. At the same time, patients do play a role in an economic market that is set up largely to benefit large companies and PLM itself. We have little knowledge about the extent to which users know how third parties, commercial or otherwise, use their data and what they think of this (Lupton, 2014). But while claiming openness and transparency as core values, PLM ignores the skewed power relationship between their patients and the commercial parties that use their data (Brubaker, Lustig, & Hayes, 2010).

This is precisely what the cooperative MIDATA is against. The essence of MIDATA is that account holders retain control over their data, in the sense that they can decide with whom they will share data and what data they will share, and that they

also have a right to any benefits. Responsiveness to participants is an important factor in giving them control over their data.

### **Participants sometimes happy to delegate control**

Individuals who find it difficult to oversee the consequences of sharing data have the option of delegating this control to the cooperative. MIDATA allows account holders to automatically give another person, such as their GP, the authority to do so. Nevertheless, it is a decision that must be made by account holders themselves. MIDATA currently assesses research on ethical and scientific grounds before asking the individual account holder for permission to share data. That means that the individual does not bear all the responsibility.

## **5.3.3 Influencing healthy behaviour and health**

### **Sharing experience helps patients get a grip but does not necessarily empower them**

PLM's biggest promise to users relates to 'personal health management'. At PLM, patients are part of a community that has a common goal, something that can have a motivating effect during treatment (Wentzer & Bygholm, 2013). Being an experiential expert is a much more active role than being a patient. The large amount of data that is shared also gives members a rich source of information in which they can seek out the information that is important to them. Interestingly enough, Wentzer and Bygholm (2013) say that this does not empower patients in the sense that individuals have more freedom to do what they want. Patient networks in fact appear to converge around a type of 'ideal' patient who behaves in accordance with protocols based on the latest research findings, and they allow very little leeway for dissenting opinions. This is contrary to the concept of personal health management and taking decisions that make good sense for the individual, based on his or her personal health information.

### **New role as researcher turns individuals into 'self-experts', but also makes them vulnerable**

Both PLM and MIDATA clearly consider involving individuals/patients in research as an important part of 'personal health'. Both platforms enable patients to collect data about themselves, giving them a new role as researchers of their own health. In doing so, the individual gains a form of expertise that can be called 'self-expertise' (Heyen, 2016), a trend that can be traced back to the Quantified Self movement. Any broader shift in people's roles and associated responsibilities has individual and collective consequences that we must examine. It remains to be seen whether people are capable of deducing the consequences of their everyday behaviour from data and of acting accordingly (Frost & Massagli, 2008). Moreover, as the subject of

their own research, people are not only resilient, but also vulnerable – patients' decisions are likely to be dictated mainly by health considerations, even though other values that are not always guaranteed, such as autonomy, privacy and solidarity, are also at stake.

### **Doubtful whether patient is truly at the centre**

Involving people in research not only means N=1 research, but also research in larger groups of patients. The data that people collect about themselves may be valuable for medical research in the broad sense. The promise is that this will put the patient back at the centre of the healthcare system, but the question is to what extent the patient really is in charge here. PLM claims that it puts 'patients first',<sup>117</sup> but we have seen that information sharing is largely a unidirectional affair in which data flow to its research partners. Another question is whether the accumulated statistics properly represent the patient's experience. If putting the patient first means listening more closely to the patient's needs, then the research should be qualitative in nature and the patient should be more involved in setting up the research.

### **Patients who are incorrectly informed lose control**

Finally, we can question the underlying principle of putting people in control. Patients become more resilient, but also more critical of practitioners and the healthcare process. They may also become more vulnerable, in fact, because they share data with third parties without gaining any direct benefits and without always being able to control this aspect. While patients are better informed on the one hand, their new position may also lead to them being misinformed – after all, they interpret their own data and draw conclusions from the experiences of others. Patients can also be demanding. In a certain sense, this may mean that healthcare providers and policymakers have less control over patients. The question is who *is* in control and what this means for the healthcare system.

## **5.4 Public platforms summarised**

We investigated two collective platforms in this chapter, PLM and MIDATA, in which people themselves take the initiative when it comes to their health (and health data), the aim being to track their health and to share information with fellow patients. In exchange for members' data, PLM presents those data in a comprehensible manner and allows its members to compare their data and share stories. MIDATA focuses on giving people greater control over their health and their

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<sup>117</sup> Retrieved from <https://support.patientslikeme.com/hc/en-us/articles/201245710-What-are-the-company-s-core-values-> in July 2018

data by serving as a collective data vault, with members deciding for themselves whether and which data they share with third parties.

Although we refer to these two platforms as 'public', differing interests appear to be at stake in their underlying revenue models. PLM is now a commercial enterprise, while MIDATA, as a cooperative, is still owned by its members. The platforms communicate transparently about these underlying revenue models, but PLM users receive a relatively low return on their investment. The platform's economic value lies with the commercial parties that use the data. MIDATA offers the option of delegating control over data to a group of experts and representatives. This is a welcome development, as individuals do not always understand the consequences of data sharing.

The two platforms differ considerably, however, when it comes to the level of control that people have over data sharing. MIDATA regularly asks users to consent to data sharing, and the platform has a committee that assesses data use by third parties. It is important that researchers and parties in the healthcare sector establish firm, overall guidelines governing the use of data obtained from public platforms setting out how these data can best be used for research. There are no such guidelines at the moment.

To get people more actively involved in research by sharing their data, it is important to conduct (qualitative) research on how best to encourage participation. The law requires the recipients of such data to provide feedback to individuals, but more should be done to share the findings of research based on their data with them.

Sharing data for the benefit of fellow patients and research is a central tenet of both public platforms. It is a form of data solidarity that is consistent with the idea of improving public health through 'big data analysis'. At the same time, we have witnessed a reversal in the tendency to release or link as much data as possible. Large companies are setting poor examples in this regard and people have therefore grown wary.

## 6 Overarching analysis and discussion

Chapters 2 to 5 described four different services – online portals, PHEs, health apps, and public platforms – that store and share digital health data with the aim of giving people more control over their health. The services differ in their functionalities but they also have things in common. In this chapter, we will synthesise our findings and analyses. The overarching themes that underpin the four digital health data services converge here and we provide answers to our three research questions.

1. What impact do digital health data services have on healthcare practice and on the Dutch healthcare system? (Section 6.1)
2. To what extent does using these different services allow people to take charge of their data by administering and sharing them and, consequently, to manage their health? (Section 6.2)
3. What are the wider implications of using these services for society? (Section 6.3)

This chapter concludes with a summary of our main conclusions (Section 6.4). Chapter 7 then discusses possible action that can be taken for each conclusion.

### 6.1 Implications for the Dutch healthcare system

Personal data management and data sharing were also possible in the past, for example when people received copies of their own medical records. But the digitisation of health data is increasing the scale and scope of data sharing, with both positive and negative consequences for the relationship between people and patients. A new allocation of responsibilities is needed between healthcare professionals, patients and other parties, including developers of such services.

#### 6.1.1 New relationships and responsibilities

##### The participating patient

The relationship between patients and healthcare professionals is changing. Patients are now tasked with responsible data sharing, and they refer to self-

tracked data, for example from an app or a PHE, during appointments with healthcare professionals. In the case of online portals, firm agreements are needed on whether and how healthcare professionals and patients should use data they enter themselves and the portal's various functionalities. As a result, people will have to do more themselves, as our study shows. They will have to check that the data in their medical records are correct, monitor vital signs themselves instead of having the hospital do so, and update other professionals about the data.

Public platforms have added a new dimension to existing information-sharing relationships (between healthcare professionals and patients), with interactions between healthcare industry and medical science on the one hand and groups of patients on the other ('patients like you'). Patients gain a network in which they can learn from other people's experience, for example patients with similar conditions who are undergoing treatments different to their own. Platforms such as MIDATA and PLM are making more and more information available about the course of an illness within specific patient groups, or about readmission to hospital after taking certain drugs. So far most of this information goes to pharmaceutical partners (in the case of PLM), but the promise is that individual patients will also 'benefit' at some point.

### **Liability of healthcare professionals as coaches**

Analysis of the four services shows that, in addition to providing physical care, healthcare professionals are expected to coach their patients, for example through secure messaging in online portals or PHEs. They give patients tools that should help them in their health and healthcare process, including home health monitoring apps and devices. As a result, healthcare professionals sometimes feel tension between their responsibility to provide treatment and patients' needs. For example, it is difficult to reconcile 24/7 availability for messaging with the existing set-up of healthcare. This study has not considered the extent to which it is even advisable for healthcare professionals to be available 24/7.

Healthcare professionals are particularly worried about liability for using or not using data that patients make available to them through services. When a healthcare professional asks a patient to monitor his or her own vital signs, the professional is usually also responsible for checking the patient's outcomes. A healthcare practitioner is also liable if he or she decides to access patient data collected by other healthcare practitioners or through a health app or digital service (after obtaining the patient's consent) and use it in an assessment. But it is precisely such assessments and data appraisals that are surrounded by considerable uncertainty. For example, how can the healthcare professional determine whether the quality and reliability are good enough for the data to be factored into decision-making and advice?

In addition, healthcare professionals are concerned about the confidentiality of the data in the medical record and the risk posed to such confidentiality when data are removed from the healthcare provider's 'factual control', for example because an electronic copy of that data is shared with other parties through an online portal or PHE.

### **Developers bear only limited responsibility**

Developers and providers of digital health data services are aware of their heightened responsibilities with regard to interoperability, security and data protection. The user agreements drawn up by the developers of PHEs and online portals make patients and healthcare practitioners responsible and liable for data sharing. The online portals also explain the responsibilities and rights of users with respect to their own health data. For example, the Karify portal publicises its efforts to ensure data ownership among its users, as does MIDATA in the guise of its collective data vault. The various services make less of an effort when it comes to facilitating and supporting data sharing by their members. An access log to PHEs and online portals would show which data are shared with whom, but not all services have a digital logging mechanism of this kind in place.

As the user agreements for PHEs and health apps attest, the various services explicitly do not take responsibility for any actions that users undertake based on the data contained by the services. It is up to the individual to interpret data (or experiences) and to decide what to do about distressing outcomes, for example. Users are solely responsible for deciding to change their behaviour or share their data. They can ask healthcare professionals to coach them, but they do so on their own initiative, increasing the workload in the healthcare sector. If the service is integrated into healthcare practice, then the healthcare professionals are responsible (in part).

As we saw above, the rules and regulations and the allocation of responsibility meant to guarantee responsible data sharing are often still focused on the various categories of personal data, whether or not health-related and whether or not situated within the medical domain. With the dividing lines between domains becoming more blurred, experience has shown that this is a useless distinction; after all, individuals now have copies of their medical data, healthcare professionals can make good use of lifestyle and other data, and non-medical data combined with other data can also tell us something about our health.

### 6.1.2 Trusting the health data market

The emergence of several forms of digital health data services in the Dutch healthcare system is broadening the scope of the health market. The distinction between public and private or within and outside healthcare is fading. The arrival of new commercial operators in the health and healthcare domain requires us to weigh up our options carefully. As the case studies show, not all of the services on offer strike the right balance between individual or public interests on the one hand and the developer's or service provider's commercial interests on the other.

Commercial services are interested in marketing a product, i.e. the data service, that is as profitable as possible.<sup>118</sup> Developers do not make money from collecting and using health data (e.g. through resale), although this does happen indirectly. They use data for analysis purposes so that they can offer both healthcare providers and consumers and patients personalised advice and information. A 'personalised service' of this kind is not a service that is tailored to the individual, but rather to 'people like you'. They combine the data of all users to deliver better services to their end users, but how they do so and with what data remains unclear.

The PLM platform is an exception in this study because it does make money by reselling user data to pharmaceutical and other companies. Its users receive no payment for this. Recent research has shown that our health data also have economic value for commercial parties that offer health apps other than those analysed in this study (Zang et al., 2015).

Working with major companies such as Google and Apple, but also Zorgdomein or Chipsoft, is no guarantee that data will be shared and analysed as agreed, even if the terms and conditions are specified. Acquisitions and a change of direction can shift the focus of these companies and invalidate agreements.<sup>119</sup>

#### **No revenue model**

There is currently no sustainable revenue model for online portals, PHEs and platforms such as MIDATA. The supply of PHEs (under development) appears to outstrip the demand on the market and in the healthcare system. Stakeholders must ensure that high-quality, reliable PHE developers survive and continue to deliver.

For a long time, developers were unsure about the business case for online portals, until the introduction of a statutory obligation to furnish online access and the

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118 All services examined in this study are commercial services, with the exception of MIDATA, which is a cooperative

119 Retrieved from <https://www.spaink.net/2018/11/21/weet-wie-je-in-huis-haalt/> in November 2018; Karin Spaink in *Het Parool* 21 December 2018

various VIPP schemes proved game-changers for portal developers. The cost of setting up and servicing online portals has remained excessive for healthcare providers, however, and they are not convinced of the added value of online access, as became clear at the *Digital Healthcare and Ethics meeting* organised by Electronic Commerce Platform Nederland and Nictiz. More research<sup>120</sup> is needed on their cost-effectiveness and the implementation of such portals has yet to be evaluated.

Financial sustainability is also a concern for platforms such as the MIDATA cooperative. PLM is much more competitive than other (patient) platforms such as MIDATA and its Dutch spin-off, My Data My Health. It is difficult for small public platforms to compete with large healthcare and commercial parties without a sound revenue model (Purtova, 2017). Nonprofit public platforms, including the Holland Health Data Cooperation (HHDC), currently depend on subsidies. A sustainable revenue model requires willingness on the part of external parties to pay for the service, as well as a critical mass of users to ensure the accumulation of enough data. As we have shown, the parties investigated in this study have not yet satisfied these prerequisites.

### **PHE market under development**

PHEs occupy an unusual position in all this. They belong to a market that has yet to emerge, according to several respondents. Policymakers and health insurers stand behind this nascent market<sup>121</sup> but the absence of a revenue model makes developers cautious about entering it. No one knows whether there will be a demand for PHEs in the healthy population. However, several developers did apply for the MedMij Financial Incentive Scheme and some 60 candidates have signed up to the MedMij system. This study shows that developers are focusing on a specific patient group, usually chronic patients. Starting from there, they will explore whether it is feasible to develop PHEs for a broader target group.

### **Competition for health data**

Health data is of enormous value to medical science and can improve healthcare. Initiatives such as MIDATA (or its Dutch spin-off, My Data My Health) and PHEs are working to collect these data and share them with researchers and other parties. Platforms such as PLM and large pharmaceutical companies are also seeking access to these health data.

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120 Digital Healthcare and Ethics meeting ('Digitale Zorg en Ethiek') organised on 22 November 2018 by Nictiz and ECP

121 See for example: <https://www.medmij.nl/artikel/subsidieregeling-impulsfincanciering-pgo-leveranciers-gepubliceerd/>. But according to personal contacts in government, it has been suggested that a PHE could be covered under the basic health insurance package or that the health insurer will assume (partial) payment of PHEs. We are unaware of any official communication on this subject.

Much is expected of the health data market, with many different initiatives and services emerging in a relatively short period of time. But there is also considerable uncertainty about the sustainability of the revenue models that underpin the various services. Several PHEs have already gone into liquidation or shut down in the run-up to the PHE market. Online portals are now required by law, but there is minimal evidence that they lead to cost-effective or better quality care. The other services, including health apps, have yet to prove their worth as well. Most services therefore focus on specific target groups such as chronic patients, a more likely sales market and source of monetary and quality gains and backed by evidence that patient self-management or empowerment can be successful.

### **6.1.3 Interim conclusion for ‘implications for the Dutch healthcare system’**

Digitalisation and digital health data services have the potential to improve healthcare, but interoperability remains a hot issue. Many services are still under development or their use is limited, and health apps have trouble retaining users in the long term.

This report discusses promising initiatives and the groups for whom they are effective: chronic patients, healthcare practitioners amongst themselves, and high-educated people who are keen to improve their health, for example. The online portals in mental health and addiction care focus on blended care, with digital and face-to-face healthcare being coordinated such that patients who so desire can participate digitally in their own healthcare. At the moment, the different categories of services only share lessons learned and best practices sporadically. Not only are PHE developers learning from one another but they are also drawing lessons from existing good practices in the mental health and addiction care portals, while health apps are learning from public platforms such as MIDATA. Such cross-fertilisation must be encouraged.

There have as yet been few attempts to identify or understand the implications of the shifting responsibilities of healthcare professionals, patients and developers. For example, the concept of patient participation means that patients are now assigned tasks within the healthcare process that they did not previously have. We note that patient responsibility has yet to be defined in this context, and that patients should not only be regarded as data sources and data holders, but must have the opportunity to benefit from their responsibility. It is also often unclear what the responsibility of healthcare professionals is.

Data sharing with third parties across the boundaries of the medical domain begs the question of whether such sharing actually serves the public interest, for instance by improving healthcare. For example, are the data we share of good quality and are they adequately protected? It is in any case clear that sharing data with third parties changes the balance of power within and outside the healthcare sector. Not only do we and our doctors know more and more about our bodies, but other parties also know more and more about our health. People need better support and protection in managing and sharing their health data.

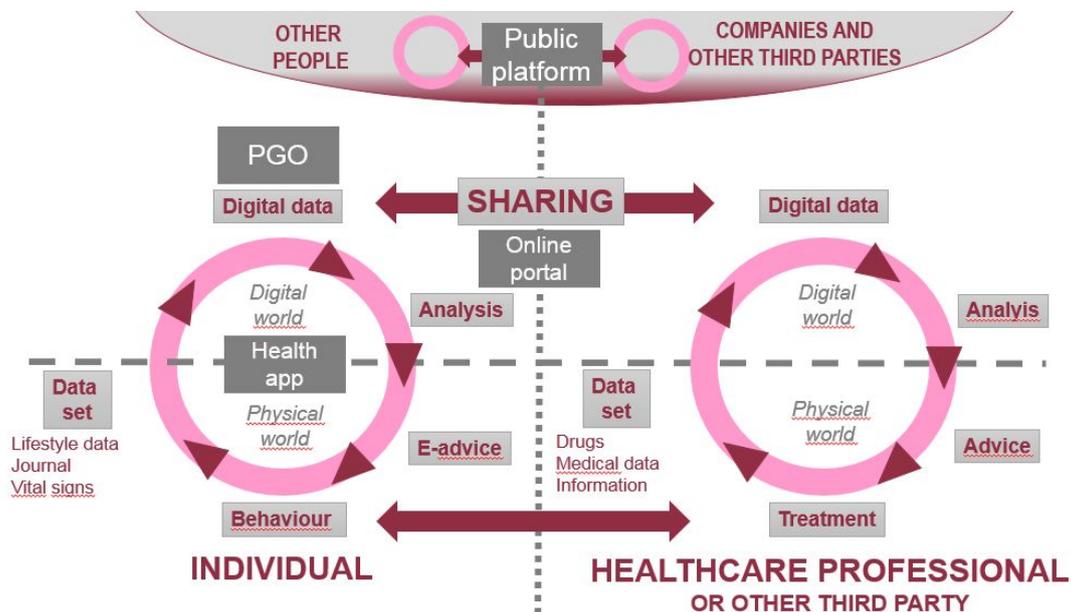
## **6.2 Personal health management**

During our study, we examined three aspects of personal health management in each case study:

1. To what extent can people take decisions themselves about the service?
2. To what extent do people control their data?
3. To what extent can people use the services to influence their health as they see fit (see also Table 1 in the Introduction)?

We provide a cross-service analysis of these three aspects below in three separate sections. The starting point is the double data loop and the way in which digital health data services: a) collect data, b) share and combine data, c) analyse and implement, d) advise, intervene, provide feedback, and e) then actually change behaviour in the physical world.

Figure 3 Double data loop for digital health data and advice



### 6.2.1 Decision-making

What decisions can users take with regard to digital health data services? What exactly does it mean to have control over one's data? It is not clear which decisions we can take ourselves and which decisions are made for us by the various services. To take our own decisions in the digital context means that we need to know in what way we can decide about our health and health data, and with whom we can discuss this.

#### Decisions taken by users

The public is more likely to trust services if they are certified or offered by healthcare professionals, but the guidelines, certifications and quality marks are diverse and difficult for ordinary people to understand. PHEs have the MedMij quality mark, which guarantees secure and protected data sharing but not the quality of the data being shared or the programmes offered through the PHEs. Health apps have the KNMG Medical App checker, the GGD AppStore and NeLL. There is also a CE Mark for medical apps. All check only a fraction of the many apps and aspects that require clarification. Regarding PHEs, the MedMij Foundation, which grew out of the MedMij Trust Framework and began operating on 1 January 2019, provides certification and oversees the information flows between PHE suppliers, healthcare providers and the public. The MedMij system does guarantee the secure transfer of data between the various MedMij-certified partners in this manner, but not the intrinsic quality of the services they offer. It also

says nothing about what happens to the data when they are delivered to another service or party. Similar oversight or initiatives are non-existent for online portals or public platforms,<sup>122</sup> and the Trimbos Institute's quality mark for online mental health and addiction care services was discontinued in December 2018 due to funding issues.<sup>123</sup> The reliability of platforms such as MIDATA is assessed mainly on the basis of information found on their websites and what other parties have to say about them. It is difficult to ascertain the quality of the services and the effectiveness of the online programmes that services offer.

The services must also take decisions, for example how to display information, whether users will be able to influence the interface, whether they can choose which apps that they want to link to one of the PHEs (from a pre-selected list), or (in the case of the mental health and addiction care portals and PHEs) whether they can choose which programmes they want to follow. The mental health and addiction care portals show that patients deliberately select functionalities that meet their needs and disregard others. For example, one person likes communicating using the messaging portal, while another prefers personal contact.

#### **Decisions taken on users' behalf**

Decisions are also taken on users' behalf. It would not be conducive to user-friendliness if users had to specify their preferences every time they used a service. Firm agreements regarding standards and uniform language are necessary for uniform data transfer within the healthcare system. There are no such agreements for data transfer between health apps and online portals. Health apps and public platforms also take decisions in offering pre-defined categories of diseases, symptoms and treatments.

Our study of digital health data services also shows that when services (or rather their developers) take decisions for us, more transparency is required, for example about which information we are being offered and in what way. That is especially true when the service – whether it is an online portal or MIDATA's MIMOTI app – coaches or motivates us to adopt healthy behaviour. Sometimes developers take such decisions in consultation with healthcare professionals and they determine which programmes the online portal makes available. Sometimes they also do so in consultation with patients, who help decide whether the information should be available in spoken or written language and/or in animations. The patients we interviewed regard the information provided by the portals and practitioners as reliable. They trust experts to deliver accurate information and to explain when something is unclear. They are not as trusting of health apps and PLM.

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122 Retrieved from <https://www.kiesbeter.nl/artikelen/zorgthemas/keurmerken-in-de-zorg/index> in January 2019

123 Retrieved from <https://www.trimbos.nl/actueel/nieuws/bericht/onlinehulpstempel-voor-de-ggz-stopt> in December 2018

Decisions are also taken out of users' hands by the underlying automated processes. Self-learning algorithms structure, integrate and interpret data for users and offer them personal advice. We see that these self-learning algorithms are used by health data services and beyond to 'profile' people and to predict healthy or unhealthy behaviour. Partnerships between health insurers and local authorities, for example in the 'SamenGezond' app, define which decisions users are allowed to take without the users knowing that their data have influenced this (see also the 'AI' oval in the above figure). It is often impossible to determine precisely which information is being used and how it has affected the calculations and results of the algorithms. Developers do not disclose the quality of the data, which study sets are being used in machine learning, or whether there is any bias in the results. Nevertheless, users base 'personal' decisions on these automated processes to some extent.

### **Not everyone has decision-making skills**

Decision-making requires users to be skilled enough to take charge of their health data and to be willing to do so. The most recent national eHealth monitor survey (Wouters et al., 2018) shows that people generally do not have the skills to work with these types of health data services and are reluctant to do so. Our research reveals that, for the time being, MIDATA, PLM, online portals and other initiatives mainly attract those who are already in the forefront of using digital services. We know that the interviewed mental health and addiction care patients actively decide on the type of guidance, treatment and support that they want. Deliberately choosing to not receive therapy online is also a patient decision. Chronic patients are keen to work with PHEs because they expect to gain a better overview of the data that various healthcare professionals have on them.

Vulnerable people, for example those with low (digital) literacy skills and the elderly, need more support. They are often less self-reliant and less able to take decisions about their own health data. Many are also chronic patients whose condition has affected their cognitive and physical capacities, regardless of their educational background (WRR, 2017). Ensuring that services are easily accessible (simple language, orderly presentation of information, etc.) can also support users. It appears that offering fully digitised healthcare services will not guarantee equal access to healthcare.

### **Shared decision-making**

The case studies illustrate that shared decision-making can help people make choices in their health process. One important factor in facilitating personal decision-making is for services to be properly integrated into everyday healthcare practice, whether at home or in a healthcare setting. Online portals, for example,

are integrated into healthcare practice, whereas PLM is integrated into a network of fellow patients. It is clear, then, that the decisions users take depend heavily on their environment.

It is by no means a matter of course for such services to be integrated into healthcare. Healthcare professionals have traditionally tried to protect patients and not empower them to take charge of their health and health data. We can already find best practice examples. Shared decision-making between patient, healthcare practitioners and, where necessary, family members and informal carers is vital to the effective use of online portals in the mental health and addiction care sector. That is also the case for MIDATA, where a special committee makes a predetermination of sensible user options for data sharing with researchers. But there are very few signs that others are taking these best practices on board.

Policymakers have also emphasised the importance of shared decision-making between healthcare professionals and patients, explicitly linking this to mandatory specified consent from 1 July 2020 onwards. However, it is unclear how shared decision-making will actually play out in the real world, for example during a consultation between a patient and a GP or medical specialist. What if someone who is not currently under a healthcare professional's care decides to share or not to share data? Who is the other party in shared decision-making then, and how will it take place?

## **6.2.2 Control over data**

Having control over our data means that we understand how the services use our data and that we can decide with whom we do and do not want to share data. Data sharing is at the heart of the double loop, shown in Figure 3, giving rise to new opportunities for analysis and coaching, not only for ourselves but for others as well.

### **Access to data and data ownership**

To exercise control over our data, we must have access to them. Besides poor interoperability, the development and acceptance of online portals, PHEs and similar services have been hampered by endless discussion between healthcare professionals, developers, the public and policymakers about ownership and accessibility of health data. When people are in possession of digital copies of data from their medical records, they are responsible for them. However, some healthcare professionals feel that it would be better for ownership of these data to be retained by the medical sector. Developers are keen to advertise the fact that their services regard the individual user as the data owner; since all they want is

access to the data not ownership. Initiatives such as MIDATA, for example, are based on the principle that people own their health data and are therefore entitled to store them in a safe place themselves. Various PHE suppliers also indicate that their members own their own health data.

Ownership of digital health data is a thorny legal issue,<sup>124</sup> but we do have legislation governing data accessibility and portability (Hooghiemstra, 2018). However, as Hooghiemstra points out, most of this legislation dates from the pre-digital era and addresses medical confidentiality. Medical confidentiality refers to a professional duty of confidentiality undertaken by healthcare practitioners; they are not permitted and cannot be required to share data with others unless the patient consents to this or information is shared within the context of treatment (i.e. data is shared with another healthcare practitioner involved in the treatment of the patient). This allows patients to be completely honest with their practitioner. The ease with which data in medical records can be shared with others has triggered a call for 'patient confidentiality'.<sup>125</sup> The concept has not been laid down in the law as yet, but various parties have recommended extending the same protection to health data that are not subject to the requirement of medical confidentiality. For example, copies of data from a medical record stored in an online portal or a PHE would be protected automatically, reducing pressure on individuals to share their data (Hooghiemstra, 2018).

Merely having access to data is not the same as being in control of data. We may have access to the data held by various services without being able to decide who may do what with our data.

### **Control over data sharing**

Increasingly, online portals, PHEs and the MIDATA platform offer more control over data sharing. For example, the Medical Treatment Contracts Act (WGBO) makes it mandatory for physicians to maintain a medical record for each patient. Patients can request access to and a copy of these data, for example through an online portal. Which data are shared and with whom is usually subject to the patient's consent. The idea behind PHEs and MIDATA is to enable people to manage and share their data themselves, giving researchers and their other healthcare practitioners better access to those data, for example. These services also offer best practice examples of how people can in fact control their data. PKB's PHE, for example, uses an access log so that users can see who has had access to which data and with whom which data have been shared. At MIDATA, account holders

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124 Retrieved from <https://www.smart-circle.org/beyonddata/beyond-data/beyond-data-een-juridisch-perspectief/> in May 2018

125 Retrieved from <https://www.smarthealth.nl/2018/07/25/naast-het-medisch-beroepsgeheim-is-een-patientgeheim-hard-nodig/> in September 2018

delegate some of their authority to an ethical and scientific committee capable of taking informed decisions about sharing data with sound research projects. The individual account holders can also decide for themselves whether or not they wish to participate in such projects.

We cannot take for granted that all services share data securely and with our consent. PLM gives its users only one opportunity to decide whether or not to maintain control over their data. Once data have been shared, it is virtually impossible to regain control. Patients do not get a direct return on investment for the information that PLM shares with third parties. The health apps investigated in this study take the GDPR into account, but it is not clear with whom data are shared in every case. Some health apps have data sharing as a 'standard' feature, unbeknownst to the user (Zang et al., 2015). For example, an earlier study by the Rathenau Instituut (*De meetbare mens*, Geesink et al., 2016) describes a case in which an app automatically transferred data collected by an insulin pump to the manufacturer.

### 6.2.3 Influencing health

This section discusses the extent to which the various health data services offer feedback on users' behaviour based on their data, thereby helping them to change their behaviour.

#### **Digital twins**

The digital health data displayed in apps, portals, PHEs or public platforms create a 'digital twin' for us, as it were. Our digital twin consists of measures of our physical and mental health (and digitised versions of such measures, or calculations that produce a combined score). We may test our physical and mental fitness ourselves or, for example, have our doctors do so. PHEs and the MIDATA public platform combine several of these digital twins scattered across our various medical records, apps and home health monitoring devices into a single digital environment (Webster, 2002). Sharing the data of multiple digital twins is thus an important component of the double data loop (see Figure 3). As we collect more and more information from various sources, we also accumulate more and more details about the physical and mental health status of our 'digital self'. But does more information actually make us any the wiser?

Our study shows that in the case of online portals, health apps and PHEs, there are questions about the various components of the double data loop. What is the quality of the data collected? To what extent do the context and categorisation of

the data affect their analysis? And to what extent are our health data being used in a manner that we can understand?

Digital tracking and monitoring also causes people to feel detached from their bodies to a certain extent, as exemplified by the patient who told us about her experience of digital weight management. On the one hand, this may make it easier to reflect on and be honest about what the data mean. On the other, feeling detached from one's observed physical or mental state can lead to feelings of alienation. The extent to which people genuinely perceive a quantified representation of phenomena as themselves differs from one person to the next. In other words, all these numbers and values must also be made meaningful, by ourselves or by others. In the end, this also has implications for the extent to which we are willing or able to adapt our lifestyle behaviour based on feedback from e-coaches, for example. But do these data actually reflect how we interpret our present or ideal state of health?

### **Interpreting data in context**

Having an orderly overview of their health data does not automatically mean that users also understand what these data mean for their own health or their own healthcare process. Chronic patients often benefit from an overview because they know how to interpret their lab results, a point made by initial trials with PHEs and by the academic literature on self-management, empowerment and behavioural change using online access to data or mobile healthcare. Many chronic patients are capable of seeing the connection between changes in their lifestyle, their health and these results. Patients may also feel more confident about the data or advice when the information they see is properly structured.

Yet, not everyone understands what different health data tell them about their health and lifestyle, and such information can also mean different things to different people. Services respond to this by interpreting the data for their users. For example, online portals, PHEs and health apps display raw data in charts showing cut-off values. This interpretation or analysis helps us to understand what our digital twin's data are telling us about ourselves in the physical world. The services compare our data with those of others 'just like you', score our values in relation to 'the average', and may also tell us how we feel and whether there is any specific advice that might apply in our case. But, as shown in previous research by the Rathenau Instituut, a patient with rheumatoid arthritis does not always experience his or her condition the way a doctor would expect based on the parameters (Geesink et al., 2016).

The risk, according to our workshop participants, is that the far-reaching digitisation of health data and data sharing will rob people of the context and interpretation normally provided by healthcare practitioners. As a result, data of poor quality can

enter the double data loop and those who use these data, be they healthcare professionals, consumers or patients, will be unaware of or unable to gauge their quality. Whether we are talking about blood pressure, number of steps per day, or a consultation in hospital, context is always needed in addition to raw data. In the case of blood pressure, that means knowing when the numbers are too high and knowing the quality of the blood pressure monitor and the quality of the reading itself. Context subsequently produces knowledge that can help change behaviour.

### **Feedback according to standards**

The underlying idea is that we change our behaviour in the physical world by monitoring our health and lifestyle and by interpreting our digital data against standards of 'healthy behaviour' and our own attitudes towards healthy behaviour and wellbeing. The question is to what extent the information provided by the services actually leads to a change in our behaviour.

Earlier research by the Rathenau Instituut has shown that there is a considerable gap between monitoring aspects of health, such as blood pressure, and actually changing behaviour (Kool et al.2014). A change of behaviour requires several rounds of interpretation. Digital health data services compare the values we have recorded with standards of 'healthy behaviour'. In the case of the pedometer, we compare the number of steps we have taken to the 'standard' of 10,000 steps per day (Kool et al., 2014). The present study confirms that there are several rounds of interpretation. Patients who use online portals see cut-off values for their blood counts or fill in questionnaires and get feedback on the results. The message reads: 'You are feeling mentally vulnerable right now because you're not physically fit: your blood count indicates that you have low levels of iron in your blood.' The final round of interpretation is when we compare the readings and advice with our own attitudes towards healthy behaviour and wellbeing, or with the attitudes of our family and friends. We can then use this feedback to work on improving our health. In other words, our perception of our health depends increasingly on target indicators or on the standard that the service prescribes. But is that standard actually correct? For example, has it been validated?

Online portals, apps, public platforms and PHEs use gaming, defined targets, bonus systems and other mechanisms not only to give users structured information but also to help users to interpret data and to motivate them to change their behaviour. One example would be the mental health and addiction care online portals, which offer patients instruction videos and other guidance on coping with challenging situations (going to a shop) and changing their behaviour. It is often unclear to what extent such guidance – for example e-coaching in health apps – incorporates the most recent research on the best way to change lifestyle behaviour. Even so, controlled trials show that app-based e-coaching can be an

effective tool for improving users' physical and mental health (Rathbone & Prescott, 2017; Scott et al., 2018).

How limited is the image that the 'standard' gives us about our health? As our study shows, it is often unclear whether the advice that is supposed to motivate people to change their behaviour is actually the best advice for them, or even whether it complies with medical guidelines. There is no scientific basis for the 10,000-step regime, for example,<sup>126</sup> and it is certainly an unadvisable target for those suffering from pelvic instability; they should work on their health and build physical activity not by counting steps but in an entirely different way. Nevertheless, masses of people keep track of their daily steps and find it perfectly normal for others to do the same. Some services even encourage people to deliberately step outside familiar frameworks. For example, PLM urges patients to take a more experimental and investigative approach, one that may not always be in line with existing treatment protocols.

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126 Retrieved from <https://www.theguardian.com/lifeandstyle/2018/sep/03/watch-your-step-why-the-10000-daily-goal-is-built-on-bad-science> in October 2018

#### **6.2.4 Interim conclusion for ‘personal health management’**

Personal health management has various dimensions: decision-making alone or in consultation with healthcare professionals within the context of a service, responsible viewing and sharing of data, and regulating healthy behaviour. Not everyone is capable of handling all of these dimensions. We are not always willing or able to take every decision ourselves. Decision-making should not be seen as an individual process or responsibility, since the decisions we take depend largely on the context in which we use a service. For example, which decisions do we want others to take for us? Shared decision-making is recommended, but is far from common across services. Having access to our medical data and being able to share that data with others also gives us more control over our health data.

Our study of the four different types of service shows that before we can decide whether or not to share health data with healthcare practitioners and third parties, we must be aware of the different interests at stake. Interests other than our own can play a role: financial, social, or standards of healthy behaviour. These interests may conflict with those of an individual or of a group of care recipients. Unauthorised officials have already been known to demand access to a benefit claimant’s medical records, for example. Such situations make it difficult for people to trust that they do in fact control their health data and can share it with others confidentially. Transparency is needed not only concerning the way the collected data are shared and used but also with regard to the underlying revenue model on which the various developers and providers base their services. Our research shows, for example, that the three app developers and providers recognise the need to be transparent about their revenue model, but that there is no ‘watchdog’ for this yet. Mechanisms such as access logs (such as the one used by PKB) and patient confidentiality practices help boost public trust in personal data management.

The quality and reliability of the data entering the double data loop are a frequent topic of discussion. The literature on the various types of services and their contribution to cost-effectiveness, better quality of care, behavioural change or patient empowerment shows that not all patients benefit from using them (Jilka et al., 2015; Rathbone & Prescott, 2017; Scott et al. 2018). Yet, in the case of specific groups that use specific services in a clearly defined context, the ability to access and control their data appears to make them feel more in charge of their health. An evaluation of how services are used would provide more clarity but a straightforward list of the services on offer along with a trustworthy assessment of the reliability of data sharing and/or the quality of the service would also support people in their decision-making. Transparency on the part of services about pre-

programmed choices will help users to assess the value of the information and advice provided in their own situation.

It is clear that giving people access to their health data does not automatically mean that they understand their state of health and change their behaviour accordingly. Not everyone understands what the different health data tell them about their health and lifestyle, and the data can also mean different things to different people. The risk is that the far-reaching digitisation of health data and data sharing will rob people of the context and interpretation that healthcare practitioners provide. People must identify with the standards on which the services base their apps, and the underlying parameters must also be made known. In the end, it is up to the users of health data services to decide how they can and will use their data for the sake of their health.

## **6.3 Social and ethical issues**

The development and use of digital health data services is not only impacting our healthcare environment and healthcare system (Section 6.1), or the way in which we, as members of the public, manage our health (and control our health data) (Section 6.2). The parallel emergence of the various services and their networked nature, combined with more data sharing and data linkage, is also raising various social and ethical issues.

### **6.3.1 Consequences of combining data**

Exercising control not only means the ability to manage and share health information but also to protect and secure such highly sensitive data. Many best practice examples can already be found in this area. The EU's GDPR, the Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act (Wabvpz) and its associated general administrative regulation have put data protection and data security firmly on the map. Data security must meet the highest standards. MedMij-compliant PHE developers meet designated standards for secure and reliable data transfer. MIDATA focuses entirely on protecting the privacy of members. Data are stored on a secure server with a minimum of metadata. Of course, some services, such as lifestyle apps and, in our study, PLM, are less privacy-friendly and transfer data to other parties.

These improvements have not removed every concern about protecting our privacy and the security of our health data. The fact that people now also administer their digital health data through the various services may increase the pressure on them

to share these data. Healthcare professionals are also concerned that simply allowing people to make digital copies of their records for themselves may result in violations of medical confidentiality. The data are no longer protected under the Dutch Medical Treatment Contracts Act (WGBO) then. Additionally, people currently have little means of protecting themselves against external pressure. Moreover, once they have shared their information, it becomes possible to combine data from a mental health and addiction care portal with a lifestyle app, for example. That is precisely the sort of personal data – health- and non-health-related – that large companies combine and that can have adverse consequences for our society.

### **6.3.2 Clarity about control remains unclear**

Our four case studies (Chapters 2 to 5) show that there is still confusion about the exercise of control over health data among individuals, government and healthcare professionals. The formal and technical arrangements are already in place: we have legislation that governs control and it is facilitated by means of online access, PHEs and specified consent. But do people actually have the power to manage their own health and control their health data?

This study shows that we have less to say in the matter than expected. Data are categorised in advance, standards are embedded in the technology, and the data that underpin the advisory algorithms are unknown. It is especially important to recognise that embedding AI or machine learning into digital health data services can both augment and limit people's autonomy. There is so much information available that we scarcely know where to start, so having others organise and structure our data for us does support our decision-making. However, it is important for patients (or other representatives) to be involved in the structuring process and to help identify which decisions should be left to users.

### **6.3.3 Equal access and poor skills**

Ensuring equal access to health care in the digital transition is a prominent policy concern but it is also an evolving issue. The report *Weten is nog geen doen (Putting knowledge into action)* by the Netherlands' Scientific Council for Government Policy argues that people must not only have cognitive capacities but also the capacity to act on what they have learned (WRR, 2017).

#### **The pioneers, and the rest**

The expectation is that health data digitisation will be especially appealing to high-educated, white men or women who are already health conscious. It is also

expected to be beneficial for many chronic patients. For example, the most recent national eHealth Monitor survey revealed that 24% of the chronic patients surveyed had heard of PHEs (Wouters et al., 2018). Experience shows, however, that the target group is not always confined to high-educated people or chronic patients but rather consists largely of those who were already deeply engaged in their health.<sup>127</sup> To date, this is still quite a small group of patients. The case studies also show that until the various health data services are less labour-intensive to use (e.g. users have to log in several times to retrieve data or enter data manually in an app), they may well be embraced by chronic patients but not by the broader population.

### **Not everyone has the skills**

The question is to what extent those who so wish are actually capable of acting on the information provided by health data or on the feedback delivered by health apps or public platforms. We may be expecting too much (Mackey et al, 2016). In addition to having the necessary digital skills, people must be able to interpret their digital health data correctly. This means collecting and assessing information, understanding the situation and context, setting goals, taking action and implementing plans, sticking to a plan and coping with the related emotions. It is precisely those groups most likely to call on the healthcare system – the elderly, people with a low socio-economic status, the intellectually impaired, the illiterate, people with serious mental or complex disorders, and migrants – who often lack the above skills.

### **Awareness of the ‘digital health divide’**

Digital health data services can both narrow and widen the digital health divide. The digital healthcare gap is the gap between people who make basic and more passive use of the internet and people who take a more creative and in-depth approach to health matters online. Generally speaking, people in the former category have a lower socio-economic status and a lower level of education, although this is certainly not always the case (Prainsack, 2018). Platforms such as Kijksluiter and online portals such as Karify, Therapieland and Minddistrict, which use accessible language and a lot of visualisations, are broadly accessible. At the same time, we still see many services that do not reflect the life experience and perceptions of people with low literacy levels, for example.

Digitalisation should be an option, not an obligation, and there must be alternatives for those unwilling or unable to take that route. The Rathenau Instituut has already argued for two ‘new human rights in the robot age’, the first being the right to not be measured, analysed or coached.

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<sup>127</sup> Digital Healthcare and Ethics meeting (‘Digitale Zorg en Ethiek’) organised on 22 November 2018 by Nictiz and ECP

It is important for healthcare professionals and patients that digital health data services are not merely a means to increase the efficiency of healthcare. This brings us to another new ‘human right in the robot age’ previously advocated by our institute, i.e. the right to personal, human contact. Potential improvements in the efficiency of healthcare benefitting those willing and able to participate in the digital transition should also be shared with those who are unwilling or unable to do so. If healthcare insurers and government start requiring healthcare providers to furnish a percentage of their healthcare online, the healthcare gap may extend from patients who are unable to participate to healthcare practitioners who are unable or unwilling to do so. Now that government is committed to increasing the use of online portals and PHEs, the freedom to use or not use such portals and PHEs is under fire.<sup>128</sup>

### 6.3.4 Health as the standard

Digital health data services use lifestyle and health data to draw conclusions about people who have similar traits. As a result, we can expect healthcare to be personalised but personal health management to be standardised.

#### **Standardising personal health management**

It is becoming increasingly common for health data services to be used in situations outside the healthcare domain, for example when people wear devices with sensors or share data with researchers through a data vault. Health data services are creating a new market for tracking, monitoring, and disciplining the body, lifestyle and behaviour (Kool et al., 2014), and in that sense they are standardising the way we take responsibility for our health. For example, PHEs may intensify two (contrary) trends: on the one hand, the ‘medicalisation’ of health (because we ‘know too much’) and on the other hand, ‘lifestylisation’ (because we are increasingly able to quantify behaviour and health status and because we can problematise ‘poor lifestyle’).

That means it can also become ‘normal’ for healthcare professionals to ‘prescribe’ these services for patients. Other stakeholders, such as healthcare insurers and employers, may also have a stake in our growing tendency to monitor ourselves continuously and share health data, for example because they want us to be physically and mentally fit for work.

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128 Certainly when the underlying subsidies maintain such criteria as ‘At least 10% of patients who have had (DTC-relevant) contact with the hospital in the past 30 days have logged into the patient portal’, and ‘In the past 30 days, 25% of all patients (based on DTC contacts) have logged in to the patient portal or the link to a PHE’.

### **Data sharing as a public good**

We see tension in the various initiatives between having access to data for our own use and sharing data for a public purpose. Some of these initiatives, such as MIDATA, consider our health data not as a personal asset but as a public good. They frame health as a shared goal and this means that data must be shared, but also that, as a public good, data must be well protected. Instead of collecting data for individual purposes, we collect and share data for a common purpose: to improve public health and prevent and cure diseases. The Dutch Minister for Medical Care, Bruno Bruins, recently referred to this as ‘data solidarity’.<sup>129</sup> Data solidarity is the sharing of data for the public good of health. Not only the government, but also researchers (Prainsack, 2017, 2018) and the developers of health data services such as MIDATA emphasise data solidarity.

But how much solidarity do we have with people who, according to research, incur higher health costs due to unhealthy behaviour or a significant probability of illness? Are we still prepared to organise and pay for their healthcare? As one commentator put it, ‘More than ever, people are responsible active consumers who take decisions based on transparent information and who, as responsible citizens, do what is necessary and pay for it themselves’ (Dehue, 2014, p. 236). How much solidarity do we feel with people who end up victimised, for example because they have shared data with dubious parties or because they have been given a wrong diagnosis based on misinterpreted data?

Data solidarity may therefore conflict with the principle of solidarity on which our healthcare system is based, especially if the data are misused. Data sharing contributes to analysis and profiling. The predictive capabilities of algorithms and profiling make it possible to define or make explicit who is ‘healthy’ or ‘exhibits healthy behaviour’ and who not. When profiling is no longer used to help people but to label them as ‘problem cases’, the result may be exclusion from healthcare and supplementary insurance. Unwanted profiling can also lead to an imbalance in the supply of healthcare or even to poorer quality healthcare.

### **6.3.5 Interim conclusions for ‘social and ethical issues’**

The rise of digital health data services not only has consequences for the organisation of healthcare or for us as individual citizens, but it also has a far-reaching impact on the way we organise our society. Encouraging control activates

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<sup>129</sup> Kamerstukken II 2018/2019, *Kamerbrief Data laten werken voor gezondheid*, 15 November 2018, Reference 1440757-183490-DICIO

individuals to take (better) control of their health. This study shows that it is precisely this control that still needs to be fleshed out in everyday life.

At the same time, the message is that it is important to work on maintaining or improving our health, and that data sharing is part of this. What is now a right, i.e. to share data and to work on being healthy using health apps, may become an obligation. Profiling is useful for personalising ehealth advice, but it also has drawbacks. In recent years, privacy and security have improved considerably, making data sharing increasingly reliable. The arrival of more and more services and the growing tendency to encourage people to share their data for 'a greater good', however, opens a back door, and perhaps even a front door, to jeopardising the careful handling of sensitive health data. Data solidarity might run counter to the principle of solidarity on which our healthcare system is based when data is mishandled or misused.

## **6.4 Conclusion for 'overarching analysis'**

The parallel emergence of the various health data services and their networked nature, combined with more data sharing and data linkage, is having an impact on healthcare, on individuals, and on society as a whole. To understand this impact, we need to look at trends and developments both within and outside healthcare. As our health data are digitised and become easier to share, combine and analyse, we not only gain more control over those data ourselves but we also relinquish control, for example to large companies that are not based in the Netherlands and are less concerned about the Dutch healthcare context and the arrangements that apply here.

This study shows that there are consequences when data sharing is unreliable, especially when people are offered easy access to more sensitive data. The ambiguous status and hybrid nature of the different services – are they medical tools or consumer products? – heighten the uncertainty and complexity. Apps that can link to PHEs and online portals, data uploaded to public platforms: it is unclear who is in control over what and when. When data from different sources and of varying quality are combined, uncertainty ensues about their reliability and their use within the healthcare system. Poor quality data are shared without users, patients, individuals or professionals knowing this or being able to assess their quality. The result is bad advice and a potentially adverse impact on health. Using unknown, non-transparent algorithms to profile patients/people may lead to decisions that have far-reaching consequences for us. All too often, there is a lack of transparency about the use of algorithms and the underlying revenue models of the various services. 'Personal health management' becomes 'health management by others'.

Medical data can leak out of PHEs and online portals through the least secure party in the chain. People and healthcare professionals who use medical devices or medical apps have no protection in that case. The information may be viewed by unknown third parties or used by new providers of healthcare or insurance that are not regulated in the medical domain or outside the Netherlands.

The monopolisation of health data by large companies is of particular concern. These companies, but also institutions, can combine health data with non-health data from other sources and thus generate profiles. Examples include the partnerships between PLM and pharmaceutical companies, but also between apps, community health services and Bol.com (the 'Dutch Amazon'). Our investigation of public platforms has revealed that companies or institutions need a critical mass of data to survive in the current data economy. It is difficult for smaller cooperatives to keep their heads above water, even though they in particular set a good example of responsible data management. Because large companies are powerful and have easy access to data, the consequences can extend beyond the health domain and into work, relationships, mortgage lending and public life. An app that has been approved could then put medical and health data into the hands of third parties. The information would not be used for the benefit of the relevant individuals and could lead to exclusion or discrimination based on profiling.

The four previous chapters have already explained how these digital services are changing relationships in healthcare. This change creates opportunities but also poses risks to the high standard of healthcare in the Netherlands and the pursuit of personal health management in a way that has a lasting, positive impact on both individuals and society.

The linking of health data can further disrupt relationships in the health domain and beyond. The developers of digital services in the healthcare sector, government and patient associations are aware of this. In recent years, we have witnessed a reversal in the tendency to release or link as much data as possible. Responsible parties are cooperating in living labs and test environments on using data that will improve healthcare and produce evidence-based interventions. In this context, the point is not to collect as much data as possible but to ensure good data quality and meaningful analysis leading to better healthcare. This is consistent with what the Rathenau Instituut calls 'directed digitalisation', where the focus is on the goal of better health and – whenever possible – personal health management and where such public values as privacy, autonomy, quality healthcare, shared decision-making and inclusion are at the centre. The Netherlands is a global leader in this respect. The revenue model that underpins these services is not based on selling data or creating money-making profiles but on offering data services, or rather high-quality healthcare and prevention services (ehealth).

Governance of healthcare digitalisation, a government task, should therefore no longer focus on encouraging as much sharing of as much data as possible, but on recognising excellent initiatives that are being developed explicitly in a healthcare context. There are plenty of best practice examples. Government should also monitor initiatives and products that make health claims but do not live up to them and ultimately undermine healthcare. The close relationship between the various digital health data services magnifies existing challenges in such areas as certification and quality control, insurance coverage for services and healthcare, liability, and health data security. It appears that we are tackling each of these challenges separately. We have a certification regime for medical (non-lifestyle) apps and for PHEs, but not for online portals and public platforms. We must also consider effects that lie beyond the quality of care but concern the healthcare system and society as a whole.

The ideal scenario is to manage, share and combine digital health data, but we want too much and we want it too soon. The existing services are only evidence-based for part of the population, i.e. for chronic patients, for people in good health and for a healthcare context that supports the integration and improvement of digital services in the work and healthcare process. In the opinion of the Rathenau Instituut, 'health at the centre' should be the new ideal and involve services that are used purposefully and in accordance with best practices, as explained in this report. This brings us to the three main conclusions of this report:

1. There are no frameworks governing the use of digital health data services and no coordination of such use, either in the medical domain itself or in its interaction with the non-medical domain.
2. There are not enough safeguards in the data chain, i.e. the processes of generating, accessing, sharing and using health data.
3. There are limits to personal health management; access to healthcare and health is not sufficiently guaranteed.

Chapter 7 discusses what actions can be taken for each conclusion.

## 7 Conclusions and possible actions

The digitisation of health data creates opportunities for better, more personalised healthcare and is meant to help people to participate in their healthcare process and to improve their health. Various digital services will make it possible to share and use electronic health data.

In May 2018, the Rathenau Instituut published the report *Responsible digital health management. More data, more control?*, which examines how the Netherlands is developing and implementing a system for accessing and sharing health data digitally. The report concludes that stakeholders are not looking closely enough at the changes that will be necessary in healthcare practice, at the different types of patients and their needs, at the role of healthcare practitioners in implementation, or at the use of digital data by third parties outside the healthcare system. The study showed that, as development of the system of digital access and sharing of health data proceeds, a broader discussion of digital health management will be needed.

The present report focuses on the parallel emergence of various digital services for accessing, sharing and using health data. Chapters 2 to 5 described online portals, PHEs, health apps and public platforms in that order, in each case detailing the service's functionalities, the stakeholders, their interests and responsibilities, the practical implications of using the service, and to what extent it can empower people to manage their health. Chapter 6 followed with an overarching analysis of how these digital health data services are affecting healthcare practice and the healthcare system in the Netherlands and the extent to which they help people to better manage their health. Chapter 6 also addressed the social and ethical issues raised by the development and use of these services.

The chapter closed with three overarching conclusions:

1. There are no frameworks governing the use of digital health data services and no coordination of such use, either in the medical domain itself or in its interaction with the non-medical domain.
2. There are not enough safeguards in the data chain, i.e. the processes of generating, accessing, sharing and using health data.
3. There are limits to personal health management; access to healthcare and health is not sufficiently guaranteed.

Chapter 7 links each of these conclusions to relevant trends and developments. In each case, it also discusses which actions can be taken to ensure that digital data services support personal health management in a manner consistent with our

shared concept of society, in which people and patients act autonomously when they can and receive professional help when they need it.

## **7.1 No frameworks, no coordination Conclusion 1: There are no frameworks governing the use of digital health data services and no coordination of such use, either in the medical domain itself or in its interaction with the non-medical domain.**

Chapter 6 found that the impact of data sharing extends beyond the healthcare domain. As it becomes more commonplace to use digital health data services and to share our data, we can expect to see far-reaching effects on our healthcare system. The various health data services will be increasingly interlinked, with health data circulating outside the familiar doctor-patient relationship on an ever-widening scale within a network of public and private partners. So far, rules applicable within the medical domain (e.g. medical ethical reviews) are not being informed by rules outside that domain (e.g. the GDPR) or vice versa. It would be advantageous if they did inform each other, however, since non-medical data can also tell us something about our health. Healthcare professionals are concerned about the confidentiality of medical information when digital copies of that information are removed from their control. The introduction of digital health data services thus has consequences for relationships within the healthcare sector, requiring the clarification or new allocation of responsibilities for accessing and sharing health data and the quality of care. There are no legal or conceptual frameworks that impose a broader social responsibility on service providers, healthcare providers or companies, nor is there any proper coordination of their development.

### **7.1.1 Frameworks and coordination: current trends and developments**

#### **Working on the basic infrastructure**

Government is working with healthcare parties on the basic infrastructure for health data accessibility and interoperability.<sup>130</sup> It is doing so through the Dutch National Health Information Council (Informatieberaad Zorg, a partnership between representatives of the healthcare sector and the Ministry of Health, Welfare and Sport), the Trust Framework of the MedMij Programme, and programmes such as the VIPP schemes for medical-specialist care and for mental health and addiction care, the VIPP Care scheme, and the OPEN Programme. Key stakeholders, including government agencies, the Dutch Patient Federation, the Association of

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130 Kamerstukken II 2017/18, 27529 nr. 156. *Visie digitaal ondersteunde zorg en uitwerking actielijnen.*

Healthcare Providers for Healthcare Communication (VZVZ) and overarching healthcare organisations, have cooperated on establishing the Healthcare Information Modules and the Basic Healthcare Data Set. Nictiz advises on interoperability standards commonly used in the medical domain with a view to clarifying and supporting a uniform language (recording information from the healthcare process unambiguously for multiple use so that patients and caregivers can have access to the required care information anytime and anywhere) and machine-readability.<sup>131</sup>

Referring to faltering progress in IT within the healthcare sector, the Minister for Medical Care, Bruno Bruins, recently stated in a Letter to Parliament that he wants *'...to take concrete steps towards making electronic data exchange in accordance with the appropriate information standards a statutory obligation. I will also ensure that all parties fulfil their role and achieve results'*.<sup>132</sup> His aim is to lay down a statutory basis for digital data transfer in the healthcare domain that emphasises secure transfer, privacy of transfer and the anticipated improvement in the quality of healthcare. He is less concerned about the impact that data transfer is having on the entire system of digital services that are willing and able to share data.

### **Cooperation with developers changes healthcare practice**

Healthcare providers and government are interested in the better integration of digital health data services within healthcare practice, for example by modifying existing healthcare processes. Developers also play a role in this context. For example, the developers of online portals can offer feedback on how portals are used by both healthcare professionals and patients so that providers and professionals can learn how best to integrate the portals into their healthcare practice. Little of this knowledge is shared, however. A recent government initiative, the 'Zorg van Nu' website,<sup>133</sup> surveys all manner of technological solutions, but offers little information about their quality or their implementation in healthcare practice.

### **Financial resources**

The various subsidies that have been made available and government's position that a 'market for PHEs must be created' show that there is financial support for the basic infrastructure for data transfer between healthcare professionals and patients. A sustainable revenue model has yet to be found, however. Services focusing on specific target groups, such as chronic patients, are an exception to this.

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131 Retrieved from <https://www.nictiz.nl/standaardisatie/interoperabiliteit/> in November 2018

132 Kamerstukken II 2018/2019 *Elektronische gegevensuitwisseling in de zorg*, 20 December 2018. Reference 1456422-184986-DICIO

133 Retrieved from <https://www.zorgvannu.nl/> on 15 January 2019

### **International developments**

Progress is also being made on health data transfer abroad. The Netherlands is working with other EU Member States to make patient summaries – abridged versions of medical records that summarise the most important information, such as medications – available throughout Europe. While this will encourage secure and reliable data transfer, there is less concern for the impact of improved data sharing on relationships in healthcare, or for a new allocation of responsibilities; that is now up to the developers of digital health data services and healthcare professionals. For example, the EU is developing a Privacy Code of Conduct on mobile health (mHealth) apps,<sup>134</sup> but app developers scarcely if ever reference the use of this code in their work.

### **7.1.2 Actions that can clarify or update frameworks and coordination**

#### **1. Establish ownership of the various responsibilities, including liability in medical interventions, more explicitly in agreements**

It is clear that no one ‘owns’ many of the constituent problems (interoperability, organisational obstacles, privacy, liability if something goes wrong), especially in the less regulated non-medical domain. Ownership needs to be established at all levels, whether it resides with individuals/patients, medical professionals, developers, health data platforms, researchers or government. Clarify existing agreements and allocate responsibilities, for example healthcare professionals’ liability when using data originating from their patients’ digital services, and the responsibility of individuals when sharing their data with third parties, including an explanation of what could happen if they are not careful about sharing.

#### **2. Establish broad codes of conduct for the development of services, including services that lie outside the medical domain**

Ensure that common (action-ethical) frameworks and forms of oversight within the medical domain can also be used in or adapted for the less regulated non-medical domain. For example, a code of conduct for developers and service providers, even those that make use of artificial intelligence, would extend the scope of responsibility and awareness beyond data security and privacy alone. Examples include the codes of conduct that the European Commission has already initiated with regard to disinformation and privacy in mhealth, and the Artificial Intelligence

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<sup>134</sup> Retrieved from <https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-been-finalised> in December 2018

Impact Assessment (AIIA) recently launched by Electronic Commerce Platform Nederland and TNO.<sup>135</sup> These codes of conduct should contribute to transparency about which data are transferred, data quality and what advice can be based on data.

### **3. Maximise learning from best practices in healthcare**

Governance of healthcare digitalisation, a government task, should no longer focus on encouraging as much sharing of as much data as possible, but on recognising and implementing excellent initiatives. Healthcare providers, service providers and the general public will all benefit if we can learn from existing best practices when using different health data services within healthcare. The knowledge generated in the meantime, for example through the subsidised VIPP programmes, should be disseminated more effectively. Organise a platform or other mechanism to identify best practice solutions both for the technology itself and for its practical implementation and evaluation.

## **7.2 Not enough safeguards in the health data chain**

### **Conclusion 2: There are not enough safeguards in the data chain, i.e. the processes of generating, accessing, sharing and using health data**

Digital health data services are in fact a technical solution that gives people control over their data and allows them to share data confidentially with others. The Netherlands is still in the process of developing the data transfer system within the healthcare sector and between the traditional healthcare domain, the personal domain of individuals, and commercial parties. As a result, trust mechanisms are, as yet, underdeveloped. This is about trusting ourselves; trusting our capacity to think and act when accessing, checking, interpreting and sharing (or consenting to share) our digital health data. We must trust that we are not alone in this but can make the right decisions in cooperation with healthcare professionals and/or loved ones. But we must also be able to trust the quality and reliability of the services and the data that are shared.

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<sup>135</sup> Retrieved from <https://ecp.nl/wp-content/uploads/2018/11/Artificial-Intelligence-Impact-Assesment.pdf> in November 2018

## 7.2.1 Current actions for building trust in the health data chain

### Government and semi-public programmes

Policymakers are taking various steps to build trust in individuals' ability to manage and share data. In his Letter to Parliament, *Data laten werken voor gezondheid* (Let data work for health), Minister for Medical Care Bruno Bruins explains the measures he is taking to secure this trust, including making data more accessible and encouraging PHEs.

The Structural Specified Consent (GTS) Programme is working to make specified consent transparent. However, with the number of specified consent decisions expected to exceed 150, the system is anything but clear and user-friendly, which means that it offers no support in decision-making.

Government is encouraging us to develop our digital skills through the cross-ministerial programme NL DIGIbeter.<sup>136</sup> It is encouraging developers to design applications to be intuitive and inclusive.<sup>137</sup> Nevertheless, it can be difficult to get cooperation with interested parties and stakeholders on new technologies off the ground. The minister assumes that healthcare professionals will have more confidence in our ability to manage our health data when more effective arrangements are put into place for protecting the medical data held by individuals. The Ministry of Health, Welfare and Sport has asked the Dutch Patient Federation to investigate how patient confidentiality (as described in Chapter 6) might improve protection of sensitive data outside the medical domain.<sup>138</sup>

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### Quality marks for security and quality, and oversight

There is a wide array of different services that promise to support us in accessing, managing and sharing our health data. The public is more likely to trust a service when it is certified or provided through a healthcare professional. The guidelines, certifications and labels are diverse, however, and hard for ordinary people to understand. Best practice examples can be found in such Dutch initiatives as the GGD AppStore, the KNMG Medical App checker and NeLL and, outside the Netherlands, in the NHS Apps Library. Regarding PHEs, the MedMij Foundation provides certification and oversees the information flows between PHE suppliers, healthcare providers and the public. In doing so, it ensures the secure flow of data but not the quality of the services' content. It also says nothing about what happens

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136 Retrieved from <https://www.digitaleoverheid.nl/wp-content/uploads/sites/8/2018/07/nl-digibeter-agenda-digitale-overheid.pdf> in November 2018

137 Kamerstukken II 2018/2019 *Kamerbrief Data laten werken voor gezondheid*, 15 November 2018, Reference 1440757-183490-DICIO

138 Retrieved from <https://www.patientenfederatie.nl/nieuws/voorkom-dat-patientgegevens-vogelvrij-worden> on 22 January 2019

to the data when they are delivered to another service or party. No such initiatives or oversight mechanisms exist for online portals and public platforms. So far, the Health and Youth Care Inspectorate (IGJ) has limited itself to monitoring product safety and the safe use of products. The IGJ is the designated oversight authority under the Medical Appliances Act (WMH). But not every app or other example of ehealth is a medical device; the StressCoach and SamenGezond apps do not fall under the IGJ's supervision, for example. The IGJ also ensures that the use of digital health data services by healthcare institutions leads to good and safe healthcare.

### **Improving the quality of collected data**

In addition to medical data, we increasingly generate data ourselves using self-tracking devices and by reporting our observations and experiences. Research specialising in converting these 'raw' data into relevant data is under development. For example, special algorithms can extract valuable information from open text fields, or raw self-tracked data, and not only in medical records but also from platforms such as Patients Like Me. Public platforms such as MIDATA or OpenHumans categorise and standardise data in the same way in an attempt to control the continuous production of data.<sup>139</sup> An important development at international level is data documented in accordance with the FAIR principles.<sup>140</sup> These principles ensure that data are Findable, Accessible, Interoperable and Reusable and that they are kept permanently for analysis or research. The FAIR principles show that data and algorithm quality have become more prominent issues on the policy and research agenda. At the same time, experience shows that making datasets FAIR is a laborious and time-consuming process.<sup>141</sup>

## **7.2.2 Actions for building trust in the health data chain**

### **4. Build on the concept of patient confidentiality and supplement it with technological citizenship**

People must trust that they are in fact capable of taking charge of their own data. Because they themselves are the 'source holders' or owners of the health data used by the various health data services, they are also accountable for responsible sharing, both within and outside the medical domain. The individual patient rights that apply within the medical domain, such as self-determination and privacy, are inadequately guaranteed outside the medical domain. Building on the concept of

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139 During the BeyondRCT conference (25 September 2016), Bastian Greshake Tzovaras of Open Humans and Juuso Parkkinen of MyData talked about their efforts to get a grip on the data in their data vaults, for example.

140 Retrieved from <https://www.force11.org/group/fairgroup/fairprinciples> in January 2019

141 Retrieved from <https://www.scienceguide.nl/2018/07/hoefairmoetenopendataensoftwarezijn/> in January 2018

'patient confidentiality' will make a significant contribution to protecting people and their data outside the medical setting.

Patient confidentiality can be complemented by 'technological citizenship', a broader set of rights and duties that ensures that people are skilled, resilient and capable of engaging in debate. *'Technological citizenship is the collection of rights and duties that makes it possible for citizens to profit from the blessings of technology and protects them against the attendant risks. In our digital age, it not only concerns such risks as breaches of privacy or identity theft but also long-term issues such as what kind of people we want to be'* (Van Est, 2016).<sup>142</sup> In practical terms, this means that we must continue to invest in the digital skills of the public and professionals. There are limits to these skills, however, and so people should also be able to turn to an authority or fund, for example, where they can receive guidance about data sharing (for example, by means of dashboard<sup>142</sup> that provides an overview and helps them understand what they control), and where they can seek redress if data are shared or used unlawfully or result in an incorrect diagnosis or change in behaviour.

#### **5. Define precisely what shared decision-making entails**

We must be able to trust that there are healthcare professionals and/or loved ones who are willing and able to help us decide on questions of data access, data management and data sharing. Decision-making is not always a solo responsibility. It is important to clarify who is responsible for initiating shared decision-making between healthcare professionals and patients about data components: the healthcare professional (and which one?), the individual, and/or an independent third party? The combination may differ depending on the healthcare context and service involved. In addition to specified consent, we should be investigating dynamic forms of consent such as those used in MIDATA.

#### **6. Make safeguards ensuring the quality and reliability of data and data sharing transparent and put appropriate oversight mechanisms into place**

We must be able to trust the quality of the services and the data that they use and share. Developers of services should be required to explain how they guarantee the quality and reliability of data (e.g. when collecting data themselves through an app) and data sharing. This not only means that they should, where required, have the necessary CE Mark but also that they should provide explanations that are comprehensible to the user, for example about the medical standards that they have applied.

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142 One example would be TNO's Privacy Dashboard, which it developed for pregnant women.

The **quality mark of the MedMij Foundation** only covers the quality of data transfer from PHEs, and not the quality of the service itself or the quality of other services (or their data transfer). And PHE providers that enter the health market without the MedMij quality mark cannot be excluded. Oversight of these parties must be regulated in some other way, so that unwelcome services that put the quality and reliability of data and data transfer at risk can also expect to be penalised.

There should also be greater clarity about the status of such organisations as NeLL and the GGD AppStore and the way in which they complement quality marks and oversight by the IGJ and the Dutch Data Protection Authority (AP). These organisations can only advise and cannot intervene if apps do not meet quality standards. Moreover, the criteria against which the various services are evaluated as ‘secure’ and ‘trustworthy’ are not transparent. In addition, there should be independent quality marks for every type of service. See that the criteria used to assess the various services are drawn up by experts and patient representatives, as is the case with NeLL or MedMij. The AP and IGJ ‘watchdogs’ should cooperate, for example to exclude providers that do not have the MedMij label (or other quality mark for services other than PHEs).

## **7.3 Limits to personal health management**

**Conclusion 3: There are limits to personal health management; equal access to healthcare and health is not sufficiently guaranteed.**

Digital health data services give people the right to control their health data. Those who are willing and able to do so assume responsibility for sharing their health data. But in reality, the voluntary nature of such control is under threat. To persuade people to share their data in support of healthcare for themselves and others (and to make it more affordable), we need more comprehensive safeguards addressing the voluntary nature of data sharing and the real benefits for personal health management.

### **7.3.1 Voluntary nature of services: current trends and developments**

#### **Agenda-setting by government**

Government explicitly wants control over data sharing to be available to all those who are willing and able, but it does not want such control to be regarded as an

obligation. *'The quality of healthcare should not be different for people who are unable or unwilling to take control.'*<sup>143</sup> In addition, the Dutch authorities have recently drawn attention to the social and ethical issues that accompany data and big data analyses in the health and healthcare domain. The Minister of Medical Care intends to put human rights and data analyses (including artificial intelligence, self-learning algorithms, big data, etc.) on the agendas of existing consultative bodies and has instructed the Netherlands Centre for Ethics and Health (CEG), for example, to publish *a monitoring report on ethics and ehealth*. Agenda-setting by government is important but it will not necessarily get the developers of digital health data services and/or their users, including healthcare providers, healthcare professionals and consumers, to address the relevant social and ethical issues. Our study shows that real-world complexity makes it difficult to guarantee the voluntary nature of the services and access to healthcare.

### **7.3.2 Actions for guaranteeing the voluntary nature of the services**

#### **7. A governance system must be established that will strike the right balance between the individual and the collective interest.**

Individuals may benefit from having access to their digital health data and from being able to share those data with others – for example because they can then participate in decisions about their own health process – but such data also have a collective value for research that focuses on improving public health. At the same time, access to digital health data should not exacerbate the strain on the solidarity framework that underpins the Dutch and European healthcare systems. Developers of services, healthcare providers, patient representatives, government and companies will have to work together to protect and promote individual autonomy, to ensure careful and secure data sharing for the public good, and to guarantee a solidarity-based healthcare system. What this requires is the participation of the public and feedback from parties with whom we share our health data. For example, what do researchers do with our data? How concerned are health data services about people's digital skills (limited or not) and how do service providers involve the public in developing their services? The fund mentioned under Action 4 can also play an important role here, encouraging people to share data but also seeing that they are compensated if something goes wrong.

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143 Kamerstukken II 2018/2019 *Kamerbrief Data laten werken voor gezondheid*, 15 November 2018, Reference 1440757-183490-DICIO

**8. Never lose sight of the right to not be measured, analysed or coached and the right to meaningful human contact.**<sup>144</sup>

People who are uninterested in digital healthcare services must also be able to depend on receiving good quality healthcare and on having equal access to healthcare. Healthcare providers and patient representatives must continue to stand up for these people, even if health insurers and government insist on more efficient and cost-effective healthcare.

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144 In its report *Human rights in the robot age: Challenges arising from the use of robotics, artificial intelligence, and virtual and augmented reality*, the Rathenau Instituut argues that existing human rights should be upgraded and clarified and that two new human rights should be established (Van Est & Gerritsen, 2017). First of all, people should have the right to not be measured, analysed or coached, the right to refuse online profiling, tracking and coaching. Second, people should have the right to meaningful human contact, the right to choose human contact above contact with robots. These two new human rights must also be applied when using digital health data services in healthcare.

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## Appendix A: Respondents and guidance committee

### List of stakeholders and experts interviewed

Name	Organisation	Subject
André Boorsma	TNO	Apps
Arina Burghouts	MedMij	PHEs
Bettine Pluut	Nictiz / ESHPM	EHR / PHEs / general healthcare digitalisation
Client A		Online portals
Client C		Online portals
Client K		Online portals
Client L		Online portals
Client M		Online portals
Client S		Online portals
Floor Borgonjen	Philips VitalHealth PHE	PHEs
Gaston Remmers	Mijn Data Onze Gezondheid	Public platforms
Geert Munnichs	Rathenau Instituut	EHR / general healthcare digitalisation
Guido van 't Noordende	Whitebox	EHR/ PHEs
Harm-Jan Wessels	Philips (Forcare)	general healthcare digitalisation
Henk-Jan Zwolle	Stresscoach app	Apps
Hero Torenbeek	VitalHealth	PHEs
Inkie Theus	Karify	Online portals
Jaco van Duivenboden	Nictiz	EHR/ PHEs / general healthcare digitalisation
Jan van der Beek	Carepoint / Patients Know Best	PHEs
Jarno Meijer	Therapieland	Online portals

Jeroen Pronk	Menzis Samengezond	Apps
Joeri Veen	Menzis Samengezond	Apps
Johan Krijgsman	Health and Youth Care Inspectorate (IGJ)	EHR / general healthcare digitalisation
Kamal de Bruijn	Ministry of Health, Welfare and Sport	PHEs
Koen Hogenelst	TNO	Apps
Marc Lenselink	Chipsoft	EHR / PHEs / general healthcare digitalisation
Marcel Heldoorn	Dutch Patient Federation	PHEs
Marieke Timmer	Orikami (MS Sherpa app)	Apps
Marike Wijnberg	Menzis Samengezond	Apps
Marion Driessen	Ministry of Health, Welfare and Sport	EHR
Marlene Gigase	Positive Health Accelerator / Ivido	PHEs
Matthijs Spruijt	Therapieland	Online portals
Pieter Jeekel	Zelfzorg Ondersteund	PHEs / general healthcare digitalisation
Remco Timmer	Philips VitalHealth PHE	PHEs
Robbert Smet	Philips	PHEs / general healthcare digitalisation
Roderik Kraaijenhagen	Vital10	PHEs
Rozanne van Diggelen	Karify	Online portals
Suzanne Baars	Human Genome Foundation	Public platforms
Tjarda van der Groot	Ministry of Health, Welfare and Sport	EHR
Wouter Heijnen	Totem Open Health	PHEs / general healthcare digitalisation

**Digital Personal Health Management workshop, list of participants**

Rathenau Instituut, The Hague, 30 May 2018

Name	Organisation
Wouter Tesink	VZVZ
Eugène Loos	University of Amsterdam
Robbert Smet	Philips
Erwin van Boxtel	Thebe
Joel Buiter	Health and Youth Care Inspectorate (IGJ)
Esther Bloemen	Zuyd University, Personal Health Train
Alf Zwilling	VZVZ
Andre Boorsma	TNO
Jaco van Duivenboden	Nictiz
Maartje Molenaar	Chipsoft
Lidewij de Bont	KNMG
Arina Burghouts	MedMij
Jochen Mikolajczak	Ministry of Health, Welfare and Sport
Wouter Heijnen	Whitebox
Elisabeth van Schaik	IKONE
Bettine Pluut	Nictiz
Robbert van Bokhoven	Pharos
Evelien Vos	Chipsoft
Anja Moonen	Zilveren Kruis

**Guidance committee for the Health Data Project, June 2017- January 2019**

Position	Name	Job title
Chairperson	Roshan Cools	Rathenau Instituut Board, professor of Cognitive Neuropsychiatry at Utrecht University
Secretary	Maartje Niezen, on behalf of Melanie Peters	Senior project coordinator / researcher for the Digital Health theme
Member	Hester van de Bovenkamp	Associate professor of Political Science / Health Care Governance at Erasmus University Rotterdam
Member	Tamar Sharon	Associate professor at Radboud University
Member	Marleen Stikker	Waag Society
Member	Tineke Slagter-Roukema	General practitioner, former chairperson of the EHR Expert Committee in the Dutch Senate. Also former chairperson of the supervisory board of Martini Hospital and chairperson of the Dutch National Association of General Practitioners (LHV).
Member	Sjaak Nouwt	Legal specialist at KNMG

Erik Gerritsen, Secretary-General of the Ministry of Health, Welfare and Sport, was also involved in setting up the project and kept the research team abreast of relevant developments throughout the project.

## Appendix B: Method

We consulted 40 respondents in all by conducting 25 interviews and 11 discussions and by organising a workshop on digital personal health management for 19 respondents. Of these, nine were experts, seven patients / patient representatives, two healthcare providers (one of which was also a developer), four policy makers, 25 developers/spokespersons of digital service providers, and eight other stakeholders. Appendix A lists all the respondents and their job titles. We consulted a relatively large number of developers to ensure that we could describe the various services accurately in this report. They outnumber the experts and other stakeholders, such as patient representatives. However, many of the developers do collaborate with patients and physicians.

The interviews in this study were semi-structured (open questions). The topic list was modified depending on the type of health data service. The interviews were face-to-face and lasted about an hour. They were recorded using audio equipment and transcribed verbatim. We also held discussions in both the exploratory phase (October/November 2017) and the concluding phase (October/November 2018). There are no recordings of these discussions, only minutes of the meetings. Three researchers, Maartje Niezen, Rosanne Edelenbosch and Lisa van Bodegom, developed a code tree with basic codes derived from the research design and our initial analysis of the transcripts and minutes. New themes that emerged later were assigned new codes and added to the code tree.

We compared the material obtained from the interviews and discussions with data drawn from the media and social media, grey literature publications (including policy reports), and academic literature.

The May 2018 workshop attended by 19 experts and stakeholders was meant to verify and/or falsify the interim results, and to take the first steps towards formulating possible actions based on input from the field (see Appendix A for a list of participants). Prior to the workshop, we distributed an initial report to the participants based on an analysis of the preliminary research data. The report describes opportunities and obstacles associated with digital personal health management. Participants were then invited to fill in gaps and subsequently to attend a moderated discussion where they were asked to come up with actions that would support citizens' control over health data and thus promote citizens' health.

Various steps have been taken to improve the verifiability of the study. For example, the interviews were recorded (with the interviewee's consent) and

transcribed verbatim. For control purposes, all respondents also received a draft version of this report, specifically with reference to passages quoted from the minutes / interviews, so that they could correct any factual errors (Creswell, 2003). A guidance committee consisting of six experts and stakeholders was asked to provide feedback and to comment on a draft version of this report (see Appendix A, final table). They were specifically asked to comment on the actions and how well these align with current trends and developments. The internal review was carried out by a substantive editor who had no previous involvement in the study.

This study is based on multiple case studies (Hutjes & van Buuren 1992). Case study research is, by definition, difficult to generalise. It is not the aim of case study research to arrive at general statements about reality, but rather to gain a deeper understanding of a specific local phenomenon, in this case personal health management using digital health data services (Boeije, 2008). The different categories of health data services and the specific services within these categories exhibit close similarities but also considerable differences, e.g. in terms of their stage of development and use. The online portals in the mental health and addiction care sector are now part of everyday healthcare practice, whereas most PHEs are still under development.

## Appendix C: MedMij update

### The MedMij Programme

The MedMij Programme was launched in June 2016. Its mission is to ensure that ‘anyone who so wishes has access to their health data in a personal health environment’. Headed by Dutch Patient Federation, Nictiz centre of expertise for eHealth and the Dutch Ministry of Health, Welfare and Sport, the programme is devising rules for the secure and standardised collection of health data from various sources (source: MedMij.nl). That will give patients a single, comprehensive digital environment in which they can securely access, manage and share personal health information, regardless of where it is stored, with healthcare practitioners whenever and wherever they like. The rules are laid down in the MedMij Trust Framework. The system comprises the most important agreements regarding the organisational and technical parameters within which PHEs are to be developed and the financial infrastructure on which they are to be based, among other things. For example, it includes:

- standard participant agreements
- a processor agreement template
- and governs the legal context between healthcare providers and patients and their service providers.<sup>145</sup>

### MedMij and the Supplementary Provisions for the Processing of Personal Data in Healthcare Act (Wabvpz)

The MedMij Programme serves to implement the Supplementary Provisions for the Processing of Personal Data in Healthcare Act (WABVPZ), which entered into force on 1 July 2017. The Act defines additional rights regarding patient access to and sharing of their health data. The key aspects here are:

- Digital access to medical records. As from July 2020, individuals will be able to ask a healthcare practitioner to make their personal data, as documented in the practitioner’s medical record, available free of charge in a standard format, i.e. a format that is structured, widely used and machine-readable.
- Specified consent. As from July 2020, individuals will be able to state digitally which healthcare providers are permitted to make which types of data available to certain occupational groups. It is important to note that patients

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145 See, for example, <https://afsprakenstelsel.medmij.nl/display/PUBLIC/Deelnemersovereenkomsten>  
<https://afsprakenstelsel.medmij.nl/display/PUBLIC/Modelverwerkersovereenkomst>  
<https://afsprakenstelsel.medmij.nl/display/PUBLIC/Juridische+context>  
Retrieved in January 2019

- will not be obliged to consent to their medical data being shared electronically with other healthcare practitioners.
- An obligation on the part of the healthcare provider to inform its patients about the digital data transfer.
  - The provision that health insurers, medical examiners, occupational physicians and insurance doctors must never be able to access the patient's electronic data through an electronic transfer system.

For a detailed survey of the legislative frameworks, agreements and rules, see the Rathenau Instituut's earlier report, *Responsible digital health management* (Niezen & Verhoef, 2018). The Act does not necessarily call for the establishment of PHEs, then, but rather for standards and secure portability of (machine-readable) data between systems or platforms. PHEs must therefore meet at least these requirements to qualify for MedMij certification. Current legislation focuses primarily on information sharing between a healthcare provider and patients within the context of treatment.

### **MedMij participants**

PHE suppliers may register as candidate participants in the MedMij Trust Framework. As from 1 November 2018, they will also be able to obtain actual certification as a MedMij-approved PHE. To do this, the PHEs currently under development will embark on a qualification procedure. We know that 25 PHEs will commence this procedure because they are making use of the available incentive funding. Other PHE suppliers may also register for the qualification procedure. The quality mark will guarantee that, at the very least, MedMij-certified PHE suppliers will

- enable users to share health data securely and easily with healthcare practitioners using their app or website
- make it possible for users to access and use the data securely; and
- display the data in a comprehensible manner.

### **Test environments**

Two test programmes are under way to examine the practical functionality of the MedMij Trust Framework. One of these is PROVES, which is testing proofs of concepts for the technical requirements applicable to PHE suppliers and the suppliers of healthcare provider information systems. Zorgverzekeraars Nederland (ZN), an organisation that represents ten Dutch health insurers, is the principal for this programme and it has commissioned VZVZ (main contractor) and VECOZO (national node for digital communication in healthcare) to investigate how the architectures of central facilities (such as the Healthcare Provider Address Book or ZAB and the connection to the National Health Data Switchboard), as well as the facilities of Specified Structural Consent (GTS) and MedMij, operate in real-life situations. On behalf of MedMij, PROVES is exploring how the Trust Framework

affects the transfer of data between PHEs and the healthcare information systems operated by healthcare providers (XISs).

The second programme is the MedMij Support Programme. Through this programme, MedMij is helping healthcare providers, PHE suppliers and suppliers of healthcare provider systems build the necessary MedMij gateways from the healthcare providers to the MedMij system, often at regional level (the gateways are the MedMij 'plugs' or network points that provide access to the healthcare information systems and PHEs). CarenZorgt PHE, for example, says that it is involved in one of the test environments. *'CarenZorgt is currently conducting a trial in collaboration with MedMij to make real-time medication data from the LSP data exchange system operated by the VZVZ available in its web app. This new functionality ensures that healthcare users will soon be able to access and view their own medication data in CarenZorgt's online environment. They can also give healthcare practitioners consent to view relevant healthcare data. CarenZorgt has been involved in the development of the MedMij Trust Framework since the inception of MedMij.'*<sup>146</sup>

The various test environments are meant to investigate basic parameters for implementing PHEs within the healthcare system. Technical obstacles are still the biggest hurdle, in particular the gateway from the healthcare information systems used by the healthcare providers. The necessary organisational agreements are also increasingly a topic of discussion, but so far no real lessons have been learned and documented (respondent 16).

A third programme is expected to commence in the first quarter of 2019, in which three controlled 'go-lives' will be set up to combine the findings of PROVES and MedMij Support, and to implement the transition to PHEs in real life.

### **MedMij Foundation**

The Trust Framework has been transferred officially from the MedMij Programme to the MedMij Foundation. As from 1 January 2019, the foundation has two directors, Ronald Gorter and Theo Hooghiemstra. The foundation bears final responsibility for the system, as described in the Trust Framework itself and as guaranteed in its articles of association. The foundation MedMij thus guarantees the importance of the Trust Framework, takes responsibility for management and is the owner of the MedMij quality mark.

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<sup>146</sup> <https://www.fmtgezondheidszorg.nl/carenzorgt-wil-grootste-persoonlijke-gezondheidsomgeving-pgo-van-nederland-woorden/>  
and  
[https://www.telegraaf.nl/financieel/2399735/zorgapp-van-nedap-wil-de-grootste-woorden?utm\\_source=google&utm\\_medium=organic](https://www.telegraaf.nl/financieel/2399735/zorgapp-van-nedap-wil-de-grootste-woorden?utm_source=google&utm_medium=organic)

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