

Consumer eHealth

Advice on public health and healthcare

The Council for Public Health and Health Care (*Raad voor de Volksgezondheid en Zorg*, RVZ) is an independent advisory body for the government and parliament. The organisation is dedicated to facilitating qualitative, accessible and affordable healthcare. To this end, it issues strategic policy recommendations. The Council's advisory reports are written from the citizen perspective with recommendations that are bold and visionary whilst remaining realistic.

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Essence of this advisory report

In this advisory report the Council for Public Health and Health Care draws attention to the emergence of consumer eHealth. The Council defines consumer eHealth as information and communication technologies offered directly on the market to consumers without the intermediary of care providers, the aim of which is to support or improve users' health.

Developments in consumer eHealth are occurring rapidly and they could have profound consequences for the supply of and demand for healthcare in its current usual form.

Consumer eHealth responds directly to people's wishes and offers people solicited and unsolicited possibilities. The regular healthcare services are inadequately prepared for the developments that lie ahead and this problem will not solve itself. Measures must be taken to ensure that consumer eHealth is safe and useful for people and society.

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Summary

Developments in eHealth are occurring rapidly. In this advisory report the Council for Public Health and Health Care draws attention to the emergence of consumer eHealth. The Council defines consumer eHealth as information and communication technologies offered directly on the market to consumers without the intermediary of care providers¹, the aim of which is to support and improve users' health.

Consumer eHealth responds directly to people's wishes and offers people solicited and unsolicited possibilities. It offers users the opportunity to shape their personal healthcare for themselves as far as possible.

Examples include apps for smartphones and wearables (mobile Health or mHealth), health platforms and personal health records (PHRs). Smartphone add-ons and applications, such as smart contact lenses and electronic chips in medication, are further options. Not only does this concern lifestyle and prevention but also self-diagnostics and self-treatment.

Consumer eHealth does not yet play a significant role in the current healthcare system. However, developments are set to occur in rapid succession and consumer eHealth could profoundly change the regular healthcare services in various ways. The Council expects that consumer eHealth and the regular healthcare services will become partially intertwined. A number of components offered by the regular healthcare services could also be substituted by consumer eHealth.

Care is set to become increasingly time and locationindependent. The relationship between patients and care providers will change. Consumer eHealth enables people to take greater control of their personal health. An increasing number of self-diagnosis and self-treatment possibilities will arise. Care providers are likely to focus more specifically on complex diagnostics and joint decision-making, in which personal considerations play an important role. They will furthermore continue to assume a key role in caring for the vulnerable. The range of consumer eHealth services offered has brought new players to the healthcare market, who (in part) are internationally and commercially oriented.

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¹ In this context care providers may be engaged in welfare, preventive healthcare, or in the provision of care and cure services.

The changes described pose dilemmas. Important concerns that must be addressed are the practicalities and impracticalities of self-management, the risk of medicalisation, the shifting balance of power, new earnings models, sharing data and data accessibility. These aspects will become more acute in the event of the further intertwinement of consumer eHealth with the regular healthcare services.

The Council has identified a number of core problems arising from the intertwinement of consumer eHealth with the regular healthcare services, the most important of which lie in three different areas, according to the Council:

- safeguarding the use and exchange of data;
- the accessibility and use of consumer eHealth by patients and clients who lack the ability and the competencies to be able to use it properly;
- the quality of the applications.

The use and exchange of data

The framework conditions for data processing are currently inadequately geared to the advent of consumer eHealth and the ensuing changes in healthcare. Currently hardly any data collected by care providers and data collected by the relevant individual with the aid of consumer eHealth tools are exchanged electronically.

Vulnerable groups

Developments in consumer eHealth can help people shape their personal healthcare for themselves. However, the question is whether this will apply to all citizens to the same degree. There seems to be an overlap between the group of people with low health literacy skills and those with low digital skills. That group will be less able to use the eHealth applications that are currently available.

Quality of applications

To facilitate the intertwinement of consumer eHealth with the regular healthcare services, it is important to obtain insight into the clinical benefit of applications. The appropriate research methods for demonstrating the clinical benefits of eHealth applications are lacking at present.

Furthermore it is difficult for consumers to obtain and maintain a good picture of the appropriate applications that meet their needs and wishes. At present insufficient information is available on aspects that are important for the selection process of the consumer and/or the care provider

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for an application, such as earnings models and the use of data (by third parties).

Potential solutions

Consumer eHealth can contribute to improving citizens' health. Consumer eHealth is on the rise and is expected to become increasingly important and more comprehensive. Developments are occurring rapidly, they could have profound consequences and wide-ranging interests are at stake. The developments that lie ahead can merely be partially predicted at present and merely be partially influenced. The regular healthcare services and consumer eHealth are predicted to become increasingly intertwined. However, intertwinement poses a number of problems.

In the Council's opinion a specific policy is feasible and desired for a number of these problems. In this advisory report the Council focuses on measures to be taken, in the knowledge that the introduction and wider deployment of consumer eHealth will largely be driven by the possibilities offered by technology, the capability of businesses and institutions to create appropriate digital applications and consumer receptiveness to those applications.

The Council's main recommendations are as follows:

Quality

In association with universities, university medical centres and in line with international developments, Nictiz and the National Health Care Institute (*Zorginstituut Nederland*) should develop an appropriate methodological framework for the scientific evaluation of the clinical effectiveness (clinical benefit or added value) of consumer eHealth medical applications.

Professional, consumer and patient organisations should initiate the development of a quality mark for consumer eHealth self-diagnostic and self-treatment medical applications. The quality mark should enable consumers to read what quality or other criteria the application complies with. Where possible alignment should be sought with national and international initiatives already undertaken.

Vulnerable groups

The government should support, also financially, third-party initiatives to develop and/or adapt applications for use by vulnerable groups, including applications specifically designed for certain rare conditions.

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The use and exchange of data²

The government must ensure a reliable authentication mechanism for all consumers/citizens/care providers/patients in relation to third parties, including businesses, such as the consumer authentication system developed by banks for Internet banking. Reliable authentication methods are a condition for consumer/patient control over permissions to view and access their digital health data and provide protection against identity fraud.

On the basis of a public-private partnership the government promotes the establishment of a neutral system of binding agreements and uniform standards for exchanging information between consumer eHealth applications and professional eHealth, with consumer/patient control. Their personal data will be protected by *privacy by design*³.

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² See the advisory report *Patient Information* (RVZ, 2014a) for further relevant recommendations on patient confidentiality and standardisation.

³ Privacy standards are incorporated in the organisational and technical design of information systems.

1 About this advisory report

1.1 Background

This advisory report was issued following the request for advice made by the Minister of Health, Welfare and Sport, as set out in the 2014 *eHealth, Self-Management and Health Skills* Work Programme. The question addressed in the work programme is as follows:

How can the content, application, wider deployment and use of eHealth services be optimised, taking account of the current and anticipated future needs and capabilities of the different patient categories, and the demand for care?

1.2 Problem definition

The Dutch healthcare system is facing a number of challenges. Dutch citizens are living longer on average, they more often suffer from chronic illnesses and impairments and they participate more (CBS Statline, 2013; RIVM, 2014c). In addition the percentage of people over 65 is set to rise from 14% in 2000 to 24% in 2030 (CBS Statline, 2013) while the percentage of people over 75 is similarly set to increase significantly. This means that the demand for healthcare will increase and its nature will change. Regional differences have been identified in the development of healthcare demand (TNO, 2014a; 2014b; 2014c; 2014d). Consequently the government is faced with the high costs of care, which are expected to continue to rise (CPB, 2011). A shortage on the labour market is also expected to occur (CPB, 2005).

The government hopes to overcome these challenges by encouraging and enabling citizens to take responsibility for (maintaining) their own health as far as possible. The Minister of Health, Welfare and Sport views eHealth as a means of reinforcing self-management and for this reason has set concrete objectives to promote the use of eHealth (TK, parliamentary paper/Kamerstuk II, 33750-XVI-28).

The generally accepted definition of eHealth is 'the use of information and communication technologies, mainly Internet technology, to support or improve health and healthcare' (RVZ, 2002; Krijgsman et al., 2013).

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Developments in eHealth are occurring rapidly. However, its use is falling short of expectations. In its advisory report *Health 2.0* (RVZ, 2010b) the Council formulated recommendations to promote the implementation of eHealth. The recommendations in the above advisory report still largely apply to date.

Furthermore the Council has identified a new trend in eHealth: the emergence of consumer eHealth. The Council defines consumer eHealth as information and communication technologies offered directly on the market to consumers without the intermediary of care providers⁴, the aim of which is to support and improve users' health. Examples are apps⁵ for smartphones and wearables (mobile Health or mHealth), health platforms⁶ and personal health records (PHRs). In the future smartphone add-ons and applications, such as smart contact lenses and electronic chips in medication, could also be used. In addition self-diagnosis and self-treatment applications will be further developed and are anticipated to become available. The demand or need for these applications will be partly created in that demand for an unknown product cannot, or need not yet be specified (RVZ, 2015b).

The Council believes that individually tailored care and patient empowerment are goals worthwhile pursuing. Joint decisionmaking and self-management, in the sense of shared implementation, are relevant concepts in this context (RVZ, 2013). It is important to approach a person as an individual from a biopsychosocial perspective and to share control and responsibility in the care relationship (Duggan, 2006). This emphatically involves enabling people to shape their personal healthcare for themselves as far as possible. In some cases this means offering people options for taking charge of their personal healthcare. Every individual, however, has different

A health platform is a platform in the field of healthcare.

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⁴ In this context care providers may be engaged in welfare, preventive healthcare, or in the provision of care and cure services.

⁵ The terms 'eHealth applications', 'apps' and 'applications' are used interchangeably. An application can be more than simply a mobile app.

⁶ "A 'platform' is a system that can be programmed and therefore customized by outside developers - users - and in that way, adapted to countless needs and niches that the platform's original developers could not have possibly contemplated, much less had time to accommodate." (Marc Andreessen, 2007)

preferences and more especially capabilities, and they may differ per situation. Care is also linked to vulnerability and vulnerable people. Individually tailored care means taking account of these differences.

Consumer eHealth could serve as a means for personalising or individually tailoring health and welfare, prevention and healthcare to citizens in a patient-centric manner by interacting with the patient concerned. In this context health is increasingly taken to mean the option to adapt and apply selfmanagement (Huber, 2011).

The emergence of consumer eHealth is not an isolated trend. Although developments can only be partially predicted, the Council expects consumer eHealth to become partially intertwined with the regular healthcare services. This will bring about considerable changes in care surrounding health and illness, and welfare and behaviour. The consequences could be profound and wide-ranging interests are at stake. The intertwinement of the regular healthcare services with consumer eHealth also poses a number of problems.

In the Council's opinion a specific government policy is feasible and desired for a number of these problems. In this context the Council refers to measures the government itself can take, in the knowledge that the introduction and wider deployment of consumer eHealth will largely be driven by the possibilities offered by technology, the capability of businesses and institutions to create appropriate digital applications and consumer receptiveness to those applications. It is not the objective to control this development, but rather to make it useful for people and society.

What questions does the RVZ answer?

In this advisory report the Council focuses on the emergence of consumer eHealth and the fundamental changes it may bring about in healthcare.

The main question to be answered in this advisory report is: How should current and future policy take account of the emergence of consumer eHealth and the potential transformation of healthcare brought about by this development?

The questions to be answered are:

- What does the emergence of consumer eHealth look like?

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- What changes will the emergence of consumer eHealth bring about in healthcare, and for citizens and society due to its intertwinement with the regular healthcare services?
- What facilitative and/or regulatory conditions are required to enable the emergence of consumer eHealth and the potential transformation of healthcare, and to avoid negative side effects?

Purpose of this advisory report

In this advisory report the RVZ aims to inform the reader of the emergence of consumer eHealth and the fact that this could potentially change today's healthcare landscape. The Council's recommendations aim to contribute to establishing the appropriate framework conditions for using the possibilities offered by consumer eHealth and to mitigate the risks as far as possible.

Scope/delineation

The Council has adopted a broad perspective and gives consideration to health, welfare, prevention, and care and cure where possible. This broad perspective has been adopted given that the focus of the recommendations lies on healthcare organised by and around citizens/consumers rather than on the current segmentation of healthcare. The Council examines a number of aspects or constituent aspects and/or examples in detail.

Not every individual has the desire or the skills/ competencies to be able to use eHealth applications independently. A number of people have a strong preference for personal contact with care providers. The final advisory report focuses on possibilities for all citizens bearing this subtle distinction in mind.

In this advisory report we refer to individuals in their role(s) as a patient, citizen, insured party, employee, care recipient, care provider, employer, consumer and client.

The Council does not discuss developments in the field of technology, health and healthcare, such as robotics, 3D and 4D printers, biotechnology, neurotechnology and nanotechnology, sensors, artificial intelligence and drones.

The elaboration of the ethical aspects of eHealth does not form part of this advisory report either. Possible ethical issues, however, have been identified in the advisory report (Appendix 3). The Centre for Ethics and Health (*Centrum voor*

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Ethiek en Gezondheid, CEG) may possibly address this topic in 2015.

For the purpose of this advisory report the Council also wishes to highlight the advisory report *Doorlichten doorgelicht*. *Gepast gebruik van health checks* (2015) ('Examinations examined. The appropriate use of health checks') issued by the Council for Public Health and Health Care.

The recommendations formulated by the Council in this advisory report focus on the medium term.

1.3 Preparation of the advisory report

Alongside seven internal background studies (RVZ, 2015b; 2015c; 2015d; 2015e; 2015f; 2015h; 2015i) three external background studies were carried out at the request of the RVZ for the purpose of substantiating the recommendations (IQ healthcare, 2014; TNO, 2014e; RVZ in association with Flim Project Management, 2014f). The summaries of these internal and external background studies have been collated (RVZ, 2015i). In addition to individual interviews conducted with various people and organisations (see Appendix 2) the RVZ organised six meetings with experts on the topic addressed in this advisory report (see Appendix 2).

1.4 Structure of this report

Following this introductory chapter, Chapter 2 contains a detailed analysis of the emergence of consumer eHealth and the possible consequences of its anticipated intertwinement with the regular healthcare services. Chapter 3 examines the possible dilemmas arising from intertwinement. Chapter 4 follows with a detailed analysis of the core problems arising from the intertwinement of consumer eHealth with the regular healthcare services. Chapter 5 presents potential solutions for the core problems identified and Chapter 6 contains a summary of the concrete recommendations contained in this advisory report.

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2 The emergence of consumer eHealth

2.1 Introduction

Developments in the field of consumer eHealth are occurring rapidly. In this chapter the Council outlines possible developments in consumer eHealth, which could potentially have a significant impact on the regular healthcare services. Interest among citizens is growing and commercial parties (including those not involved in the provision of healthcare) are embracing this development en masse.

For the purpose of this advisory report, the Council makes a distinction between consumer eHealth and professional eHealth. These terms and their underlying concepts are explained in detail in Sections 2.2 and 2.3.

The latter section also describes the emergence of consumer eHealth. Consumer eHealth and professional healthcare are expected to become intertwined because people will start asking for intertwined healthcare services. This is likely to bring about fundamental changes to care surrounding health and illness, and to welfare and behaviour. The possible changes are examined in Section 2.4.

2.2 Professional eHealth

We have used the term *professional eHealth* for eHealth applied and developed by, for or in association with care providers. Under Dutch law the Medical Treatment Contracts Act (*Wet op de geneeskundige behandelingsovereenkomst*, WGBO) governs the relationship between care providers and patients. Pursuant to the Act the care provider is responsible and liable for everything that takes place under the treatment contract, and hence is also responsible and liable for the use of eHealth applications.

The Council has issued various advisory reports on (professional) eHealth in the healthcare sector or neighbouring fields in the past, see Appendix 3 and the list of publications.

The advisory report *E-health in zicht* (RVZ, 2002) ('eHealth in Sight') specifically examines the possibility of professional eHealth improving the quality, efficiency and accessibility of healthcare.

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Recommendations have also be put forward in the advisory report *Patient Information* (RVZ, 2014a) that could help promote the implementation and wider deployment of professional eHealth based, for instance, on recommendations concerning standardisation and registration at the source.

Appendix 4 contains a summary of previous eHealth advisory reports issued by the Council. The study accompanying this advisory report entitled *Adoptie van professionele eHealth* (RVZ, 2015b) ('The Adoption of Professional eHealth') examines the advancement of professional eHealth in detail.

2.3 Consumer eHealth

This section discusses a new development in eHealth: the emergence of consumer eHealth. The Council defines consumer eHealth as information and communication technologies offered directly on the market to consumers without the intermediary of care providers, the aim of which is to support or improve users' health.

Consumer eHealth is typically offered directly on the market to the consumer with a view to supporting and improving health without the intermediary of care providers. This means that products and services do not reach the consumer/patient through 'medical channels' but target the consumer/patient directly (RVZ, 2015c).

In the Netherlands eHealth applications are currently used mainly for lifestyle purposes. A growing number of *healthy* people use modern technology to gather all sorts of information on their daily life. Good examples are the popular lifestyle gadgets which, for instance, monitor the amount of physical activity, sleep cycle or heartbeat. Measurement values can be forwarded via a smartphone (mHealth). The term used for the self-measurement of data is 'quantimetric self-tracking' (RVZ, 2015c).

Furthermore companies such as Apple, Google, Samsung, Philips and Microsoft have developed health platform development tools (HealthKit, GoogleFit, Sami, digital HealthSuite and HealthVault respectively). These platforms integrate information collected by apps, provided the information is from the same provider. The Apple Health app is therefore linked to the HealthKit health platform. Apple can also facilitate a connection with the EPIC hospital information system, which enables care providers to share information.

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Google Fit focuses solely on the integration of lifestyle information.

Social media, including Facebook, are also looking into healthrelated functionalities, which for the time being have a focus on a healthier lifestyle (RVZ, 2015c).

Future developments

Consumer eHealth currently used in the Netherlands mainly has a lifestyle focus. However, significant developments are taking place in the field of self-diagnostics and self-treatment.

Consumer eHealth is an international market. New applications developed abroad are expected to appear on the European market soon.

In this advisory report the Council addresses new developments that could have a profound impact on the Dutch healthcare system.

Major developments are being seen in the field of diagnostics. More and more tools used by physicians are being made available to the wider public. It will become possible for people to carry out all sorts of diagnostic measurements themselves on their body or in their body fluids, such as blood and urine, facilitated by the rapid developments occurring in sensors, which are becoming smaller and more affordable.

Developments in self-diagnostics, however, are more profound. The IBM Watson supercomputer is already being used to support medical decision-making with the aid of artificial intelligence. This WatsonPaths decision support system was only available to physicians. However, a consumer version is now under development (IBM Research http://www.research.ibm.com/cognitivecomputing/watson/watsonpaths.shtml). The expectation is that consumers will be able to enter complaints, symptoms and any measurement values and will receive a probable diagnosis or advice on what to do next. While Watson's activities are currently limited to a few disorders, its scope is likely to expand considerably.

The range of self-treatment possibilities will also expand as a result of consumer eHealth. It has now become common practice for people suffering from diabetes mellitus to not only measure their blood glucose levels but also to adjust their medication themselves. The self-diagnosis and self-treatment possibilities for all sorts of complaints and disorders will

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increase significantly in the future and people will more often receive *machine-generated* treatment advice.

The table below shows the potential application areas of consumer eHealth (RVZ, 2015h).

Туре	Aim	Example
Reference	To provide	Hulp op zak
(information)	information and	('Pocket aid') app
	general advice	
Wellness	To provide insight	Stappenteller ('Step
	into behaviour and	counter') app,
	promote health by	Runkeeper app
	measuring and	(running),
	monitoring body	Gewichtdagboek
	values collected by	('Weight diary')
	the consumer	app
Prevention	To provide	PreventieCoach
	information on	(Prevention
	health risks,	coach') app,
	behaviour and	HealthCare Alert
	epidemics in the	app
	locality	
Type I diagnosis	To make a diagnosis	Moet ik naar de
	based on symptoms	dokter ('Should I
	, <u>,</u>	go to the
		doctor') app,
		DermaWizard app
Type II diagnosis	To make a diagnosis	SkinVision app
1 0	based on symptoms	11
	combined with	
	information collected	
	by the individual.	
Type I therapy	To provide	Lage Rugpijn
	therapeutical advice	(Lower back
	based on a known	pain') app
	diagnosis, medical	. /
	history and personal	
	preferences	
Type II therapy	To check the results	Consumer-
	of active	specific version
	therapeutical aids or	not yet available
	to exercise influence	, ,
	on the results	
Monitoring	To measure and	ListenApp,
0	monitor (vital) body	AirStrip Patient

 Table 2.1
 Consumer eHealth application areas

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	values to confirm the	Monitoring
	diagnosis or to check	
	therapy	
Communication	To bring users into	WhatsappDoc app
	contact with other	(contact a
	users, care providers	physician by
	or other authorities	smartphone),
		online forums
Combination	To measure and	Under
	monitor through an	development
	online digital	-
	platform (vital) body	
	values, identify and	
	diagnose	
	abnormalities; draw	
	up a treatment plan	
	based on personal	
	preferences and	
	medical history	

Source: Background study *Consumenten-eHealth en de zorg van de toekomst* (RVZ, 2015h) ('Consumer eHealth and healthcare in the future').

The information provided above illustrates that consumer eHealth will increasingly focus on areas that are currently reserved for the regular healthcare services provided by care providers, in the field of both diagnostics as well as treatment. Consumer eHealth should therefore not only serve as a substitute for something that people have always done themselves, but people will also in fact need to arrange more and other elements of healthcare themselves. Consumer eHealth and the regular healthcare services are set to become partially intertwined.

2.4 Expected consequences of consumer eHealth

The background study *Consumenten-eHealth en de zorg van de toekomst* (RVZ, 2015h) ('Consumer eHealth and healthcare in the future') paints a picture of what the healthcare landscape might look like in the future to illustrate what could change as a result of the emergence of consumer eHealth. The point of departure is to enable people to shape their personal healthcare as far as possible for themselves. This possible future scenario is based on interviews (see Appendix 2), expert meetings (see Appendix 2), the background studies accompanying this advisory report and a literature study.

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Needless to say, this should not be interpreted as an attempt to predict the future.

The Council assumes that a development will take place in which consumer eHealth and the regular healthcare services will become increasingly intertwined.

This section describes three possible future changes. They are: the changing healthcare relationship between patients and care providers, changes in the nature, time and place of healthcare provision and new actors in the healthcare landscape. These changes have either not yet occurred or have occurred to a limited extent.

The healthcare relationship between patients and care providers

From a patient perspective, several different categories of patients can be distinguished (Kingma, 2013):

- the uninformed patient (pre-Internet): the patient goes to the doctor unprepared (without knowledge) or when in doubt;
- 2. the educated patient (post-Internet); the patient visits the doctor equipped with the knowledge he or she has independently obtained thanks to medical platforms (on the Internet);
- 3. the quantified patient (quantified self): the patient visits the doctor equipped with knowledge and data.

This will change with the advent of consumer eHealth. In addition to the three categories described above, there will be two new patient categories in the near future:

- 4. the self-diagnosing patient;
- 5. the patient administering self-treatment.

The latter two categories are not new in themselves. After all, self-diagnosis and self-treatment, if any, always take place before making the decision on whether or not to go to the doctor. This decision in fact requires self-diagnosis: does the nature of the complaints/symptoms warrant a doctor's visit or will a self-care product suffice? In the future, however, consumer eHealth is expected to offer people many more and alternative possibilities for diagnosing and administering treatment themselves. Knowledge of health, illness and behaviour will moreover become more widely accessible.

The increased possibilities for self-diagnosis and self-treatment could lead to medicalisation. Merely because people will start thinking more about themselves in medical terms and will have far more possibilities to act accordingly. Medicalisation could

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also be brought about by the algorithms used in the application. Algorithms are still undergoing development and continuous improvement. If they are (still) suboptimal, there is a likelihood that the reports/or advice may be incorrect. Based on this process in certain cases, however, there is real likelihood that an inadequate diagnosis and/or inadequate treatment may be given.

The developments described above will change the relationship between the patient and the care provider. Consumer eHealth can enable people to take greater control over their personal healthcare.

They will do so using consumer eHealth applications, but people will also increasingly obtain healthcare and healthcare solutions from the *crowd*. Forums and online communities will become more important. Care providers will enter the process at a later stage (or in some cases will no longer be involved) and will be expected to take on a different, more coaching role. Knowledge and the expert role of care providers will more often be called into question.

This does not mean that care providers will no longer have a role. Particularly where complex problems are concerned, they will take on an important role in processes, such as more complex diagnostics and joint decision-making. Precisely the step in moving from a proposal for possible interventions to making decisions based on personal considerations will usually be taken jointly. Furthermore the care providers' guiding role in certain cases is essential for obtaining insight into the available options.

Care providers are also expected to retain an important role in the provision of care for more vulnerable people. Care clearly also has a bearing on vulnerability, and not everyone is able to and/or has the desire to shape their personal healthcare for themselves. Taking control does not mean that people should carry undue responsibility if they do not wish to or are unable to do so themselves. The point is that they should be given room to decide for themselves, where and whenever possible.

As a result of these changes the need will arise for new professions with an emphasis on new competencies and skills to match the changing roles. The job content of common professions will (partially) change. A need will also arise for care providers who can link up knowledge of ICT and allied healthcare with the healthcare domain.

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The nature, time and place of healthcare provision The emergence of consumer eHealth is also anticipated to change the nature of healthcare. The current and future situation are visualised in figure 2.1.

It paints a picture of the potential shifts in the nature of healthcare arising from the emergence of consumer eHealth. This clearly is a very simplified representation of complex reality.

Figure 2.1 The nature of healthcare; current and future situation



Current situation

The left-hand diagram shows the current situation. Consumer eHealth does not yet play a significant role in the current healthcare system, except in the area of wellness. While people, who may or may not be suffering from one (or more) chronic illnesses, do use apps and technology to monitor their health, the information obtained is generally not yet actively used by care providers and health insurers. If an application already reports an abnormal value, the patient is advised to consult the regular healthcare services.

Potential future situation

The right-hand diagram shows the nature of healthcare in a potential future situation. Consumer eHealth is set to play a role in wellness, prevention, self-diagnosis and self-treatment.

Wellness apps are expected to be used to measure an increasing number of aspects. These apps will integrate information from various areas of life and will provide individually tailored lifestyle advice on factors such as sleeping, nutrition, stress and physical activity.

Changes will also take place in the 'old' domains of prevention and healthcare.

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From a *patient/citizen* perspective, consumer eHealth applications can tailor preventive advice more specifically to the individual. 'Normal values' (within a certain band) can be individually determined. Individualised health targets can be visualised with 'feed forward' based on big data analysis. Feed forward makes it possible to anticipate using an individual reference framework (TNO, 2013). Furthermore, possibilities could arise to better visualise the results of following up on preventive advice. This can help to personally motivate people.

Diagnostics and treatment by the healthcare provider can partly be substituted by self-diagnostics and/or self-treatment by the individual. The moment at which the regular healthcare services become involved will increasingly be postponed. Substitution will take place.

By regularly measuring the body's basic functions and comparing measurements to previous personal and target values, deviations from an individual's normal pattern can be identified at an early stage. Self-diagnostic applications can generate additional information. On account of the huge volumes of data the advice will become more refined and more individually tailored.

The advice will in this case be *machine-generated* and will therefore be individually tailored, based partly on the measurement data entered. Possibilities will increasingly arise to incorporate genetic traits, medical history and comorbidity in the machine-generated expert analysis, if desired. It is important to be aware that the standards from the technology used are in fact integrated into the machine-generated information.

While this analysis and the advice issued are tailored to the individual, they are not necessarily personal. Expectations, needs, norms and values are personal and relate to the individual and cannot be weighted by systems. In cases involving complex diagnostics and/or difficult decisions and considerations, consultation with the care provider is still required. The patient and care provider will jointly be able to weigh up personal and individual expectations, needs, and norms and values relating to a certain choice. Joint decision-making will enable the patient and the care provider to agree on 'subjective' personalised advice and any treatment.

Furthermore the *care provider* could substitute a larger portion of the regular healthcare components with eHealth applications. Consumer eHealth could help boost the wider deployment of professional eHealth.

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Where locations are concerned, under the current system citizens/patients are still largely tied to a physical location for the provision of healthcare. This will change. With the aid of consumer eHealth, the patient will no longer need to go to a certain location for all types of professional care. Communication among people and their care providers in the care process will no longer primarily be face-to-face (under one roof). Indirect communication will increase, whereby the healthcare consumer and care provider will not necessarily be in the same location and communicate at the same time. Partly due to consumer applications and the intertwinement with the professional healthcare services (non-invasive), specialist medical care will increasingly be administered at home. Healthcare will become increasingly location and time-independent. The physical infrastructure will need to meet different requirements. This will have significant consequences for the design of the physical infrastructure and for the use (and value) of current properties.

The changes described will not only affect the current cure and prevention services. Consumer eHealth could also bring about changes in the healthcare services in line with professional eHealth, for instance, such as domotics, in diagnostics and in examining new questions or provisional changes, and in monitoring, interpreting, and qualifying parameters for a chronic condition. This will have significant added value for people suffering from a chronic condition, particularly those with chronic multimorbidity. Personal care, however, and particularly the 'care' aspect, will for the time being largely remain hands-on.

Actors in the healthcare landscape and external actors Under the current healthcare system various actors are involved in the healthcare process, an overview of which is provided in the background study entitled *Consumenten-eHealth en de zorg van de toekomst* (RVZ, 2015h) ('Consumer eHealth and healthcare in the future').

Under the current healthcare system innovation is mainly initiated by pharmaceutical and technical companies or care providers, and technology (professional eHealth) is offered to the patient in consultation with the health insurer. Consumer eHealth enables people to discover, invent and use applications which they believe have added value (subjective quality).

Consumer eHealth will be a new market which in principle is open to all. Both traditional and new providers are active on

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the consumer eHealth market. Traditional providers, such as care providers, occupational health and safety management services, pharmaceutical companies, insurers, patient organisations, municipalities and the municipal health service (GGD) often work in collaboration with ICT service providers. New players are parties who were previously active in the business-to-business market and are now focusing on consumer eHealth. A number of the newcomers previously acquired a market in another domain. They are new to the health domain. Furthermore a growing group of start-ups are focusing on health (TNO, 2014e). New providers may partly have other interests, on account of opportunities for different earnings models.

New providers usually do not have their head office in Netherlands or in other European countries. The market is becoming increasingly globalised.

Links in the supply chain could disappear. Travel agencies that have been rendered redundant as a result of people making their own online travel bookings are a typical example, yet the same fate may also await the 'old-style' diagnostic labs, for instance.

New consumer eHealth providers could apply different earnings models. An earnings model consists of a business model and describes how a business creates added value, in most cases money (Indora, 2014). There are different earnings models for consumer eHealth, examples of which are given below.

A possible earnings model is based on regularly selling a product or product upgrades. An application can also be offered to the consumer free of charge because the earnings model is based on advertisements, for medicine for instance. Based on the information provided in the advertisements, consumers may start asking for these products. A third party could also pay for the consumer's use of the application. That party might be a care provider, employer or health insurer. Certain conditions are often attached. Other earnings models focus on offering additional services, such as legal, technical or medical support through call centres. A company that has developed a specific application hires a call centre equipped with technical or medical specialists to offer an additional service linked to the application. This enables both businesses to earn money on the use of the application. A further potential earnings model that is set to play an increasingly important role is selling information collected and derived from the use of various eHealth applications. Valuable data

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can be collected through *datamining* - "specifically searching for (statistical) relationships among huge volumes of data to, for instance, set up profiles or compare and reinterpret scientific research" (Ottenheijm and Jacobs, 2014) - and sold to other parties for various purposes. There is a likelihood that the information collected will be used for other purposes and/or even misused. Consumers are not always aware of this.

2.5 Conclusions

On account of the anticipated intertwinement of consumer eHealth with the regular healthcare services, changes are expected to take place in the *healthcare relationship between the patient and the care provider, in the nature, time and place of healthcare provision* and in the *actors in the healthcare landscape.* The following chapter outlines the dilemmas that could arise with the launch and wider deployment of consumer eHealth. Chapter 4 subsequently provides a detailed analysis of the core problems arising from the intertwinement of consumer eHealth with the regular healthcare services, and Chapter 5 sets out the potential solutions to these core problems.

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3 Consequences of consumer eHealth for the regular healthcare services

3.1 Background

Chapter 2 outlines the anticipated developments in consumer eHealth and the changes that could arise as a result of the potential intertwinement of consumer eHealth with the regular healthcare services. This chapter summaries the possible dilemmas. They will become more acute in the event of the further intertwinement of consumer eHealth with the regular healthcare services

3.2 Dilemmas

Commodisation and personal contact

The developments in consumer eHealth and the intertwinement with the regular healthcare services will enable healthcare to be tailored more to individual needs by means of technical applications and the processing of big data. Machinegenerated, objective, individually tailored advice is an increasingly likely option.

Firstly the advice is objective and individually tailored in the sense that it is possible for the machine expert to use all the available information (big data). This might include the relevant medical literature which keeps the machine expert fully up-to-date. Secondly, it is objective and individually tailored in the sense that opportunities will increasingly arise to incorporate genetic traits, medical history and comorbidity in the machine-generated expert analysis in advance, if desired.

However, the standards applicable to the technology used will in fact have been integrated into the machine expert's analysis. In this sense it will not be possible to provide completely objective advice. This issue is examined further on in this chapter.

Because people themselves will be arranging more aspects of their personal healthcare and because healthcare will vary from its current form, less face-to-face contact is expected to take place (under one roof). This may raise the question of whether the caring and warm aspects of healthcare provision can in fact be safeguarded in the digital forms of healthcare. In short, will healthcare become significantly commoditised? A further question is whether the possibility of face-to-face contact

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(under one roof) will remain intact, if desired. Will it still be possible to partially choose a non-digital form of healthcare or 'should' everyone go completely digital?

Healthcare is not expected to digitise entirely. However, care providers and patients will increasingly receive support in the form of individually tailored advice generated by a machine expert. This will create more time and room, particularly when it comes to complex decisions, for care providers to provide added value in respect of subjective considerations and in their coaching and guiding role. Room will thus be created for personal considerations during the joint decision-making process with the care provider. Wider options for giving personal care, perhaps via a computer screen, also apply to care in the home environment.

Self-measurement and the risk of medicalisation

Consumer eHealth will enable people to start gathering information from various areas of life and offer scope for individually tailored preventive advice on factors such as sleeping, nutrition, stress and physical activity. Moreover people will be able to make their own diagnosis based on the information they have gathered and to administer (part of the) treatment. This will consequently give citizens greater insight into the state of their health, enable them to take preventive action and enable intervention at an earlier stage should a potential disorder be diagnosed.

Self-measurement and other consumer eHealth applications could, however, also lead to medicalisation. People will be increasingly occupied with their health. They can also be encouraged to do so by others. Health information will be exchanged through social media. Care providers can ask people to monitor certain information. In remoter scenarios health insurers could also start asking individuals to demonstrate the efforts they themselves have undertaken (see also 'Personalisation and the use of information for other purposes' further on in this chapter).

Medicalisation is taken to mean undue medical intervention in human life. Consumers are generating ever more data because they are increasingly measuring body parameters. Applications can help consumers interpret values and determine whether they deviate from normal values. This could potentially create a 'risk-averse society', in which every single deviation from the standard must be examined. Particularly if the standards built into the application have been set in a certain manner or if the algorithms used have not yet been adequately developed, this

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could create demand for the provision of additional healthcare from the regular healthcare services. Uncertainty and the demand for healthcare could be fuelled by supplementary information, including advertising, generated by the application. There is a likelihood that consumer eHealth will lead to medicalisation. On the other hand, sufficient clarity on the basis of self-diagnosis may save people and consequently society from paying a visit to the regular healthcare services.

As stated, the algorithms used in the applications are still undergoing development and continuous refinement. In some cases underdiagnosis and undertreatment are also conceivable, particularly in the early stages of these developments.

Guidelines can play a role in helping to reduce medicalisation arising from consumer eHealth. However, yet again this poses problems. The use of guidelines for quality assurance purposes could fundamentally change. Guidelines are designed for groups and are no longer adequate in a situation of personalised, individually tailored diagnosis and treatment. Standards and similarly guidelines will therefore be increasingly determined at the international level.

Encouraging self-management and an insufficient range of services

The intertwinement of consumer eHealth with the regular healthcare services would enable people to take more control over their medical information and would enable them to decide for themselves who they wish to involve in their personal healthcare and when. Opportunities will arise to enable healthcare and support to be provided on a time and location independent basis. People will be given the opportunity to shape to a greater degree their personal healthcare for themselves.

Consumer eHealth can help increase the freedom of choice. Should the need arise for a range of professional healthcare and welfare services, then as a result of the developments described these could increasingly be offered across the 'boundaries', and by wide-ranging parties. Should a range of professional services be required, this should be organised and offered to suit an individual based on his or her needs and wishes. The required information should be available for the relevant parties, including the individual concerned.

For the purpose of this advice, the Council conducted an eHealth survey among the municipalities in conjunction with

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the Caring City (*Zorgende Stad*) theme highlighted in the Digital Cities Agenda.

The survey revealed that the use of consumer eHealth applications and their integration into the range of regular welfare, prevention and healthcare services offered is still limited at the municipal level at present. However, the decentralisation of tasks from the central government to the municipalities (the Participation Act [*Participatievet*], the Social Support Act 2015 [*Wet maatschappelijke ondersteuning* (Wmo) 2015] and the Youth Act [*Jeugdwet*] does in fact offer the opportunity to reinforce this process (RVZ, 2015g).

If people are to shape their personal healthcare as far as possible for themselves, this situation will need to be improved. In the municipal domain in particular, where citizens are assumed to be capable of acting independently, it is vital to ensure that sufficient funds are made available for this purpose.

As described, a range of professional healthcare and welfare services should ideally be able to be offered across the 'boundaries' to actually enable people to take charge.

Another issue is whether the range of commercial services in fact will automatically meet the specific needs and wishes of all citizens. We are all potential users of consumer eHealth applications. On the one hand, particularly because of its international scope consumer eHealth offers opportunities for making viable investments where rarer conditions are concerned. Initially, however, relatively healthy people are expected to be the primary target group for consumer eHealth providers, who will subsequently gradually expand the scope of their services to other target groups. Initially, the range of services for certain target groups is not expected to be offered primarily by commercial care providers. There is a risk that people suffering from rarer conditions will have fewer possibilities for supporting their personal healthcare with consumer eHealth applications.

An inadequate range of services for certain target groups is unacceptable, not just from a human perspective but equally from a social perspective. One of the background studies carried out for the purpose of this advisory report in fact showed that eHealth applications for the 'more difficult' target groups can definitely contribute to possibilities that would enable them to shape their personal healthcare for themselves (IQ healthcare, 2014).

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Box 3.1 IQ Healthcare scoping review: 'eHealth for the elderly'

The IQ Scientific Institute for Quality of Healthcare (IQ healthcare) conducted a scoping review in 2014 to examine to what extent the use of eHealth applications can help improve elderly self-management and empowerment. The studies used described eHealth interventions with three broad objectives in mind: monitoring information, online patient contacts with care providers and providing health education.

In 13 of the 19 studies a positive effect was seen on selfmanagement. eHealth also seemed to help the elderly deal with their illness and seemed to influence their behaviour arising from increased self-effectiveness and knowledge. eHealth also had a positive effect on quality of life and health. Lastly, clear indications were found that eHealth can support the process of living at home independently.

The studies that did not show any effects were all studies with a maximum follow-up period of one year. However, IQ healthcare argues that if behavioural change is the main goal, the result can only be expected to be seen in the longer term.

A comment made in the scoping review, however, was that such positive results could only be achieved with intensive guidance during the implementation of the intervention and that publication and/or selection bias could not be ruled out.

Before large-scale eHealth interventions can be applied to elderly people suffering from one or more chronic conditions who are living at home, IQ healthcare says that further research will need to be carried out among larger groups of elderly (where more tailoring is required) and among the elderly with limited physical and cognitive capacity. Research is also required to be conducted into the harmful effects of eHealth interventions, such as social isolation.

Source: Background study *Scoping review over de toegevoegde waarde van eHealth voor zelfmanagement bij ouderen.* ('Scoping review on the added value of eHealth for elderly self-management') IQ healthcare, 2014.

Personalisation and the use of data for other purposes With applications that use aggregated patient data and other big data results, machine-generated individually tailored advice now seems an increasingly likely possibility. Individually tailored diagnostic and treatment advice can have significant

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added value for both people and society. Such advice will cover wide-ranging areas, including prevention.

Not only people and care providers, but also employers, businesses and health insurers would derive considerable benefit from the information collected as it will enable them to acquire insight into behaviour, individual efforts and the potential for people to improve their health. As stated, this information can contribute to tailoring interventions by the regular healthcare and welfare services or employers more specifically to individuals in a non-anonymised manner. However, this information could also be used for other purposes.

There is a risk of unauthorised or inappropriate use. The analyses and information could be used for profiling individuals or groups of people. This could generate relevant knowledge that could be used (and also sold) for all kinds of purposes.

Based on the increased likelihood of individually tailored advice, a moral duty and perhaps even an actual duty may in fact arise to collect data. Self-measurement (medication adherence, diet, physical activity, sleep and blood sugar levels) as an objectifiable medication adherence benchmark should be made conditional for certain reimbursements under the health insurance package. The requirement to collect data is rooted in the moral expectation that people will commit to specific advice and act in accordance with a certain standard. Whether they actually do so can easily be demonstrated on the basis of a big data analysis at a later stage.

People could as it were start being monitored.

Power of international commercial companies and consumer control

As a result of the capabilities of consumer eHealth, greater focus could be placed on people's needs and wishes. People will be able to design and determine their personal healthcare to suit their individual needs and partially implement it. The healthcare relationship between the patient and the care provider will be put on a more equal footing. Ideally people will be given control over and access to their medical information.

However, the question is whether consumers will in fact be able to exert any real influence. A problem surrounding rights and responsibilities is the lack of available binding open

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international or other standards and the enforcement of these standards. Because large commercial companies determine their own standards, data cannot be exchanged between applications originating from different companies. Companies protect their position by keeping the key to the information to themselves. Consumers cannot automatically use another supplier's range of products. There is a risk of 'vendor lock-in' (RVZ, 2015c). There is not much an individual consumer can do about this.

In the current situation power in the healthcare sector is divided across the patient/citizen, the care provider (and healthcare organisation) and the insurer. They will be joined by a fourth player in the new situation: large internationally oriented, commercial ICT businesses (non-healthcare). This could even give rise to an entirely new kind of dynamics. Nissenbaum (2010) asserts that large international ICT companies could even become more powerful than states. It is not clear who will directly determine the agenda and according to what rules the game will be played.

The various risks and threats will moreover be largely influenced by the earnings models used by the various parties and the ensuing interests. The background study *Financiering en bekostiging van eHealth* ('Financing and Funding eHealth') (RVZ, 2014f) examines the various earnings models and interests in greater detail.

Another potential development in the balance of power is that health insurers too may penetrate deeper into the consumer eHealth market. They could, for instance, start offering applications directly to consumers. The more consumer eHealth becomes intertwined with the regular healthcare services, the more likely it is that health insurers will actually begin to act as care providers. This could even result in a considerable shift in the balance of power.

Performative role of technology

Technology is not value-free. Norms and values about 'What is good health?' and 'What is good healthcare?' are implicitly integrated into the applications. Similarly, standards relating to the use of technology are interwoven with the application. While the launch of e-mail seemed to be a major step forward in written communication between people, it simultaneously created new standards. In the past it still was possible to reply to a letter a few days after receipt, but the launch of fast e-mail means that people nowadays expect to receive a response almost immediately. Slowly but surely expectations have

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morphed into obligations, and an apology is due from those who do not respond to a message quickly.

A good example illustrating this in the healthcare domain is written by Annemarie Mol (2000) based on a blood glucose meter. This device is used by people suffering from diabetes type I or II to check their blood glucose levels and to adjust their medication themselves if necessary, based on the values measured. The device not only enables patients to maintain normal blood glucose levels but also alters their definition of what is deemed to be 'normal'. In the past blood glucose levels were only checked on an empty stomach by the doctor. Today patients can measure their blood glucose levels any time and other criteria apply. This also concerns changes at a more concrete level. The standard establishing what 'normal blood glucose levels' are and what 'well-regulated' means can be adapted accordingly.

In short, consumer eHealth measures and attributes a value to body and other values and to user data and therefore will in a broad sense create new expectations (standards). Since consumer eHealth is being developed across the globe, international and commercial norms and values are set to play a more decisive role.

Part of the performative influence of technology proceeds unconsciously. People and technology interact with each other. People adapt their behaviour and expectations. Control/people taking charge thus cannot be considered in isolation from the technological and other context.

Cost savings and cost increases

An important question is what the emergence of consumer eHealth will mean for healthcare demand and for group health insurance costs. Group health insurance costs are expected to fall. However, there is neither any evidence nor are there any indications that this will actually be the case. In the light of these uncertainties we have set out a number of considerations pertaining to the question of whether consumer eHealth will bring about cost savings or cause costs to rise.

Initially people themselves will mainly bear the costs of lifestyle consumer eHealth. Additional costs for a healthy lifestyle will also be for account of the individual. If people stay healthy for longer and develop fewer chronic conditions, the costs of insured healthcare could potentially decline. Health insurers, employers or other parties, such as pharmaceutical companies, sometimes reimburse lifestyle

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applications. Yet people could potentially live longer and develop physical disabilities and chronic conditions at a later stage, which could potentially negate this effect (in part) and even cause lifetime costs to rise.

Self-measurement can lead to increased demand for advice and diagnosis without resulting in any ultimate health or financial gains Medicalisation poses a risk. On the one hand, selfmeasurement can lead to earlier and thus more affordable treatment if a condition is diagnosed at an early stage, particularly if other areas of life, such as work, are included. On the other hand, far more people will be diagnosed and may undergo treatment. False positive results are a further problem, for which unnecessary diagnosis costs could be incurred for insured healthcare. Transaction costs, however, are anticipated to fall. This could again negate part of the effect of the potential rising healthcare demand on the costs.

The personalisation of healthcare (using a machine expert or otherwise) will generate cost savings (Innovation and Reform expert meeting, 29 October 2014). Self-diagnosis and selftreatment could also contribute to minimising the rising costs of healthcare by substituting the professional healthcare services. Apart from 'machine learning', the use of big data could help save costs, as demonstrated by McKinsey (2011).

The improved efficiency and quality of the healthcare processes arising from the use of eHealth in general and consumer eHealth in particular, with consumer eHealth potentially having a positive impact on the use of professional eHealth, is expected to result in greater efficiency. However, this means that substitution will need to take place.

The question is whether the costs of consumer eHealth will continue to be for the account of citizens. As consumer eHealth becomes more closely linked and intertwined with the regular healthcare services, the more often the question will be raised as to who will bear the costs. An important aspect that should be considered in this context are the potential changes in healthcare entitlements, in terms of both timing and content.

Aside from the costs, financial income is another important aspect. Should income be generated from consumer eHealth, to whom will the income be allocated? To employers? To consumer eHealth providers? The income often is fragmented, which means that the income derived from individual components is not sufficiently interesting for investment

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purposes (Financing and Funding expert meeting, 16 October 2014).

In short, in view of current knowledge the Council is unable to express an opinion on the anticipated financial effects of the use of consumer eHealth.

3.3 Conclusion

This chapter describes the relevant dilemmas arising from the wider deployment and use of consumer eHealth and from the further intertwinement of consumer eHealth with the regular healthcare services.

Consumer eHealth does not yet play a significant role in the current healthcare system. Developments are set to occur in rapid succession and consumer eHealth could profoundly change the regular healthcare services in various ways. Some components of consumer eHealth could also substitute the regular healthcare services. The Council has identified a number of fundamental problems arising from intertwinement. These problems are analysed in Chapter 4.

It is important to establish certain framework conditions to enable people, care providers and society to use the possibilities offered by consumer eHealth. This aspect is examined in detail in Chapter 5.

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4 Core problems arising from the intertwinement of consumer eHealth with the regular healthcare services

4.1 Background

The preceding chapters present a picture of the emergence of consumer eHealth and its potential intertwinement with the regular healthcare services. Several dilemmas arising from the use of consumer eHealth and potential intertwinement were subsequently discussed.

In this chapter the Council discusses the most fundamental problems relating to the issue of intertwinement. This analysis serves as a prelude to the establishment of framework conditions.

4.2 Core problems

eHealth and the differences in people's capabilities and competencies

The question is whether all citizens will accept consumer eHealth applications to the same degree and be capable of using them.

For the purpose of preparing the advisory report interviews were conducted with general practitioners (GPs), clinical geriatricians and an elderly care specialist to obtain their views on the possibility of using eHealth applications (in general) for the purpose of and by the elderly target group with chronic multimorbidity. All these physicians used or had developed an eHealth application. The illustrative findings are shown in Boxes 4.1 and 5.1.

Box 4.1 Elderly with multimorbidity What do physicians say? (Part 1)

When asking the question of whether multimorbid elderly people are capable of using eHealth, the following aspects frequently recur: computer skills, physical characteristics (sight/hearing) and cognitive skills. Opinions seem to diverge on the computer literacy of the current elderly generation. Where some physicians say that nowadays the elderly skype with their children and that they should also be able to so with their GP, other physicians say that a large elderly group lack computer skills and that this therefore prevents them from using eHealth.

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Question marks were also put over elderly self-management here and there. The current elderly generation seem to have been brought up with less of an idea that they can make their own decisions on their health and personal healthcare. Information provision plays a more important role for this generation than making their own decisions. The future generation will consist of more empowered, articulate patients who want to and will in fact more actively take control over their personal healthcare.

Source: Background study Het perspectief van artsen in de onderenzorg op het gebruik van eHealth-toepassingen (RVZ, 2015e) ('The perspective of geriatric physicians on the use of eHealth applications').

For the purpose of this advisory report the Council had a summary drawn up of factors that could influence the use or non-use of eHealth in general and the required health/eHealth skills (RVZ, 2015a). These factors may be relevant for the use of both professional and consumer eHealth.

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Figure 4.1 Influencing factors

Quality of ICT				
Benefitt				
User-friendliness				
Efficiency	Informal environment			
Sense of trust (incl. safety and privacy) Enjoyment	 Socio-economic environment. Social norms and values orientation by the social environment and the individual's outlook on life. Social capital. Involvement of family, friends, informal caregivers, volunteers, local residents, self-management networks in the healthcare and support process) during our stages of life could change our social capital both in quantitative and in qualitative terms. 			
Availability/ access to ICT infrastructure	Changes in social capital often bring about changed patient preferences, values and expectations in the healthcare and support process.			
that works properly	Professional environment Formal setting for healthcare and support; stage and objective; self-manag (skills) and care recipiënt-care provider relationship (the care provider is authority, partner or facilitator)			
		State of health		
		 Nature of the condition(s) important for: (1) providing information on the condition(s) to the care recipient (2) having an individual's state of health measured and monitored, including the relevant values (weight, blood pressure, blood sugar, etc.) (3) putting individuals in contact with/enabling them to communicate with those in the same situation Severity (stage and progression) of the condition(s) decisive for: (1) Capacity (physical and mental) to acquire self-management skills and the skills to perform ADL (2) People's preferences, values and expectations during the healthcare and support process 		
			Personal eHealth/health skills	
			literacy level of education	
			eHealth/health skills can be acquired to a certain extent	
			respond to individual style of learning and the ability to learn and adapt	

Source: Background study *Gebruik van eHealth bij zelfmanagement: verschillen die het verschil uitmaken* (RVZ, 2015a) ("The use of eHealth for self-management purposes: Differences that do make a difference").

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An important influencing factor in the context of this advisory report are health skills. 'Health literacy' or health skills are basic competencies that people need in order to live a healthy life. Examples are finding your way around the healthcare system, choosing a hospital, communicating with the care provider, jointly deciding on treatment and also partly self-administering that treatment yourself (RVZ, 2013). Low health literacy skills are linked to poorer health results: poorer health and a higher risk of death (Berkman et al., 2011a; 2011b).

The correlation between low health literacy skills and poorer health results is attributable to factors such as knowledge and information, lifestyle, the use of and access to healthcare, communication with the care provider, self-management and use of medicine. Consumer eHealth can contribute to raising the patient's health skills level (NIVEL, 2014).

An important factor to consider in using eHealth is digital competence. This refers to the basic skills needed to be able to work with ICT. An EU survey (EC, 2014) revealed that *disadvantaged people* (unemployed, a lower level of education, a small pension or a low income) have poor digital skills. The survey also found that health skills are lower among people with a lower level of education in the Netherlands (HLS-EU Consortium, 2012).

In other words, there seems to be an overlap between the group of people with low health literacy skills and those with low digital skills. That group will be less able to use eHealth applications and/or to assess the indications and advice provided.

Lack of expertise and support among care providers KPMG (2012) describes major obstacles in the use of eHealth in 15 countries. The factors stated are: the high investments and the absence of a reimbursement structure, doubts about security, problems with technology, the lack of a scientific basis, inadequate change management and insufficiently committed care providers.

Online assistance imposes particular demands on the knowledge, skills and attitude of (partial) online care providers (Limper and Schalken, 2013). These 'eSkills' are written communication proficiency and typing skills, basic ICT expertise and knowledge of the capabilities and limitations of online assistance. Most care providers currently either hardly have eSkills or none at all. Professional or vocational training programmes barely place any emphasis on these skills. Care

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providers are reluctant to use eHealth in their practice due to their lack of knowledge. Trainers inadequately prepare care providers for using eHealth. In association with KNMG, the Academic Medical Center in Amsterdam (AMC) gauged the need among physicians for eHealth and ICT education in the healthcare sector (Jacobs, 2014) and found that there is a great need, even among physicians who already fulfil a leading role.

Liability inadequately regulated

Under Dutch law the Medical Treatment Contracts Act (WGBO) governs the legal relationship between care providers and patients. Pursuant to the Act the care provider is responsible and liable for everything that is carried out under the treatment contract. Full liability implies that the care provider also is responsible and liable for the acts of individuals who are involved in performing the treatment contract, so-called auxiliary persons, and for the devices used. For this reason one of the rules of conduct for physicians is that eHealth contracts should in principle be solely performed within the framework of an existing treatment contract. Otherwise the care provider is restricted to providing general advice (KNMG, 2007). If the care provider is be held responsible and liable for devices, such as eHealth applications, it must after all be aware of and be able to assess their quality and reliability.

Although such comprehensive liability (which cannot be excluded) offers the care provider in the Dutch situation a high level of protection, at the same time it impedes the further implementation of eHealth. The advancement of consumer eHealth means that care providers will increasingly be faced with ad hoc requests for advice, without a treatment contract even having been entered into. The care provider will be confronted with data generated by the care recipient with the aid of an electronic tool he or she has purchased. This problem will escalate the more self-diagnosis and selftreatment applications start playing a larger role. People will have already independently gone through a more extensive procedure before approaching the regular healthcare services.

Because counselling and issuing advice fall under the scope of the above Act, for the purpose of complying with the obligations stipulated in the Act, the care provider will tend to start from scratch, repeat the examination, etc. The Act could thus impede the intertwinement of consumer eHealth with the regular healthcare services.

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In order to make maximum use of the possibilities offered by consumer eHealth, people could start using the additional services offered by commercial companies in the form of specific services. However, these companies will endeavour to exclude any form of liability. Care recipients will in this case have considerably less protection than is possible (RVC, 2015d).

Jurisdiction and conflicts of jurisdiction still inadequately regulated

In the event that disputes relating to the application of eHealth transcend national borders, it is insufficiently clear to both patients and care providers which national law actually applies. If a physician's practice is established outside the Netherlands, the physician may determine as a condition for the provision of services that the contract is subject to the law of the country where the physician's practice is established. This may prejudice care recipients if their level of protection in the country in which the service provider is established (in this case the physician) is lower than in the Netherlands. This problem has been resolved within the European Union with the Convention on the law applicable to contractual obligations (Convention 80/934/EEC). This means that Dutch consumers/patients can invoke their rights deriving from the Medical Treatment Contracts Act (WGBO). It also means that even if the physician's practice is established outside the Netherlands, the physician cannot exclude or limit liability for a breach of contract on his or her part.

From the care recipient's perspective, it is a problem that the scope of the EU convention is limited to the EU member states, whilst a considerable number of consumer eHealth services come from the USA. If care recipients use eHealth services from providers not established in the European Union, it is not clear what law (and therefore what level of protection) applies to the contract.

Insufficient knowledge of and information on consumer eHealth applications

If a medical app is designed for diagnostic or therapeutic purposes, according to the law it is deemed to be a medical device. In that case Council Directive 93/42/EEC concerning medical devices (MDD) applies. The Dutch Medical Devices Act (*Wet op de medische bulpmiddelen*, Wmh) derives directly from this Directive. The Directive will be transposed into the Regulation concerning medical devices in the near future.

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The MDD stipulates that CE certification is mandatory for the admission of a medical device to the market (Nouwt and Vollebregt, 2012; Vollebregt, 2012). CE certification guarantees that the product meets the European requirements for placing the product on the market and that the procedures for establishing that this is the case have been completed. These requirements relate mainly to product safety and efficacy.

If a specific medical app is deemed to be designated as a medical device under the Medical Devices Act and the corresponding Medical Devices Decree, it will often be classified in the lowest risk class. This means that the company marketing the app can certify the app itself by creating and maintaining a technical file in which the safety and performance of the app are substantiated and a quality assurance system must be maintained. The MDD sets out in which cases an assessment must be performed by an independent 'registered' body. This is the case, for example, if the app contains a measurement functionality or if it controls a medical device in risk class IIa or higher (RVZ, 2015d). In the Netherlands 25 apps have now been registered as a medical device in class I (Source: IGZ, 2015).

CE certification can be attractive to suppliers in that it can help boost sales. However, since CE certification involves additional costs, in practice suppliers may seek to push the boundaries in terms of what is and what is not deemed to be a medical device. It might in fact be attractive to market an application as a device that aims to 'promote health' rather than as a 'medical' application. In that case the CE marking is not mandatory and there is also no need to comply with the requirements set out in the Medical Devices Act (RVZ, 2015d). It should be noted, however, that these products must be compliant with the Unfair Commercial Practices Act (Wet oneerlijke handelspraktijken) and furthermore that regular product liability also applies. The Netherlands Authority for Consumers and Markets (ACM) is responsible for enforcing compliance with the Unfair Commercial Practices Act. The unauthorised claiming of a CE marking falls within the scope of this Act. Similarly, the unauthorised use of a CE marketing is prohibited under the Medical Devices Act and the Medical Devices Decree.

A CE marking lays down conditions for the admission of medical apps to the market. To enable consumer eHealth to become intertwined with the regular healthcare services, however, insight is also required into the clinical benefit

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(clinical effectiveness) of an application compared with other (existing) applications and interventions. Proven comparable clinical benefit is a requirement for gaining admission to the health insurance package. There currently are few consumer eHealth applications with proven clinical effectiveness let alone cost effectiveness. At present there is a lack of appropriate research methods to enable clinical effectiveness (clinical benefit or added value) to be demonstrated (RVZ, 2015h).

Developments in eHealth are occurring rapidly and applications are being developed at a rapid pace. Consumers are increasingly taking the initiative to seek and make their own choice for an application. As outlined earlier, care providers are expected to enter the equation at an increasingly later stage. It is difficult for consumers to obtain and maintain a good picture of an appropriate application that meets their needs and wishes. This also is a problem facing care providers when they want to advise a consumer or when they want to gain an idea of the added value of an application used by a consumer. Insight into the clinical benefit can help in the selection process. Other aspects, such as earnings models, user-friendliness and the use of data (by third parties) may be equally relevant for the selection process of consumers. At present, however, information on aspects that are important for the selection process of the consumer and/or the care provider is neither adequately accessible nor clear cut.

An integrated approach must be adopted concerning the quality of applications in the event consumer eHealth and the regular healthcare services are linked up or become intertwined. This relates not only to the application itself, but also to the processes surrounding the use of an application by any healthcare organisation, care provider and care recipient. Furthermore adequate supervision is a condition. The Healthcare Inspectorate (IGZ), which is responsible for monitoring compliance with the MDD, has been actively monitoring the use of software, including medical apps, as a medical device since 1 January 2014 (Hooghiemstra and Nouwt, 2014). The coordination of supervision is furthermore being sought in a European context under the Joint Action Plan for Medical Devices (RVZ, 2015d).

Privacy concerns

It is impossible to ensure the absolute protection of privacy, in the sense of having complete control over personal data. Privacy must always be viewed in a certain context (Nissenbaum, 2010). In the healthcare sector this concerns the

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protection of health information within the meaning of the Personal Data Protection Act (*Wet bescherming persoonsgegevens*,⁷ Wbp). Health information requires a relatively high level of protection. Consumer eHealth generates a huge volume of data, which can be managed and processed by third parties (possibly beyond national borders). It is essential to ensure privacy safeguards. A specific consideration relating to the intertwinement of consumer eHealth with the regular healthcare services is linking up this information with the information generated by the regular healthcare services.

Box 4.2 Social media

Self-measurement apps can increasingly be shared online through social media. 'Data experiences', for instance, are being created which use biomedical data as a communication tool (Vleugels, 2014). Research has shown that when using social media young people initially do not take privacy as seriously as older people. This is not because they have been brought up with social media but rather relates to a stage of their development. These young people will later also attach greater importance to privacy (Steijn, 2014).

The European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 protects the right of citizens and respectively patients to privacy at the European level. The purpose of the so-called Data Protection Directive (EU Directive 95/46/EC) is to harmonise data processing laws.

The European Commission published the first new version of the General Data Protection Regulation on 12 January 2012. Contrary to the European Directive, an EU regulation directly applies to all EU member states. The European Parliament adopted the first version on 12 March 2014.

As soon as the Regulation enters into force, presumably in two years' time (2016), aspects including privacy by design will become mandatory, in other words the data protection standards must be incorporated into the organisational structure and technical design of information systems. Recommendations have already been formulated by the so-called Article 29 Working Party at the European level for the application of the Privacy by Design principles to app design (Opinion 02/2013 on apps on smart devices, WP202). This means that the processing of personal data on European territory by organisations outside Europe (such as Google, Apple, Amazon and Facebook) is

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⁷ Pursuant to Section 21 of the Personal Data Protection Act health information is taken to mean all data relating to physical and/or mental health.

also governed by European data protection law. Until that time, this does not yet apply.

Health data managed by commercial third parties outside the healthcare sector should, under social, financial or legal pressure, be made accessible to individuals or organisations outside the healthcare sector. Consumer/patient information generated outside the healthcare domain in fact is not protected by patient rights under the Medical Treatment Contracts Act (WGBO). Medical confidentiality is an important example of such a patient right. Without the protection of medical confidentiality, the police, Ministry of Security and Justice, and the intelligence services, such as the National Security Agency (NSA), can demand data without being entitled to refuse to give evidence. The RVZ's earlier call for patient confidentiality provided for by law is more urgent than ever for consumer eHealth (RVZ, 2014a).

Concerning the possible misuse of information, the Council furthermore wishes to draw attention to the risks of identity fraud arising from the current, extremely inadequate mechanisms for reliably authenticating patients/consumers, particularly beyond the government domain. There must be certainty that the person who digitally claims that he or she is a certain person is in fact that person. Authentication can also pose a problem for care providers when using eHealth applications. A good example of successful consumer authentication are the Internet banking methods developed by banks. At present there still is no reliable means of authentication that can be used nationwide for consumer eHealth free of charge and this is a serious problem for the wider deployment of consumer eHealth.

Lack of a widely supported, safe and reliable form of data processing

People become a source of knowledge and information in their consumer, patient and citizen roles.

Access to and the use of knowledge and information is crucial in enabling people to shape their personal healthcare for themselves. This aspect is equally important in the collaboration between multiple care providers. It should be possible to share and use knowledge and information across 'boundaries' and this should ideally be organised with the individual as the point of departure. This applies to welfare, prevention and healthcare. Conditions must be created which offer the possibility, if desired by the individual, to link up and

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exchange (certain) consumer eHealth data and (certain) data generated by the relevant care providers in certain situations.

Huge volumes of health data are generated by consumer eHealth. At aggregated level health data can be linked to data from other sources.

Scientific and other information can be derived from the analysis of these huge volumes of data, or big data, which could prove extremely valuable for scientific research, for instance. However, it could also be misused. Sharing anonymised data in that case is a condition and this must be carried out in a secure and reliable manner.

At present information collected by the relevant care providers and the individual is hardly exchanged. In a future scenario, in which people will tailor their personal healthcare as far as possible to suit their individual needs and wishes, it is vital to ensure a widely supported, secure and trusted data processing environment. If adequate conditions fail to be created, standards, frameworks, facilities and procedures will be determined by the various commercial suppliers (of consumer eHealth) and their earnings models. This could seriously impede citizens and society from using the possibilities offered by consumer eHealth. Safeguarding the privacy of individual care providers and citizens is a key consideration.

Another question is who will have access to the big data (at aggregated level) in anonymised form and who has disposal of and control over the results of any big data analyses. An important component of the business model of some companies that offer health platforms might consist of income from the sale of information derived from big data. People often are unaware that their data can be sold. The purchasing parties will be financially strong companies. Public bodies and research institutions, such as universities, will be less financially able to purchase this information. This could disadvantage academia and make public tasks more expensive (RVZ, 2015c). Moreover further possibilities will not be used to their full potential, or not at all.

Lack of standardisation

As already pointed out in the advisory report *Patient Information* (RVZ, 2014a), as yet there are no regulations that provide for uniform information standards, at both the national and European level. This concerns reproduction, storage and export standards. This implies that all parties that offer eHealth applications determine the standards used themselves as a consequence of which systems are incompatible and

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automated data therefore cannot be exchanged, leading to fragmentation, inefficiency, errors, the unnecessary duplication of enquiries/examinations, etc. There also are more specific problems (RVZ, 2015c).

Innovative start-ups come up with new standards for new applications from time to time. If they prove to be successful, larger companies can further develop these applications and bring them to the market as proprietary standards. This can force smaller start-ups out of the market or they can be taken over (RVC, 2015c). Data can also be lost as a result.

Information stored on the (eHealth) platform of a certain supplier on the basis of supplier-related standards at present is difficult to exchange and/or transfer to another platform. Certain devices, apps or platforms only work if they originate from a certain supplier, or if relevant agreements have been made. One such example is the electronic exchange of data from a health platform containing digital medical records from care providers. As stated in Chapter 3, there is an inherent risk of vendor lock-in (RVZ, 2015c).

In the EU Directive on the application of patients' rights in cross-border healthcare (9 March 2011) the EU highlights the importance of interoperability between ICT systems in member states. Reference is made in this context to the European Patients Smart Open Services project (epSOSproject) aimed at building infrastructure to facilitate the crossborder interoperability of digital healthcare systems in Europe.

At the request of the EU member states, in 2009 the European Commission drew up the eHealth Action Plan for the period 2012-2020. Due to the rapid technological developments, such as the emergence of medical apps for smartphones, the action plan required an update. The current eHealth Action Plan 2014-2020 was therefore drawn up. It was adopted by the European Parliament at the beginning of 2014. The European Commission will start working on international eHealth standards under the direction of the European Commissioner for the Digital Agenda. Standards, protocols and procedures will also be developed for eHealth traffic between the EU member states (RVZ, 2015d).

4.3 Conclusion

The Council has identified a number of core problems arising from the intertwinement of eHealth with the regular healthcare services. Major problems include the differences in

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people's capabilities and skills, a lack of information to enable consumers to make choices and the lack of a widely supported, safe and trusted form of data processing. The potential solutions for the problems outlined are explored in Chapter 5, based on which concrete recommendations are provided in Chapter 6.

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5 Potential solutions

5.1 Background

In the preceding chapters the Council explored the emergence of consumer eHealth and explored the possible consequences for the regular healthcare services. Chapters 3 and 4 examined the associated dilemmas arising from this development and the most fundamental problems relating to the intertwinement of consumer eHealth with the regular healthcare services.

Consumer eHealth is on the rise and is expected to become increasingly important and more comprehensive. Developments are occurring rapidly, the consequences could be profound and wide-ranging interests are at stake. The developments that lie ahead can merely be partially predicted at present and also merely be partially influenced.

In this chapter the Council describes the potential solutions and possible ensuing measures that it deems necessary for the safe use of consumer eHealth. The Council addresses the problems that can be influenced, in the knowledge that the introduction and wider deployment of consumer eHealth will largely be driven by the possibilities offered by technology, the capability of businesses and institutions to create appropriate digital applications from technology and consumer receptiveness to those applications.

5.2 Potential solutions for new relations

This section looks at potential solutions for relations between citizens and care providers. Solutions must be found in order to facilitate in a responsible manner the intertwinement of consumer eHealth with the regular healthcare services and the associated changes in the position of the latter and the possibilities.

eHealth for all?

For the purpose of this advisory report the Council had a summary drawn up of factors that could influence the use or non-use of eHealth in general and the required health/eHealth skills (RVZ, 2015a). These factors could be relevant for the use of both professional and consumer eHealth. An overview of influencing factors is included in Chapter 4.

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Some, more vulnerable target groups could receive support when using eHealth to shape their healthcare as much as possible for themselves. This applies, for instance, to the group of people with inadequate health skills and inadequate digital skills. Further scientific research must be carried out into the practicalities/impracticalities of the use of eHealth by various vulnerable target groups.

People's capabilities and health skills levels are dynamic - they can increase or decrease. Functional impairments in the elderly, for instance, often are associated with the reduced capability to use applications. Furthermore technological developments are occurring rapidly and the (modified) capabilities and user-friendliness of applications are increasing. It is vital therefore to conduct repeated evaluations (RVZ, 2015a).

More and more target groups are likely to be served (in part) by consumer eHealth providers, particularly in the light of the globalisation of the market. On account of the global market and the exchange of basic and other techniques, it will become viable to develop or modify applications to suit specific needs. However, there still are expected to be target groups to whom this does not apply: the more vulnerable citizens and/or those with low health skills. The government should, also financially, support third-party initiatives to develop and/or modify applications for use by vulnerable groups, including applications specifically designed for certain rare conditions.

Whilst eHealth is not a panacea, the best way in which healthcare should be provided, however, should always be considered in consultation with citizens. Not everyone will want to use consumer eHealth. There should be a right to an alternative arrangement in analogy with the General Administrative Law Act (*Algemene wet bestuursrecht*), based on which citizens always have the option of receiving only faceto-face care (under one roof).

Generally speaking citizens must continue to develop their health/eHealth skills (RVZ, 2015a). Consideration should be given to placing even stronger emphasis on the development of digital and health skills as early as in primary education. An option that should be considered is to teach all primary school children computer programming.

Greater acceptance and use of eHealth applications by care providers

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For the purpose of preparing the advisory report interviews were conducted with general practitioners, clinical geriatricians and an elderly care specialist to obtain their views on the use of eHealth (in general) by and for the elderly target group with multimorbidity. All these physicians used or had developed an eHealth application. The illustrative findings are shown in Boxes 4.1 and 5.1.

Box 5.1 Elderly with multimorbidity What do physicians say? (Part 2)

In general the physicians interviewed responded favourably to the use and capabilities of their eHealth application. A frequent comment made by the physicians on digital collaborative applications was that it was difficult to connect all care providers involved in elderly patient care to the system. The costs of purchasing the system and the time invested in learning to use the application and incorporating it into their work process were found to be major obstacles. Moreover digital collaboration requires a culture change in that care providers from the different disciplines will need to look beyond the boundaries of their respective disciplines and collaborate more with each other. In order to bring about a culture change, care providers could communicate positive examples to help inspire other care providers. Training by the supplier of the application was said to be a facilitative condition for the use of an eHealth application. In addition to training, however, attention should also be paid to eHealth in general in medical education, not just in the basic and advanced study programmes but also in continuing education programmes. Making eHealth a component of care providers' training programmes will enable them to familiarise themselves with various eHealth applications at an early stage and they will acquire the necessary skills and competencies to work with the application. When working as practitioners on completion of their study programme, they can serve as early adopters within organisations that do not yet use eHealth or hardly use it all.

Source: Background study Het perspectief van artsen in de ouderenzorg op het gebruik van eHealth toepassingen (RVZ, 2015e) ('The perspective of geriatric physicians on the use of eHealth applications').

Care providers will need to be convinced as much as possible of the added value of a certain application for the quality of healthcare and their healthcare processes. This is examined in further detail in Section 5.4.

Companies also directly approach the care provider as a 'consumer'. This could offer opportunities to improve support for activities and for working on a time and locationindependent basis.

Attention must be given to personal experiences and care providers' capabilities given that the ongoing use of eHealth in

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set to bring about significant changes in their everyday work. People themselves can take over a number of tasks from care providers. This requires a culture change among care providers. This issue was examined in-depth in the RVZ's advisory report *De participerende patiënt* (2013) ("The Participating Patient").

The use of eHealth requires a professional attitude and ICT expertise, or eSkills. Moreover the level of substantive eHealth expertise among care providers could be increased (Nictiz, 2014). eHealth expertise must be continuously developed through training and education.

This applies to computer scientists with knowledge of medicine and medical practitioners with knowledge of computing science. Furthermore existing professions in other sectors could be beneficial in the healthcare sector. The needs and wishes of care providers and consumers, work processes and substantive safeguards, on the one hand, and technological capabilities, on the other, will constantly need to be harmonised and adapted.

Technological developments also open up new opportunities for training programmes. Applications could be put into a gaming context by means of *Gamification*, thus creating opportunities to promote the use of eHealth applications by and for the purpose of training citizens and care providers (RVZ, 2015c).

For information relating to professions and training programmes, please also see the advisory report *Naar nieuwe* zorg en zorgberoepen: de contouren (2015) ("Towards a new healthcare system and healthcare professions') issued by the Advisory Committee for the Innovation of Healthcare Professions and Training Programmes (Adviescommissie Innovatie Zorgberoepen & Opleidingen).

5.3 Potential solutions for the use and exchange of data

A form of intertwinement between consumer eHealth and the regular healthcare services relates to linking up and exchanging data collected by an individual and by various people involved in the individual's healthcare.

Conditions must be laid down for using data derived from various sources, including (the exchange of) electronic data and

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information. This will enable people to shape their personal healthcare for themselves and will create opportunities for intertwinement.

A potential future system of agreements and standards for using and exchanging data is visualised in Figure 5.2. The diagram provides insight into the desired possibilities for using and exchanging data to support the potential intertwinement of consumer eHealth with the regular healthcare services.

Based on the possibilities outlined, the Council recommends that the government promotes the establishment of a neutral system of binding agreements and uniform standards for exchanging data among eHealth applications and professional eHealth on the basis of a public-private partnership. This system could be aligned with international standards. One of the points of departure is consumer/patient control. Their personal data will be protected by privacy by design. It should be possible to link up data derived from various consumer eHealth applications and data generated by care providers without any problem (data portability). It should also be possible for consumers themselves to transfer data to another provider free of charge and without the intermediary of third parties. Software updates must be guaranteed.

When establishing this system of agreements and standards, consideration must also be given to the aspects of supervision and enforcement. Agreements could also be made with care providers concerning adherence to the agreed reimbursements and standards as a procurement criterion.

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Figure 5.2 Visualisation of the use and exchange of data (Neeltje Vermunt)

The point of departure in this diagram is the individual. The individual can independently collect information using various apps (on the left). One of these apps is a self-diagnosis/self-treatment app which features functionalities such as the analysis of big data from various sources (far left) to enable self-diagnostics and treatment. In addition to the information collected by the relevant individual, information is also collected by the other parties involved, usually care providers, such as a GP, a medical specialist, the home care organisation, a social worker, etc. The information collected by all the parties involved can be made accessible by linking it up and exchanging it on the basis of developing a system of agreements and standards. Applications must comply with these agreements and uniform standards.

With consent from the individual concerned, relevant data from the various files can be requested, linked up and combined on an automated basis and made accessible via a relevant dashboard.

Widely supported, trusted and secure data processing requires a high-quality authentication and built-in authorisation mechanism. Reliable authentication methods are a condition for consumer/patient control over permissions to view and

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access their digital health data and provide protection against identity fraud. This equally means that reliable authentication methods must be harmonised among care providers when using eHealth. Priority should be given to the development of workable authentication methods.

Patient confidentiality is equally important, insofar as medical confidentiality does not offer protection.

A personal health record (PHR)⁸ could serve as a dashboard for citizens. A PHR for and used by people gives individuals a central role in their personal healthcare and well-being. This will enable applications to be better tailored and integrated in an individual's daily life. Consumers can choose from various PHRs and will have the opportunity to transfer to another PHR provider while retaining their medical data.

With consent from the individual concerned and guarantees from a Trusted Third Party⁹ data can be made accessible at aggregated level in a trusted and secure manner that cannot be directly traced back to individuals. In addition to the diagnosis and treatment advice tailored to the relevant individual, the analysis of instant feedback loops and machine learning based on aggregated and anonymised data will create new possibilities for science and policy.

Inherent and instant possibilities will thus arise for healthcare provider quality assurance and performance management and automated medical expenses claims. Insight will be obtained into individual or overall performance in terms of added value to 'health and well-being' as well as 'responsible practice'. Performance-based funding will be possible. Data are destined to become the new 'black gold'.

Standardisation and interoperability

RVZ

Health platforms contain the health data of individuals and should be designated as a personal health record (PHR). In its advisory report *Patient Information* (RVZ, 2014) the RVZ advised the Minister to lay down that open international

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⁸ The PHR is a universal, user-friendly life-long tool, understandable to non-specialists, accessible at any time and at any location, for collecting, managing and sharing relevant health information and for taking control over health and healthcare and for supporting selfmanagement based on a standardised health data collection system and integrated digital healthcare services (The Federation of Patients and Consumer Organisations in the Netherlands, NPCF, 2013). ⁹ For more information, see the advisory report *Patient Information* (RVZ, 2014a)

standards must be used for the electronic exchange of data from, to and among PHRs. This will help avoid vendor lock-in and citizens/consumers will retain control over their data. The market threshold for new providers will also be lower as the consumer will be able to switch to another PHR provider or health platform without any problem.

The development of standards (interoperability) is currently being addressed by the European Commission (eHealth Action Plan 2014-2020). However, these activities do not relate directly to the PHR. The recommendations set out in the *Patient Information* advisory report concerning PHR standardisation could also be put forward at the European level.

To the extent these have already been adopted health insurers can, if relevant, increasingly start to include (international) standards as a procurement criterion.

5.4 Potential solutions for the quality of applications

To facilitate the intertwinement of consumer eHealth with the regular healthcare services, alongside a CE marking, additional insight must be obtained into clinical effectiveness (clinical benefit/added value).

A common research method used for therapeutic medical devices, the randomised controlled trial (RCT), cannot be used for the scientific evaluation of consumer eHealth applications. Similarly, the cross-sectional study used for diagnostic medical devices is not as suitable for consumer eHealth. There are no appropriate research methods for evaluating quality coupled with efficacy endpoints. Nictiz plans to examine the possibility of conducting scientific research into the clinical benefit of consumer eHealth applications, which partly assumes a short cyclical, modular character. Other organisations are also working on this issue. There are wide-ranging current and future types of eHealth applications, such as those used for self-diagnosis and self-treatment purposes. The expectation is that the relevant efficacy endpoints might well be completely different to those of a traditional clinical effectiveness study (CEG, 2007). This also means that several 'new' research methods may potentially be needed and/or that the need will arise for consensus on new forms of using existing methods for the scientific evaluation of consumer eHealth effectiveness. This could for instance be a hybrid form of qualitative and quantitative research. A framework must be defined which

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clarifies the designated method appropriate for each type of application. Matters such as responsibility for the burden of proof, supervision and funding must also be incorporated. Nictiz and the National Health Care Institute (*Zorginstituut*) could further develop this framework in collaboration with universities and university medical centres in an innovative manner, and should seek to align with international initiatives.

Proven clinical benefit is among the requirements for gaining admission to the health insurance package. Consumers will increasingly need to make their own choice for a self-diagnostic and/or self-treatment application outside the regular healthcare services, which they must be able to rely on.

When making choices consumers are also expected to have a need for other information that may or may not be related to the quality of consumer eHealth medical applications. This might for instance be information about earnings models criteria, the use of data (by third parties), data retrieval possibilities and user-friendliness. In the Council's opinion applications which allow user data to be sold to third parties without the user's knowledge - should not be used by the regular healthcare services. This should also apply to applications that promote advertising through the application as this could have a medicalising effect. The Council discusses earnings models in Section 5.6.

In collaboration with other relevant organisations, professional, consumer and patient organisations could develop additional quality or other criteria to assess (the quality of) medical self-diagnostic and/or self-treatment consumer eHealth applications, insofar as they do not overlap with CE certification under European law.

Self-evidently, initiatives from consumers themselves should also be used when developing and assessing applications, such as online review and rating systems.

To concretely facilitate the application selection processes for consumers and care providers, professional, consumer and patient organisations should initiate the development of a quality mark for self-diagnostic and self-treatment consumer eHealth medical applications in collaboration with care providers. The quality mark should enable consumers to read what quality and other criteria the application complies with.

Where possible alignment should be sought with national and international initiatives already undertaken.

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5.5 Potential legal solutions

The Council explains a number of legal framework conditions below.

International protection under the Medical Treatment Contracts Act (WGBO)

As outlined in Section 4.2 conflicts arising in the EU are governed by the Convention on the law applicable to contractual obligations (Convention 80/934/EEC). However, the Convention does not apply beyond the EU.

The government could examine whether, in relation to the EU Data Protection Directive, there is a need for an additional level of protection for other forms of international healthcare-related services and further explore whether expansion of the Convention is a realistic option (RVZ, 2015d).

Ensure that liability and responsibility are properly regulated

The issue of liability was discussed in Section 4.2.

A potential solution that might be considered for this problem is to design a lighter version of the medical treatment contract for eHealth services coupled with a light liability regime, a 'medical advice contract'. This option is elaborated in the background study *Juridische drempels voor toepassing (consumenten-)eHealth* (RVZ, 2015d) ('Legal barriers to using consumer eHealth').

However, the Council believes that it would be worthwhile seeking to establish framework conditions in such a manner that the traditional medical treatment contract would also suffice for consumer eHealth.

5.6 Potential financing and funding solutions

The Council has a strong preference for consumer eHealth that is paid directly. In the Council's opinion, the earnings model for an application should be limited to the purchase price of the application. When purchasing certain services, an additional subscription could be taken out.

Moreover the public debate concerning the costs that should be financed collectively and those that should be financed

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individually could be also be fuelled by the concerns arising from the intertwinement of consumer eHealth with the regular healthcare services.

One of the future considerations is whether entitlements to the group health insurance package could be made conditional on self-measurement as proof of medication adherence and individual contribution. This will add a new perspective to the current public debate on individual responsibility.

5.7 Agenda and research

Developments in consumer eHealth and its potential intertwinement with the regular healthcare services could occur rapidly. The consequences could be profound.

The individual should serve as the point of departure as far as possible, and healthcare, welfare and support should, if necessary, be offered across 'boundaries' as far as possible. Interaction and the exchange of products, services and data between citizens and care providers, and among care providers in the various healthcare, welfare and support sectors are important aspects that are still inadequately safeguarded.

In a remoter scenario it will be possible to provide on-thespot, individually tailored advice and to receive instant feedback on any action taken. This will provide instant insight into individual performance in terms of added value to 'health and well-being' and 'responsible practice'. Furthermore it will immediately enable all parties concerned to increase their knowledge and ability to learn. Scientific knowledge can be linked to clinical feedback loops and integrated, creating as it were a process in which guidelines are continuously developed. The use of guidelines to safeguard quality could fundamentally change. The relevant supervision will need to be adapted accordingly. Furthermore opportunities for performance-based funding will arise.

In short, the emergence of consumer eHealth and its intertwinement with the regular healthcare services raises questions that should be examined further. Each year the Nictiz eHealth monitor publishes a structured overview of the current status of and visible trends in eHealth. TrendITion publishes a future outlook. Consideration should be given to assigning Nictiz and TrendITion the task of monitoring developments on the intertwinement of consumer eHealth with the regular healthcare services. Based on the

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developments identified and the potential consequences and opportunities, in consultation with other actors (such as consumer/patient, care provider and university organisations) Nictiz could initiate an agenda for conducting further scientific and policy-related research in the broadest sense in this area. The authorities, health insurers and commercial parties could help finance follow-up scientific research by establishing a joint, independent fund for applied scientific research.

5.8 Conclusion

Consumer eHealth has considerable potential, yet it also has drawbacks. Problems will not solve themselves by allowing developments to take their course. This chapter presents potential solutions that may be conducive to making use of the possibilities offered by consumer eHealth and for mitigating the risks as far as possible. The objective is not to attempt to control this development but rather to ensure that it is useful for people and society. The final chapter contains a summary of concrete recommendations.

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6 Recommendations

Developments in consumer eHealth are occurring rapidly and they could have profound consequences for healthcare in its current form. Consumer eHealth responds directly to people's wishes and to solicited and unsolicited possibilities for people. The regular healthcare services are inadequately prepared for these developments and this problem will not solve itself. Measures must be taken to ensure that these developments are safe and useful for people and society.

The Council has formulated the following recommendations:

Quality

In association with universities, university medical centres and in line with international developments, Nictiz and the National Health Care Institute (*Zorginstituut Nederland*) should develop an appropriate methodological framework for the scientific evaluation of the clinical effectiveness (clinical benefit or added value) of consumer eHealth medical applications.

Professional, consumer and patient organisations should initiate the development of a quality mark for consumer eHealth self-diagnostic and self-treatment medical applications in collaboration with businesses and health insurers. The quality mark should enable consumers to read what quality or other criteria the application complies with. Where possible alignment should be sought with national and international initiatives already undertaken.

Vulnerable groups

The government should support, also financially, third-party initiatives to develop and/or adapt applications for use by vulnerable groups, including applications specifically designed for certain rare conditions.

The use and exchange of data¹⁰

The government must ensure a reliable authentication mechanism for all consumers/citizens/care providers/patients in relation to third parties, including businesses, such as the consumer authentication system developed by banks for Internet banking. Reliable authentication methods are a

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¹⁰ See also the advisory report *Patient Information* (RVZ, 2014a) for further relevant recommendations on patient confidentiality and standardisation.

condition for ensuring consumer/patient control over permissions to view and access their digital health data and provide protection against identity fraud.

On the basis of a public-private partnership the government should promote the establishment of a neutral system of binding agreements and uniform standards for exchanging information between consumer eHealth applications and professional eHealth, with consumer/patient control. Their personal data will be protected by privacy by design¹¹.

Training and knowledge

Universities and knowledge institutes should integrate eSkills and substantive eHealth expertise into the basic, advanced and continuing education programmes for care providers engaged in the provision of healthcare, welfare and support services.

Agenda and research

The emergence of consumer eHealth and its intertwinement with the regular healthcare services raises questions that should be examined further. Consideration must be given to issues such as opportunities for performance-based funding, ethical aspects, quality guarantees and supervision.

- Nictiz and TrendITion should be assigned the task of monitoring developments on the emergence of consumer eHealth and its intertwinement with the regular healthcare services and in coordination with other actors should initiate an agenda for conducting further scientific and policy-related research in the broadest sense in this area.
- The authorities, health insurers and commercial parties should establish a joint, independent fund for applied scientific research in the areas described above.

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¹¹ Privacy standards are incorporated in the organisational and technical design of information systems.

Council for Public Health and Health Care (RVZ)

Pauline Meurs Chair

- there

Theo Hooghiemstra Secretary-General and Director

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Appendices

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Appendix 1

Request for advice

This advisory report was issued following the request for advice made by the Minister of Health, Welfare and Sport (VWS), as set out in the 2014 eHealth, Self-Management and Health Skills Work Programme The question addressed in the work programme is as follows:

eHealth and self-management have become part and parcel of everyday healthcare practice. Developments and eHealth and self-management applications should start playing a larger role in healthcare in the near and more distant future and should be more widely deployed. This will enhance the quality, accessibility and efficiency of healthcare.

How can the content, application, deployment and use of eHealth services be optimised, taking account of the current and anticipated future needs and capabilities of the different patient categories, and the demand for care?

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Appendix 2

Preparation of the advisory report

The advisory report was prepared by the Council for Public Health and Health Care under the direction of: Prof. W.N.J. Groot Prof. D.L. Willems, from 1 July 2014 Prof. J.A.M. Kremer, from 15 September 2014 Prof. D.D.M. Braat, until 1 July 2014 Mr Bosma, until 1 July 2014

Relevant positions and ancillary activities held by the Council members: Prof. W.N.J. Groot

- Chair of the Provincial Council for Public Health in Limburg
- Associate partner, APE, The Hague
- Member of the Supervisory Committee of TopZorg/ZonMw
- Columnist and observer

Prof. D.L. Willems

- Professor of Medical Ethics, AMC-UvA
- Member of the Medical Ethics Committee for Human Research, AMC
- Member of the Medical Ethics Committee for Patient Care, AMC
- Chair of the project group for the Advanced programme in palliative care for general practitioners , Dutch College of General Practitioners (NHG)
- Chair of the Ethical Dilemmas Committee, Stichting '40-'45

Prof. J.A.M. Kremer

- Professor of Patient-Centred Innovations, Radboud University Medical Center
- Member of the Supervisory Board, Sint Maartenskliniek
- Member of the Advisory Committee, Kwaliteitsinstituut
- Strategy Adviser

An official project group assisted the Council in the preparation of the advisory report comprising:

Ms N.P.C.A. Vermunt, general practitioner (non-practising), project manager

Ms A. den Hoed, senior adviser

Mr T.F.M. Hooghiemstra, secretary-general and director

Ms M.W. de Lint, senior adviser

Ms M.L. Noteboom, communication adviser

Mr L. Ottes, physician, senior adviser

Mr A.W. van Raalte, senior adviser

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Ms A. Zarrinkhameh, adviser Ms N.I.M. van Wetten, communication adviser Ms S. de Graaf, trainee Mr J. Kok, trainee Mr H.J.M.V. Boersma, trainee Ms A.J.J. Mr Dees, project support

The Council issues independent advice. The nature of the meetings held during the preparation of the advisory report was not to seek support. The consultation partners have not committed themselves to the advisory report.

Background studies

The following background studies were conducted on behalf of the Council:

IQ healthcare wrote a background study entitled *Scoping review over de toegevoegde waarde van eHealth voor zelfmanagement bij ouderen* ('Scoping review on the added value of eHealth for elderly self-management').

TNO wrote a background study entitled *Doe-het-zelf Zorg: disruptieve effecten van consumenten-eHealth* ('DIY Healthcare: the disruptive effects of consumer eHealth').

Mr C.P.J. Flim, Flim Project Management, wrote a background study entitled *Financiering en bekostiging van eHealth* ('Financing and Funding eHealth').

In addition the project group conducted the following background studies:

- Mr H.J.M.V. Boersma and Ms N.P.C.A. Vermunt *ConsumenteneHealth en de zorg van de toekomst* ('Consumer eHealth and healthcare in the future').
- Ms S. de Graaf *Het perspectief van artsen in de ouderenzorg op het gebruik van eHealth-toepassingen* ("The perspective of geriatric physicians on the use of eHealth applications").
- Ms A. den Hoed *eHealth in het gemeentelijk domein* ('eHealth in the municipal domain').
- Ms M.W. de Lint Juridische drempels voor toepassing (consumenten-)eHealth ('Legal barriers to using consumer eHealth').
- Mr L. Ottes, physician Consumenten-eHealth: A game changer?! ('Consumer eHealth: A game changer?!').
- Mr. A.W. van Raalte *Adoptie van professionele eHealth* (^cThe adoption of professional eHealth²).

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 Ms A. Zarrinkhameh – Gebruik van eHealth bij zelfmanagement: verschillen die het verschil uitmaken (°The use of eHealth for self-management purposes: Differences that do make a difference').

Expert meetings

Six meetings with experts took place during the preparation of the advisory report.

21 May 2014, a general meeting at the Radboud REshape & Innovation Center in Nijmegen

Participants: Ms A.M. Bergen Mr L. Engelen

Dr M.T. Mr Smits

Dr K. Tates

Mr M. Voorn

Prof. L. Witkamp

Dr E.J.M. Wouters

Dr. J.A. Hazelzet Ms M. van Helden, Ms E. Jacobs J. Jochijms Ms D.M. van der Klauw, Mr S.H.D. Mr Ottenheijm

Movisie Reshape Center for Innovation Radboud University Medical Center Erasmus MC Minddistrict ZZG zorggroep Ciran TNO Nictiz/Reshape Center for Innovation Radboud University Medical Center Tilburg School of Economics and Management Tilburg University, Centre for Cognition and Communication Motivaction KSYOS Telemedisch Centrum Fontys University of Applied Sciences, Institute of Paramedical Studies

The other meetings were held at the RVZ office in The Hague.

6 October 2014, Institutes

Participants:	
Prof. N.L.U. van Meeteren	TNO & Maastricht University CAPHRI
	School for Public Health and Primary
	Care
Dr C.G. Schoemaker	National Institute for Public Health and
	the Environment (RIVM)
Ms O.M.M. Smeets	Trimbos Institute
Dr A.H. Uiters	National Institute for Public Health and
	the Environment (RIVM)
Dr I. Valstar	ZonMw
Prof. C. Veenhof	University Medical Center Utrecht

16 October 2014, Financing and Funding in collaboration with C.P.J. Flim

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Participants:	
Mr J.C. de Boer	KPMG
Ms A. Bransen	Municipality of Zeist
Mr J.V.D. Brinkmann	GGZ Noord Holland Noord
Ms I. Gaillard	The Dutch Healthcare Authority
	(NZa)
Mr J. van Gils	Redmax
Mr C.H.F. Gimbrère	The National Health Care
	Institute
Dr M. Heldoorn	The Federation of Patients and
	Consumer Organisations in the
	Netherlands (NPCF)
Ms I.C. Pastoors	The Dutch Healthcare Authority
	(NZa)
Mr M.H.C. de Romph	InEen
Mr F. Schalken	Stichting E-hulp
Mr L.M. van der Vorst	Philips Healthcare Nederland
Ms J.J.H. Waterreus	DBC Onderhoud
Mr M. Wittop Koning	KPN

29 October 2014, Innovation and Reform *Participants:*

Participants:	
Mr H. ter Brake	UNIT'4
Mr L. Darázsdi	Imtech ICT
Mr R. R. Faas	VvAA Groep BV
Mr J.T. te Gussinklo	Dutch Button Works
Mr J. van der Heijden	ZorgDomein
Mr. J.P. Hoonakker	Hans Hoonakker Management & Consultancy
Ms M. Vanderkaa	Unie KBO
Mr M. Luyten	Media-Care
Mr J. Plattel	Quantified Self Amsterdam
Mr R. Rutten	Media-Care
Mr M.C.M. van Schaik	Rabobank Nederland
Mr E. Schmitz	Imtech ICT
Ms T. Vogel	Sensire
Mr M. Wittop Koning	KPN
-	

29 October 2014, general meeting (follow-up to 21 May 2014 expert meeting)

Participants:	
Ms A.M. van Bergen	Movisie
Dr J.A. Hazelzet	Erasmus MC
Dr M. Heldoorn	Federation of Patients and Consumer
	Organisations in the Netherlands (NPCF)
Ms D.M. van der Klauw	TNO
Prof. N.L.U. van Meeteren	TNO & Maastricht University CAPHRI
	School for Public Health and Primary Care

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Mr S.H.D. Ottenheijm	Nictiz/Reshape Center for Innovation
,	Radboud University Medical Center
Mr S.T.M. Peek	Tilburg University
Dr M.T. Smits	Tilburg School of Economics and
	Management
Prof. L. Witkamp	KSYOS TeleMedisch Centrum
Dr E.J.M. Wouters	Fontys University of Applied Sciences,
-	Institute of Paramedical Studies

28 November 2014, Patients & CitizensParticipants:Mr P. AnthonioBOSK/ICT4HMs M. de BeenPharos - DutcDisparitiesDisparitiesMr D. CoeneStichting SepteMs A. CremersStichting HersMr J.P. KasdorpDe Hart & Va

Ms B. van Oost

Ms E. van Kempen

Ms M. Storm

Mr J.M. de Vries

BOSK/ICT4Handicap Pharos - Dutch Centre of Expertise on Health Disparities Stichting September Stichting Hersenletsel Organisaties Nederland De Hart & Vaatgroep Netherlands Kidney Patients' Association (NVN) Federation of Patients and Consumer Organisations in the Netherlands (NPCF) Netherlands Kidney Patients' Association (NVN) MEE Nederland

Parties consulted

The following people were consulted during the consulting process:

Prof. W.P. Achterberg

Dr I. Baars

Dr T.P. Bakker Ms C.C. van Beek

Mr F. van Bergen Mr J.G. Beun Ms P.F. den Bode Ms S.C.F. Boeker Dr P.J.M. van der Boog

Mr H. Bos Ms A.E.M. Mr Brabers, Ms D.S.J. Branje Ms F. Bremmer Leiden University Medical Center Kiwa Carity BV (now known as Fluent Healthcare BV) TNO Radboud University Medical Center Ciran **BijnierNET** Dutch Nurses' Association (V&VN) GGD GHOR Nederland Leiden University Medical Center Microsoft B.V. NIVEL Digitale Steden Agenda GGZ Nederland

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Ms D.M. van der Klauw

Nictiz Dr Leo Kannerhuis FocusCura The Dutch College of General Practitioners (NHG) The Dutch College of General Practitioners (NHG) Rathenau Institute Academic Medical Center (AMC) Reshape Center for Innovation Radboud University Medical Center Microsoft B.V. Dutch Association of eHealth (NVEH) Flim projectmanagement Health Care Inspectorate (IGZ) Nictiz MOgroep Zorggroep Thoon Respect Zorggroep Ministry of Health, Welfare and Sport National Health Care Institute Digitale Steden Agenda Association of Netherlands Municipalities (VNG) Rathenau Institute Ministry of Health, Welfare and Sport IBM Nederland B.V. The Federation of Patients and Consumer Organisations in the Netherlands (NPCF) Ieder(in) VitaValley KNMG Portavita BV Vilans Synergenta Windesheim University of **Applied Sciences** Ciran NIVEL National Health Care Institute

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Mr G.G.J. Klein Ikkink

Ms L. Kool Dr T. Kool Ms A. Koornstra Mr. G. de Kousemaeker

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Mr J.W. Krijgsman Mr M.W.M. van Loosbroek

Ms K. Martin Abello Dr F. Mattace Raso Ms S. van Maurik-Brandon

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Mr W.J. Meijer Mr R. Mooij Ms A. Mulder

Dr J. Nouwt

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Mr S.H.D. Ottenheijm

Dr M. Ouwens Dr Mr J.M.Peeters

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Ms C.J.M. van Ruiten	Ministry of Health, Welfare and Sport
Mr F. Schalken	Stichting E-hulp
Ms I. Schimmel-Verschuur	Caryon B.V.
Dr P. Scholten	Scholten Consultancy
Prof. G. Schrijvers	Health economist and former
,	Professor of Public Health,
	University Medical Center
	Utrecht (UMC)
Mr A.P.A. Schuurmans	Netherlands Federation of
	University Medical Centres
	(NFU)
Ms P.J. van Tiggelen	GGD Amsterdam and Sam
	Amsterdam
Dr D. Tijink	Platform for the Information
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Mr B. Timmermans	Ministry of Economic Affairs
Mr B. Timmers,	GP, Groepspraktijk Huisartsen
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Dr K.P. van Vliet	National Healthcare Institute
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Mr K. Voermans,	Thaesis B.V.
Mr E.R. Vollebregt	Axon Advocaten
Mr W. Vos	
Ms M.D. Wijnhoud	Ministry of Health, Welfare and Sport
Ms W.C.M. Zijlstra	Dutch Nurses' Association
	$(\mathbf{v} \propto \mathbf{v} \mathbf{I} \mathbf{N})$

The subject matter was discussed with Mr L.A.M. van Halder, Ministry of Health, Welfare and Sport on 3 February 2015.

The Council for Public Health and Health Care adopted the advisory report on 18 December 2014.

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Appendix 3

Ethical issues

- The use of big data enables companies to create a profile of their customers. If they have more information about their customers, they can offer specific products targeting the relevant consumer. A health insurer will start by asking how often customers go to the gym, but will ultimately want to know what television programmes they watch, who their friends are etcetera in order to obtain a complete 'picture'. Where do the ethical boundaries lie for how much information companies and/or health insurers should know about their customers?
- Big data can be used by health insurers to determine 'more honest' insurance premiums. Healthy behaviour can be rewarded while unhealthy behaviour can be penalised. This could, however, put pressure on the solidarity of the insurance company. Solidarity is a normative principle for spreading the costs and risks evenly across a group. By incorporating unhealthy behaviour in the individual premium, the weaker members of society, who more often have an unhealthy lifestyle, will be penalised. What should take precedence: an 'honest' premium for the individual or an 'honest' premium for society?
- When activities and body values are measured and feedback follows, 'good' behaviour will be encouraged while 'unhealthy' behaviour will be discouraged. However, diversity and freedom of choice are valuable to society. Will room continue to exist for making an 'unhealthy' choice?
- If too much emphasis is placed on the results of measurement values, the risk of a reductionist approach to health will arise. Measurement values will then become the decisive factor rather than a contributory factor. What should the role be of self-measurement values in general in relation to an integrated approach to welfare and health?
- If a patient visits a doctor, all medical information will have been filed in a patient record. The data generated by consumer eHealth can be stored on the device (smartphone) or online. Who should decide on what happens to the data? Will users always have control over their data?

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- People who use consume eHealth will be better equipped to take charge of their personal healthcare and will be able to favourably influence their health. While ever more opportunities will arise to take part in this development, not everyone may be capable of doing so. This development will, on the one hand, empower people, but could also create a multi-layered society along various interfaces. Will consumer eHealth widen the social differences? And is that a bad thing?
- Guidelines on responsible practice will for the time being be drawn up by learned professional associations. By contrast, consumer eHealth applications will increasingly be based on international standards or on standards that could in part be influenced by large companies/authorities in other countries. Commercial eHealth companies could in future even become larger than the traditional healthcare services and they could put their own mark on healthcare. The influence of professional associations and the Dutch government in this area is set to decline. Who will ultimately decide on what 'good' healthcare is? Against this background, to what extent will care providers have the freedom to act on the basis of their own professional insight?
- Face-to-face healthcare (under one roof) will increasingly be substituted by consumer eHealth. The Centre for Ethics and Health (*Centrum voor Ethiek en Gezondheid*, CEG) issued an earlier report on remote healthcare (CEG, 2010). The potential changes in this area arising from the emergence of consumer eHealth and its intertwinement with the regular healthcare services could be profound. In ethical terms this raises also new questions about the potential harm that could be inflicted on people where high-risk and/or new forms of self-diagnosis and self-treatment are concerned.
- Face-to-face healthcare (under one roof) will increasingly be substituted by consumer eHealth. Many people might even need a 'helping hand'. This is equally relevant to the domain of welfare and support. Can good quality healthcare and support in fact be provided without having direct contact with the care provider? And if so, is this actually desirable?
- Will the self-measurement of values and the increasing amount of information on illnesses lead to the medicalisation of society? And is this acceptable from a social perspective?

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Appendix 4

Previous eHealth advisory reports issued by the Council

The Council has issued various advisory reports on (professional) eHealth in the healthcare sector or neighbouring fields in the past. Furthermore a number of advisory reports contain aspects that cut across this topic. These aspects are summarised in chronological order below.

The Patient and the Internet

The advisory report Patiënt en Internet ('The Patient and the Internet') was published in 2000, a period in which the Internet had started to make inroads into society. The spotlights were on the opportunities and threats arising from what was a new medium at that time. In this advisory report the Council advised the Minister of Health, Welfare and Sport to create a health portal on the Internet where consumers would be able to find reliable and comprehensible health information. This site would also provide information on living, working and learning with a disorder or an impairment. The Council furthermore recommended that sharing patient experiences via the Internet should be encouraged and proposed that Internet cafes should be set up in care and nursing homes. Lastly, the Council advised that electronic communication among patients and doctors should be promoted.

eHealth in Sight

The advisory report eHealth in zicht ('eHealth in Sight') and the accompanying background study Inzicht in eHealth (Insight into eHealth') published in 2002 enjoyed an overwhelming response. It was a follow-up report to the advisory report concerning The Patient and the Internet, which focused on the possibilities for improving the quality, efficiency and the accessibility of healthcare through eHealth. The Council concluded that eHealth has the capacity to provide care providers at the right time and at the right place with the information they need to perform their tasks. Furthermore eHealth offers opportunities to improve the doctor-patient relationship and a greater freedom of choice for patients. It can also serve as means for meeting the growing demand for healthcare with the (increasing) scarcity of care providers on the labour market. The lack of standardisation for the electronic exchange of medical data, in terms of both

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transmission and security as well as syntax and semantics, was found to be a major problem by the Council. The Council recommended that the Minister designate an independent, publicly funded authority with the power to impose the use of open standards on care providers. The Council also proposed that a fund be established for the purpose of promoting the development and implementation of eHealth. Furthermore the Council stated that clarity should be provided on the reimbursement of eHealth applications. Insight was required to be obtained into the effectiveness of eHealth applications based on an eHealth technology assessment. The Council also pointed out that patients and consumers should accept greater responsibility for their health.

A number of the above recommendations still apply to the present advisory report: standardisation, reimbursements for eHealth services and individual responsibility for health. The eHealth technology assessment all but failed to materialise.

From Knowing to Doing

In its 2005 advisory report *Van weten naar doen* ('From knowing to doing') the Council identified the factors influencing the dissemination of improved work practices in healthcare. Best practices are slow to be widely implemented in the healthcare sector. The risk-averse and low-level entrepreneurial culture in the healthcare sector were found to be impediments, as well as funding.

The Council stated that along with financial incentives, disclosing the performance of individual care providers could be a means of facilitating rapid implementation. This would encourage individual care providers to implement best practices faster. A third cluster of recommendations relates to promoting patient empowerment. Well-informed patients/clients will help put additional pressure on the implementation of best practices.

A Healthcare Consumers' Act

The Council issued the advisory report *De patiënt beter aan zet met een Zorgconsumentenwet?* ('A Healthcare Consumers' Act') in 2006. The advisory report was urgent at the time of the political debate on the desirability of an integral Healthcare Consumers' Act which would amalgamate the legal position of patients that had been anchored in numerous acts into one single act. The Council opposed the idea and advised that the existing problems and shortcomings in current legislation should be amended. It was also recommended that a lowthreshold knowledge and advice centre should be established

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that would gather information about patients' rights and make it available to interested parties. The centre would periodically report on the implementation of patients' rights as well as propose suggested improvements.

Health 2.0: It's up to you

The Council issued the advisory report *Gezondheid 2.0 - U bent* aan zet ('Health 2.0 - It's up to you') in 2010. The report examined the opportunities and threats arising for healthcare from the then new developments on the Internet (web 2.0), particularly the development of social media, such as Facebook, Twitter and YouTube, as well as blogs, wikis and online discussion platforms.

Health 2.0 means that the patient is not a passive observer, but actively participates in the healthcare process and therefore actually is the focus of that process. The patient will be offered more scope for self-management and by taking part in social networks greater emphasis can be placed on prevention. It offers individuals the opportunity to take more charge over their personal healthcare, supported by a network of care providers and others in the same situation. This will create a different patient-doctor relationship, benefiting both parties. The doctor will be visited by an informed patient to whom he or she no longer needs to explain the most basic matters. Patients will in principle be familiar with the contents of their medical record and are aware of the experiences of other patients. The discussion in the surgery will focus on relevant matters and may result in a joint decision on the most suitable treatment plan. Apart from these opportunities, the Council also identified threats. Since everyone can provide information in the 2.0 era, there is an increasing risk of unreliable information. Moreover patients will relinquish some of their privacy because they give precedence to the added value of 2.0. Other parties could abuse this. The gap between those who are active in the 2.0 situation and reap the fruits and those who are unable to do so, the underprivileged, is set to widen.

To take advantage of the opportunities of 2.0 as far as possible and to mitigate the threats as far as possible, the Council advised that the positive elements of 2.0 be combined with 'the old Internet' - web 1.0. This means, among other things, that care providers should make available reliable substantive medical knowledge in a patient-friendly and comprehensible manner, for instance via a hospital website featuring videos and podcasts relating to research and treatment (1.0). Patients can share their experiences of the healthcare provided (2.0). The Council asked that the government structure funding of

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the healthcare system in such a way so as to ensure that adequate resources are available for patient-centric healthcare innovations, with more financial incentives to create an innovative culture. 'Perverse' financial incentives which do nothing to encourage professionals to adopt innovations of added value, or which actually encourage the retention of outdated structures and procedures, must be abolished. Health insurers should offer e-facilities to insured parties to enable them to report back on their experiences with the healthcare provided, which would enable health insurers to contract better healthcare products. Individual citizens can make a considerable contribution in bringing about the shift of tasks from care providers' to citizens. This begins with lifestyle management and preventive measures to ensure they are less likely to require the services of professional care providers. Furthermore 2.0 offers greater opportunities for selfmanagement.

Aiming for Health

In the advisory report *Sturen op gezondheidsdoelen* ('Aiming for Health') issued in 2011 the Council indicated that the current financial preconditions are keyed to financing treatments rather than achieving specific results. With a view to eHealth the Council recommended that outcome data should be recorded in medical records, so not only the diagnosis, examinations and treatment, but also the end result. In addition the Council recommended that all care providers incorporate explicit treatment objectives in their treatment and care plans. The Council believes that this is an effective means of pointing out to patients the responsibility they themselves bear for a positive outcome, for example by making lifestyle adjustments or adhering to their doctor's recommendations (patient compliance).

Control over the Electronic Patient Record (EPR) from an ethical and legal perspective

The analysis Zeggenschap over het EPD, ethisch en juridisch perspectief ('Control over the EPR from an ethical and legal perspective') was issued for the purpose of the report Zeggenschap over het Elektronisch Patiëntendossier ('Control over the Electronic Patient Record') issued by the Centre for Ethics and Health (CEG) in 2011. In the analysis a distinction is made between three groups of patients who require further legal and moral attention: those who are concerned about their privacy and the abuse of power, those who are unable or unwilling to manage data and those who actively want to manage their personal data themselves.

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The active control aspects are important where eHealth is concerned. This relates to patients who, with the aid of eHealth devices, particularly personal health records (PHRs), wish to take more control over their personal healthcare. Aspects include the right of patients to determine for themselves who should be given access to their personal health data, access control for both the care provider and the patient, retention periods and adding and/or altering data. The question was raised of whether, similar to the 'duty of confidentiality' observed by care providers, 'patient confidentiality' should be introduced to protect patients from the influence that the police and investigative services, insurers and other financial institutions, ICT companies and commercial or other parties could exert to get hold of the PHR contents. The efforts - both technical and organisational - required of all the parties concerned before the EPR and the PHR could actually be used effectively side by side were also pointed out. System suppliers would need to use open standards to facilitate interoperability.

Provisions for labour-saving innovations in healthcare

The central question in the 2011 advisory report Ruimte voor arbeidsbesparende innovaties in de zorg ('Provisions for laboursaving innovations in healthcare') was as follows: How can the spread of labour-saving innovations in healthcare be encouraged so as to put these innovations to optimum use in order to combat the imminent healthcare labour shortage? In this advisory report the Council looked at the current status of the development and deployment of labour-saving innovations, such as self-management and remote healthcare. eHealth topics such as domotics, telecare and eMental health were also examined. In the 2011 advisory report the 12 factors identified in the 2005 advisory report From Knowing to Doing focused specifically on the experience gained with laboursaving innovations. Unfamiliarity with ICT and technology were found to be an impediment particularly in nursing and care. Study and training programmes are based too much on outdated concepts. Furthermore the lack of leadership in the healthcare sector hampers the spread of different methods of organising and providing healthcare.

Self-sufficiency in old age

The central question in the 2012 advisory report *Redzaam ouder* ('Self-sufficiency in old age') was as follows: 'What measures are needed in order to guarantee proper care and a good quality of life for care-dependent elderly people in the future?'. According to the Council, what is particularly relevant in terms of eHealth is that it is essential to ensure that people continue

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to be self-sufficient for as long as possible. Citizens must invest in precautionary measures so that collective care can be guaranteed for those elderly people who ultimately cannot rely upon themselves or their network. Furthermore elderly people with complex and long-term health problems should receive care at home. In this context reference was made to the use of technology in the form of 'smart accommodation'.

The participating patient

The 2013 advisory report *De participerende patiënt* ("The participating patient") examines the question of why, well over six years after the introduction of regulated market forces in 2006, patients are still unable to sufficiently participate in the healthcare process despite the fact that they are eager to do so. Apart from individual patients being uncertain of whether they will receive the care and treatment appropriate to their personal situation and preferences, it also exacerbates the inefficiency of care. A partnership between patients and their care providers is required. Ideally they will jointly decide on the individual care to be provided (joint decision-making) and patients are actively involved in carrying out healthcare (self-management/shared implementation). eHealth could serve as an important means for implementing the recommendations made by the Council in this advisory report as follows:

- improve the reliability of general health information;
- improve specific, patient-tailored health information;
- develop and implement decision aids.

Patient information

Information provision is the topic examined by the Council in this 2014 advisory report. Information provision should organised with a focus on the patient. A proper information system is of vital importance for the effective and efficient provision of healthcare. This applies not only at the micro level to patients and care providers but equally at the meso level, where health insurers, institutions and municipalities, for instance, require information to ensure accessible and affordable goodquality care for patients, clients and residents respectively At the meso level healthcare providers also require reflective information against which to benchmark themselves and improve their services At the macro level the government requires information to safeguard the quality, accessibility and affordability of healthcare provided in the Netherlands. Information is additionally required for policy, implementation and research purposes.

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The Council concluded that there were several problem areas concerning information provision and therefore formulated the following recommendations:

- With a view to the future, a PHR should be made available to patients on a voluntary basis and with freedom of choice.
- In addition to the medical confidentiality applicable to medical records, 'patient confidentiality' should be instituted for the PHR to protect patients against improper pressure from parties, such as the police and investigative services, the Ministry of Security and Justice, life and non-life insurers, financial institutions and ICT companies.
- Ensure that the patient's privacy is guaranteed in the technical and organisational design of all healthcare information systems (Privacy by Design). Trusted Third Parties (TTPs) must ensure that the patient's privacy is guaranteed.
- All care providers should register their data, once only, in a uniform and standardised manner at the source, from where data can be reused multiple times for healthcare purposes. Non-identifiable health data must be transparent for public purposes, such as policy, implementation and research purposes.
- Ensure that the information system is properly set up from the outset on the impending decentralisation of healthcare tasks to the municipalities. Stipulate conditions for the measurement tools to be deployed and for the secure management of client data. Ensure that the provision of information can still be facilitated beyond the limits of the Health Insurance Act (Zvw), the Social Support Act (Wmo) and the Exceptional Medical Expenses Act (AWBZ, which will be superseded by the Long-Term Care Act (WLZ) effective 1 January 2015) to, for instance, monitor substitution in healthcare. Apply international open standards. Be mindful of care avoiders who could fall through the cracks due to the decentralisation of healthcare tasks. The decentralisation of healthcare tasks to the municipalities could pose additional privacy risks which can largely be removed through Privacy by Design.
- The Institute for Health Care Quality must act proactively by determining which (international) measurement tools should be incorporated in the healthcare standards and quality registrations on the recommendation of scientific and patient organisations. The registration data should be derived directly from reporting on the primary process. Healthcare

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professionals must be compelled to cooperate with the current registrations in their discipline approved by the Institute for Health Care Quality. Health insurers should include this in their conditions of purchase based on the motto: 'information also is a care service'.

- The requisite changes can only be made to the provision of information in the healthcare sector if the Ministry of Health, Welfare and Sport takes charge and the Information Consultation proceeds to take binding decisions.

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Appendix 5

Abbreviations

BMJ	British Medical Journal
CBS	Statistics Netherlands
CE	Conformité Européenne (European Conformity)
CPB	CPB Netherlands Bureau for Economic Policy
	Analysis
DSA	Digital Cities Agenda
EEC	European Economic community
EPR	Electronic Patient Record
EPIC	Engineering, Procurement, Installation and Commissioning
epSOS	European Patients Smart Open Services
EU	European Union
ECPHRFF	European Convention on the Protection of Human Rights and
	Fundamental Freedoms
GGD	Municipal Health Service
HBO	Higher professional education
IBM	International Business Machines Corporation
IGZ	Healthcare Inspectorate
KNMG	The Royal Dutch Medical Association
MBO	Senior secondary vocational education
NIA	National Implementation Agenda
Nictiz	Centre of Expertise for Standardisation and eHealth
NPCF	The Federation of Patients and Consumer Organisations in the
	Netherlands
NSA	National Security Agency
PHR	Personal Health Record
RIVM	National Institute for Public Health and the Environment
MDD	Council Directive 93/42/EEC concerning medical devices
RVZ	Council for Public Health and Health Care
SES	Socioeconomic status
ТТР	Trusted Third Parties
TNO	Netherlands Organisation for Applied Scientific Research
VNG	Association of Netherlands Municipalities
USA	United States of America
VvAA	Vereeniging voor Artsen-Automobilisten
VWS	Ministry of Health, Welfare and Sport
WGBO	Medical Treatment Contracts Act
Wbp	Personal Data Protection Act
Wcz	Clients' Rights (Care Sector) Act
Wmo	Social Support Act
Wpr	Data Protection Act
Wlz	Long-Term Care Act
ZO!	Self-Care Support

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Zvw Healthcare Insurance Act

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Appendix 6

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12/01	Work programme 2012, January 2012
11/08	Preventie van welvaartsziekten, December 2011
11/04	Medisch-specialistische zorg in 20/20, October 2011
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	11/05 - Ziekenhuislandschap 2020: Niemandsland of Droomland (background study), October 2011
	11/06 - Medisch-technologische ontwikkelingen zorg 20/20 (background study), October 2011
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	Publications used for the purpose of this advisory report (downloadable only)
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	10/14 - Krant bij het advies ruimte voor arbeidsbesparende innovaties in de zorg. November 2010
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	study accompanying the advisory report
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