



eHealth and Patients' Rights

Iris Bakx

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eHealth and Patients' Rights

eHealth en de rechten van de patiënt

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Part I

Introduction

1



A golden scale of justice is shown in a faded, background style. A diagonal blue band with a wavy edge runs from the top left to the bottom right, partially obscuring the scale. The word "Introduction" is written in white, bold, sans-serif font across the blue band.

Introduction

1. INTRODUCTION

In recent years, Dutch media have reported that physicians had been using WhatsApp to consult each other.¹ Health professionals reported that they perceived this way of exchanging information as efficient and convenient.² In the media, however, the use of this popular mobile chat application within the practice of health care brought up questions about privacy and safety.³ Various stakeholders, as well as the government, gave their opinion on the use of WhatsApp in health care.⁴ Soon after, numerous new smartphone applications for communication between health professionals were developed, claiming to have built in more appropriate safeguards than WhatsApp.⁵

Another application that was much discussed is Constamed, a website and app for online consultation. Constamed started as a platform where people could pose questions to a health professional free of charge. Perhaps the most important reason that Constamed was subject to discussion, beside the fact that it was an innovative tool for patients and physicians to communicate at any place at any time, was the fact that patients could consult a health professional who had never met them. Obviously, such a physician does not have any (medical) information about the patient. Not everyone trusted that this was a good method of health care provision.⁶ Moreover, this concept invoked questions about safety and patients' rights, such as privacy.⁷ Another question that can be posed in this respect is whether legislation

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- 1 For instance Van Noort, *NRC Next* 8 July 2015, p. 7 and Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809.
 - 2 For instance Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2312-2315.
 - 3 For instance Van Noort 2015, *NRC Next* 8 July 2015 p. 7 and Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?' *nrcq.nl*, 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809.
 - 4 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm. The Federation of Patients in the Netherlands gave a reaction in: Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809 and Van Noort, *NRC Next*, 8 July 2015, p. 7. The Dutch DPA reacted in current affairs programme *EenVandaag*, broadcasted on 23 February 2016, *Eenvandaag*, 'Medische info delen via Whatsapp', *eenvandaag.nl*. Source: eenvandaag.avrotros.nl/binnenland/item/medische-infodelen-via-whatsapp/. See also Van Noort, 'Artsen moeten stoppen met whatsappen over patiënten', *nrc.nl* 23 February 2016. Source: nrc.nl/nieuws/2016/02/23/artsen-moeten-stoppen-met-whatsappen-over-patienten-a1409107 and *Aanhangsel Handelingen II* 2015/16, no. 2203, p. 2.
 - 5 'Strijd om verovering markt medische WhatsApp', *telegraaf.nl* 23 May 2016. Source: telegraaf.nl/tech/409960/strijd-om-verovering-markt-medische-whats-app.
 - 6 For instance 'NHG voorstander van e-consult met eigen huisarts', *nhg.nl* 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts and 'Constamed: Snel antwoord van je huisarts', *consumentenbond.nl* 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.
 - 7 For example 'Constamed: Snel antwoord van je huisarts', *consumentenbond.nl* 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.

pertaining to patients' rights, such as the *Wet op de Geneeskundige Behandelingsovereenkomst* [Medical Treatment Act] (WGBO),⁸ is applicable to such online consultations.⁹ In spite of all these questions, however, Constamed received an award around that time for the best app for health professionals.¹⁰ This demonstrates that no consensus exists on what is allowed in digital health care. Therefore, legal clarity on patients' rights with respect to the application of information and communication technologies (ICT) in health care is needed. Constamed ceased to exist after 2019.

2. PROBLEM STATEMENT

The examples presented in section 1 above of the use of modern ICT in health care provision do not stand alone. The use of electronic patient records is probably the most striking example of the use of ICT in health care.¹¹

The use of ICT for health and health care is, in short, named eHealth. This health-related use of ICT is expected to improve health and health care by making health care more efficient, enhancing accessibility of health care, enlarging patient participation by providing adequate information and by enabling patients to manage their own health to prevent diseases or deterioration.¹² It is also stated that eHealth has the potential to improve people's quality of life,¹³ and that it can assist people to live independently for a longer time.¹⁴

8 *Stb.* 1994, 837 and *Stb.* 1994, 838.

9 J. Jacobs, 'Wet- en regelgeving niet klaar voor online huisartsen', *smarthealth.nl* 13 March 2014. Source: smarthealth.nl/2014/03/13/wet-en-regelgeving-niet-klaar-voor-online-huisartsen/, Maassen, *Medisch Contact* 2014, p. 578-579 and J. Jacobs, 'Bijkussende dokters of huisarts-van-de-toekomst?' *smarthealth.nl* 18 February 2014. Source: smarthealth.nl/2014/02/18/bijkussende-dokters-huisarts-van-de-toekomst/.

10 KNMG, *Medisch Contact* 2014, p. 1244.

11 Most people in the Netherlands will remember the discussion concerning the implementation of electronic patient records. These concerns were mostly related to privacy issues. See: Wetsvoorstel Wijziging van de Wet gebruik burgerservicenummer in de zorg in verband met de elektronische informatieuitwisseling in de zorg, *Kamerstukken II* 2007/08-2011/12, 31466. By now, a system in which patients can give their health professional permission for sharing (parts) of their information with other health professionals is functioning in the Netherlands. This is based on the *Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg* [Additional Provisions on processing personal data in health care act] (Wabvpz) (*Stb.* 2008, 164). See Art. 15a of this Act. Paragraph 2 of this provision enables patients to further specify their permission. This article will enter into force on a later date. (*Kamerstukken I* 2015/16, 33509, J, p. 4). In October 2019 the Minister for Medical Care announced that the entry into force of Art. 15a Para. 2 Wabvpz will be postponed. *Kamerstukken II* 2019/20, 27529, no. 192 and *Kamerstukken I* 2019/20, 27529, K. The minister refers to the advice of the Adviescollege toetsing regeldruk [Dutch Advisory Board on Regulatory Burden] (ATR), appendix to *Kamerstukken II* 2019/20, 27529, no. 192-903663 and KPMG 2019.

12 See, for instance: 'eHealth: Digital health and care, overview', *ec.europa.eu*. Source: ec.europa.eu/health/ehhealth/home_en and COM(2012) 736 final, p. 3 and 5 and, for instance, *Kamerstukken II* 2013/14, 27529, no. 130, p. 1 and 9-10.

13 *Kamerstukken II* 2013/14, 27529, no. 130, p. 3.

14 *Kamerstukken II* 2013/14, 27529, no. 130, p. 11.

Clearly, eHealth is subject to high expectations. However, in spite of the potential benefits, the incorporation of modern technology in health care is relatively slow in comparison with other services that are available nowadays over the Internet.¹⁵ A possible explanation is that health professionals as well as individuals are reluctant to incorporate ICT into the health care process. While health professionals sometimes do not see the added value of eHealth care provision or fear a reduced quality of health care,¹⁶ individuals on the other hand seem reluctant to utilise eHealth because they are unwilling to share their medical information over the Internet. A possible explanation can be found in the fact that personal health information might be perceived as more sensitive compared to other personal information, such as financial information.¹⁷ The General Data Protection Regulation (GDPR)¹⁸ supports this by classifying personal health data as a special category of data;¹⁹ this means that processing these data is subject to stricter rules.²⁰ Assuming that a fear of violation of privacy is one of the reasons patients are less likely to use eHealth, acceptability of eHealth care provision can be a problem. Acceptability of ways of health care provision and quality of health care are elements of the right to health²¹ as laid down in Article 12 of the International Covenant of Economic, Social and Cultural Rights (ICESCR).²² The Committee on Economic, Social and Cultural Rights (CESCR)²³ identified availability (A), accessibility (A), acceptability (A) and quality (Q) as the essential elements of the right to health in their General Comment no. 14 on health.²⁴ The framework laid out in this general comment is referred to as the AAAQ framework.

The aforementioned expectations seem to indicate that eHealth can make a positive contribution to realising the right to health for everyone by increasing accessibility.²⁵ Even though eHealth, at first sight, is able to make a positive contribution to the right to health by increasing accessibility, it can be questioned whether these expectations can be fulfilled.

15 See, for instance Nictz, NIVEL & Zorgimpuls, *ICT&health* 2017, issue 4, p. 15-17; Wouters et al. 2017, p. 44, 46 and 47; Krijgsman 2017, p. 12-13; Vroom 2017, p. 11-12 and RIVM, 'Data-gedreven technologie in de zorg', *vtv2018.nl*. Source: vtv2018.nl/data-gedreven-technologie.

16 Nijland & Van Gemert-Pijnen, *Medisch Contact* 2008, p. 202.

17 See, for instance: Keizer 2011, p. 377 and Kroes, *Medisch Contact* 2014, p. 1382.

18 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation (GDPR)), (*OJEU* 2016, L 119).

19 Art. 9 Para. 1 GDPR.

20 Art. 9 Para. 2 and 3 GDPR.

21 UN Committee on Economic, Social and Cultural Rights (CESCR), *The right to the Highest Attainable Standard of Health*, General Comment no. 14 (2000) on Health; 11/08/2000, *UN Doc E/C.12/2000/4* (hereafter: CESCR General Comment no. 14 (2000) on Health), Para. 12.

22 *International Covenant of Economic, Social and Cultural Rights* (ICESCR) *UN Doc GA/RES/2200A (XXI)* (16 December 1966, entry into force: 3 January 1976).

23 The CESCR is established by ECOSOC Res 1985/17 (28 May 1985), *UN Doc E/RES/1985/17*.

24 CESCR General Comment no. 14 (2000) on Health, Para. 12.

25 CESCR General Comment no. 14 (2000) on Health, Para. 12.

Moreover, questions remain about the other aspects of the right to health such as availability, acceptability and quality. The above-mentioned concerns about privacy and quality can play a role in this respect. Consequently, a study on the effects of eHealth on the right to health is desirable.

Another reason why the development of eHealth is (relatively) lagging behind compared to other e-developments, might be the lack of legal certainty. Although the application of eHealth is said to have many benefits,²⁶ uncertainty remains about what is allowed from a legal point of view.²⁷ The examples of Constamed and the use of WhatsApp by health professionals indicate this and also show that no consensus exists on the use of such applications, not even within the profession.²⁸

An important part of this legal certainty can be found in patients' rights. Even though eHealth changes the context of health care provision, patients' rights should still be respected.²⁹ This invokes the question of what the effects of these new developments in health care are on patients' rights. Many questions that came up with respect to the examples mentioned in the introduction relate to patients' rights.

Patients' rights are derived from (international) human rights law such as the inviolability of the human body³⁰ and the protection of privacy.³¹ Moreover, health law legislation, including patients' rights, is supposed to help in realising the right to health.³² In conclusion, patients' rights are human rights in themselves and must be protected.

The necessity of a study on this topic becomes evident after a quick glance at the Dutch law concerning patients' rights. Dutch civil law encompasses a body of patients' rights in the WGBO. This Act, containing most of the Dutch patients' rights, was established in 1995. At that time, technology was not as advanced as it is these days and was therefore less incorporated in health care. Patients' rights in the WGBO were primarily designed for face-to-face relationships between patients and physicians.³³ With the emergence of eHealth care

26 For instance Meijnckens 2016, p. 98-100 and *Kamerstukken II* 2016/17, 27529, no. 141, p. 1.

27 For example Wouters et al. 2017, p. 40, 42 and 69.

28 'NHG voorstander van e-consult met eigen huisarts', *nhg.nl* 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts and 'Constamed: Snel antwoord van je huisarts', *consumentenbond.nl* 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts. Constamed won the Health app award for best app for health professionals in 2014: Alderlieste, 'Winnaars Health App Award bekend', *knmg.nl* nieuws 5 June 2014. Source: medischcontact.nl/nieuws/laatste-nieuws/artikel/winnaars-health-app-award-bekend.htm.

29 See also Buijsen, *Medisch Contact* 2012, p. 1608-1611.

30 For instance Art. 10 GW, Art. 3 ECHR, Art. 5 UDHR and Art. 7 ICCPR.

31 For instance Art. 8 ECHR, Art. 12 UDHR and Art. 17 ICCPR.

32 Buijsen 2003, p. 7-8.

33 This can be seen in other systems than Dutch law as well. For example see Spradley, *Tulane Journal of Technology and Intellectual Property* 2011, p. 309 on the United States.

provision, a shift in the physician–patient relationship occurs because parts of the health care process will take place at the patient’s home, thereby redefining their role in their own medical treatment. This is also one of eHealth’s purposes: enabling patients to actively participate in their own health care process and to take charge over their own health.³⁴

3. AIM AND RELEVANCE

The question is whether eHealth enhances the protection that the existing patients’ rights provide or if those rights, on the contrary, will be difficult to maintain when eHealth is used. They might require a different interpretation in an environment of digital health care. This study revolves around the question of how to protect patients’ rights in the changing context of health care because of eHealth. In addition, the question must be asked whether there is a need for new patients’ rights, especially designed for this new way of health care provision.

This study aims to evaluate to what extent selected types of eHealth care provision can contribute to realising the right to health for everyone. The study might have a broader impact though, because it also intends to clarify the functioning and application of patients’ rights with respect to certain applications of eHealth care provision. Consequently, this study might not only be interesting to those with an interest in the effects of eHealth care provision on the fulfilment of the right to health, but also to those who are interested in the application of patients’ rights in general, in relation to eHealth care provision.

This study has both academic and social relevance. The academic relevance is the addition to the existing literature on eHealth and patients’ rights. While there is plenty of academic literature on electronic patient records and on certain aspects of eHealth in relation to privacy,³⁵ so far not much attention has been paid in academia to eHealth and other patients’ rights in the WGBO, such as the right to informed consent. Moreover, in the Netherlands not much has been written about eHealth’s expectations in relation to the right to health.³⁶

The social relevance can be found in the fact that eHealth will occupy a prominent place in health care provision in the near future. Therefore, it is worth thinking about patients’ rights

³⁴ *Kamerstukken II* 2016/17, 27529, no. 141, p. 2.

³⁵ See, for example, Van Rijen & Ottes, *Medisch Contact* 2002, issue 17; Baumer, Earp & Poindexter, *Computers & Security* 2004, p. 400-412; Nouwt, *Medisch Contact* 2010, p. 932; Keizer 2011, p. 377, Kranenborg, *Computerrecht* 2011/153 and Ploem 2012, p. 121-124.

³⁶ On both national and international levels the case is made that eHealth – among other things – will increase access to health care (for example ‘eHealth: Digital health and care, overview’, *ec.europa.eu*. Source: ec.europa.eu/health/ehealth/home_en; COM(2012) 736 final, p. 3 and 5 and, for instance, *Kamerstukken II* 2013/14, 27529, no. 130, p. 1 and 9-10), which is, according to CESCR General Comment no. 14, Para. 12(b), an element of the right to health as laid down in Art. 12 ICESCR.

in relation to eHealth. Not only the fast pace at which developments in the field of eHealth are taking place, but also the involvement of players other than the physician and the patient³⁷ leads to questions about patients' rights and additional risks. The examples mentioned in the introduction show us that legal certainty over eHealth is currently absent, and eHealth is a constantly developing field. Therefore, it is not always easy to seize these developments with existing legislation. Yet, legal certainty about patients' rights is necessary for eHealth initiatives to thrive; clear legal rules enhance the development of such initiatives.

Moreover, a critical consideration of the expectations of eHealth care provision considering the right to health can lead to a rethinking of the way eHealth must be employed in order to really contribute to the realisation of this right.

4. SCOPE AND RESEARCH QUESTION

Considering the above, the main question of this study is:

How should patients' rights be applied in eHealth care provision and what are the challenges in this respect?

The research will focus on the question of how to apply patients' rights during eHealth care provision. Recommendations will be made on the application of patients' rights as well as necessary amendments to the existing Dutch law on patients' rights regarding eHealth care provision. An important question is whether everything that is possible can or should be allowed, considering the rights of the patient. In other words, the study will analyse whether patients' rights will remain protected or if a new interpretation of the existing Dutch patients' rights is required in order to attain the same level of protection that these rights were originally intended to provide.

To answer the central research question, the study will be divided into three parts. First, the scope of the research question should be understood. This requires a description and explanation of the concepts of eHealth and patients' rights.

Therefore, the first step in providing an answer to the main question is to establish a definition of eHealth. Defining eHealth can contribute to a better understanding of the consequences the use of ICT in health care has for patients' rights. By providing a definition of eHealth, this study might contribute to understanding this concept in health care practice

37 As opposed to face-to-face health care provision. An example of players who are involved during eHealth care provision are ICT workers who might be able to view more (sensitive) information in a setting of eHealth care provision.

in general as well. This study will focus on eHealth care provision, i.e. the types of eHealth that entail actual health care provision. According to the *Raad voor de Volksgezondheid en Samenleving* [the Council for Health and Society] (RVS),³⁸ eHealth care provision includes online physician–patient contact as well as physician–physician contact by means of ICT, if this contact is related to the treatment of a particular patient.³⁹ The choice for eHealth care provision is made because this category of eHealth directly takes place in the relationship between the patient and the health professional. Because of this interaction, patients’ rights clearly play a role. Moreover, as presented in the introduction above, the use of eHealth in the relation between patients and physicians leads to questions in practice about what is allowed and what is not allowed with respect to patients’ rights.⁴⁰ This does not mean that patients’ rights are not relevant during e-care support and e-Public health, though. However, this exceeds the scope of the research.

Once it is clear what eHealth exactly is, the next step towards understanding the scope of the main question is presenting the right to health and the legal framework of patients’ rights that will be analysed. The right to health as laid down in various international treaties and regulations will be elaborated on. The right to health as laid down in Article 12 ICESCR will be emphasised. This is necessary to determine what the effects of eHealth care provision are on this right. Furthermore, patients’ rights in Dutch law will be presented to increase understanding of these rights and why it is important to protect them. This concludes the first part of the study.

The second part of the study is the main part and contains considerations on eHealth care provision during various situations of eHealth care provision. The types of eHealth care provision that are presented in this part are e-consultation (online interaction between a physician and a patient), tele-expertise (two health professionals consulting each other over a distance by means of ICT) and telemonitoring (monitoring patients’ health over distance).

As mentioned in section 1, eHealth is subject to high expectations. These expectations seem to suggest that eHealth can contribute to realising the right to health, or at least to some of its elements,⁴¹ for instance when it is stated that eHealth will contribute to increased accessibility of health care.⁴² Each of these types of eHealth care provision will be elaborated on and

38 A merger of the *Raad voor Maatschappelijke Ontwikkeling* [Council for Social Development] (RMO) and the *Raad voor de Volksgezondheid en zorg* [Council for Public Health and Health Care] (RVZ).

39 RVZ 2002, p. 17-18.

40 For instance, the 2017 eHealth monitor shows there are questions about what is allowed and what is not allowed regarding e-consultation. See Wouters et al. 2017, p. 40 and 42.

41 CESCR General Comment no. 14 (2000) on Health, Para. 12.

42 See, for instance: ‘eHealth: Digital health and care, overview’, ec.europa.eu. Source: ec.europa.eu/health/ehealth/home_en; COM(2012)736 final, p. 5 and, for instance, *Kamerstukken II 2013/14, 27529*, no. 130, p. 1.

analysed according to the AAAQ framework as formulated by the CESCR in their General Comment no. 14 on health.⁴³ This will allow the discovery of whether eHealth care provision can really live up to these expectations and to what extent this particular application is able to contribute to realising the right to health for everyone. Moreover, possible obstacles in the contribution to the realisation of the right to health will be presented, along with recommendations on what it takes for the application to be able to make a positive contribution to the realisation of the right to health. Perhaps the conclusion about certain aspects of the right to health is that some expectations of eHealth care provision should be modified.

The right to health and patients' rights are interrelated. Realising the right to health for everyone entails guaranteeing the provision of available, accessible and acceptable health care of good quality.⁴⁴ It is the health system that must meet these criteria – especially availability and accessibility – in the first place. Once health care provision in a country is available and accessible, individuals can enjoy acceptable health care of good quality. In a way, realising the right to health precedes the individual relationship between physicians and patients, and therefore precedes the conclusion of a contract for medical services provision based on the WGBO. Moreover, one of the purposes of patients' rights is to guarantee the right to health for everyone. The obligation to respect medical confidentiality is an example that shows this.⁴⁵ This right does not only intend to protect patients' individual privacy and the right to access health care, but to protect the public interest of access to health care for everyone. The idea behind this is that people will avoid seeking health care when they fear that information they share with their physician risks becoming public.⁴⁶ Moreover, respecting patients' rights is an essential aspect of acceptable health care provision. Acceptable health care provision, in turn, is a part of the right to health.⁴⁷ In that way, patients' rights are an important element of the right to health. When they are not respected, the right to health will be infringed simultaneously.

Consequently, after the right to health is discussed in relation to eHealth, the discussion of patient's rights will continue on the Dutch national level. This part of the study can assist in creating legal certainty. Where the sections on the international right to health will discuss and hold eHealth's many expectations to the light, the sections concerning Dutch national law will deal with eHealth and patients' rights from a more practical perspective. The first step in applying the WGBO, the Dutch patients' rights Act, to eHealth care provision is establishing whether and how the WGBO applies to this type of eHealth care provision. Subsequently, the right to privacy, the right to medical confidentiality and the right to informed consent will be

43 CESCR General Comment no. 14 (2000) on Health, Para. 12.

44 CESCR General Comment no. 14 (2000) on Health, Para. 12.

45 Art. 7:457 BW.

46 HR 21 April 1913, *NJ* 1913, p. 958 and Leenen/Dute & Legemaate (eds.) 2017, p. 151.

47 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

discussed. These rights are chosen because most countries seem to acknowledge these patients' rights, according to the World Health Organization's (WHO) genomic resource centre.⁴⁸ When discussing the various patients' rights and applying them to eHealth care provision, their original purpose will be taken into account as well. The study will consider, among other things, the *travaux préparatoires* of the WGBO to retrieve what these rights are intended to protect and how that can still be achieved in the context of eHealth care provision. An example of a right that might need a different interpretation with the emergence of eHealth is the right to informed consent, derived from the fundamental right of inviolability of the human body.⁴⁹ Undergoing a medical treatment without consent is an infringement of the fundamental human right of bodily integrity. The right to informed consent is developed to make sure that a patient can only undergo a medical treatment if they have given their explicit consent based on the information provided by the health professional. With the emergence of eHealth, the associated risks of medical treatment will change. Therefore, the physician's duty to provide information will change as well. For instance, the physician will have to inform the patient about the specific risks of this new form of treatment, such as technology-related problems.⁵⁰ This exemplifies that the interpretation of the right to informed consent might need to change in order to continue protecting this patients' right.

The third part of the study will review the first two parts and provide recommendations on under what conditions – according to the AAAQ framework⁵¹ – eHealth can be able to contribute to the realisation of the right to health. Moreover, recommendations on how to deal with eHealth and patients' rights in practice will be made. The study will examine whether the existing patients' rights in the Netherlands need a different interpretation or whether they should be altered in order to keep providing the same protection that was intended when the WGBO was drafted in the 1990s.⁵²

In summary, the following subquestions arise from the main question:

- I. What is eHealth, what kinds of eHealth exist and how can they be categorised?
- II. What are the right to health, the right to privacy, the right to medical confidentiality and the right to informed consent, where can they be found in legislation and what do they aim to protect?

48 WHO Genomic resource centre, 'Patients' rights', who.int. Source: who.int/genomics/public/patientrights/en/.

49 *Kamerstukken II* 1989/90, 21561, no. 3, p. 11-13.

50 For instance Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380.

51 CESCR General Comment no. 14 (2000) on Health, Para. 12.

52 *Kamerstukken II* 1989/90, 21561, no. 3 and *Kamerstukken II* 1989/90, 21561, no. 286.

- III. Considering the many expectations that exist about eHealth, to what extent can e-consultation, tele-expertise and telemonitoring live up to these expectations by contributing to the realisation of the right to health according to the AAAQ framework?
- IV. Does the WGBO apply to e-consultation, tele-expertise and telemonitoring?
- V. How do the patients' rights to informational and spatial privacy, medical confidentiality and informed consent apply to e-consultation, tele-expertise and telemonitoring and how should they be applied?

5. METHODOLOGY

The central question of this study will be mainly answered by conducting legal doctrinal research such as interpreting treaties, regulations and statutes concerning patients' rights as well as analysing doctrine and case law. Various approaches of literature study will be employed, and various legal interpretation methods such as historical and teleological approaches will be applied.

By studying literature on eHealth, documents from national and international organisations such as the WHO and the RVS, and documents by the Dutch government and the European Commission giving existing definitions of eHealth will be analysed. Moreover, various points of view from academia on this topic will be presented. Based on this literature study, a definition of eHealth will be proposed.

The central question to this study will be mainly answered by describing current patients' rights in Dutch legislation and discussing how to apply them when the health care is provided by means of eHealth. The legal history of the WGBO will be studied as well as several human rights from which patients' rights are derived, such as the inviolability of the human body⁵³ and the right to protection of privacy.⁵⁴ Legal doctrine, the *travaux préparatoires* of the various treaties, statutes and regulations pertaining to patients' rights as well as case law on this matter will be analysed. Furthermore, existing good practice guidelines related to eHealth will be presented. Examples are the KNMG Guidelines for dealing with medical data 20⁵⁵ by the *Koninklijke Nederlandsche Maatschappij ter bevordering van de geneeskunst* [Royal Dutch Medical Association] (KNMG) and the NHG-Checklist e-consult⁵⁶ by the *Nederlands Huisartsen Genootschap* [Dutch College of General Practitioners] (NHG). Such guidelines are important to determine the professional standards and are used to fill in open

53 For instance Art. 10 GW, Art 3 ECHR, Art. 5 UDHR and Art. 7 ICCPR.

54 For instance Art. 12 UDHR and Art. 17 ICCPR.

55 KNMG Guidelines for dealing with medical data 2020.

56 NHG-Checklist e-consult 2014.

norms such as the duty to act as a conscientious health care provider as laid down in Article 7:453 BW.⁵⁷

The study focuses first and foremost on patients' rights in Dutch law. The international right to health as laid down in Article 12 ICESCR is an exception. How e-consultation, tele-expertise and telemonitoring can contribute to the realisation of the right to health will be analysed by means of the CESCR's AAAQ framework.⁵⁸ General Comments of the United Nations (UN) bodies (such as the CESCR), although not legally binding, are considered authoritative.⁵⁹ To find out whether these types of eHealth care provision can contribute to availability, accessibility, acceptability and quality of health services provision, an auxiliary multidisciplinary approach will be used by studying materials from empirical studies on eHealth in relation to these topics. An example of such a study is the yearly eHealth-monitor conducted by Nictiz.⁶⁰

Even though patients' rights will be presented from a Dutch perspective, European and international law will be included at certain points. Because of the increasing importance of European and international law in national legal systems, European and international treaties and regulations, such as the GDPR, cannot be ignored and will be discussed when relevant.

The field of eHealth is currently under continuous development. This is not only a concern in the Netherlands. Therefore, this thesis is written in English. Even though the topic is Dutch patients' rights law, this study might be relevant to non-Dutch speakers who are interested in the functioning of patients' rights during eHealth care provision as well.

6. READER'S GUIDE

The first part of the study is the introduction. In this part, the first subquestion – the question of what eHealth exactly is – will be answered (chapter 2). Then, the development and content of the right to health in international and national law, and the patients' rights in Dutch national law will be presented (chapter 3).

The second part of the study and will dive into the question of whether and under what conditions eHealth can contribute to realising the right to health for everyone and what the

57 Hartlief 2009, p. 17-22 and literature cited there and Leenen/Dute & Legemaate (eds.) 2017, p. 71 and the literature cited there.

58 CESCR General Comment no. 14 (2000) on Health, Para. 12.

59 For example, general comments on the Convention on the Rights of the Child (CRC) are regarded as authoritative in the advisory opinion of Solicitor-General Spronken, ECLI:NL:PHR:2015:1295, on HR 30 June 2015, ECLI:NL:2015:2465, *NJ* 2016/40, m.nt. Mevis.

60 For instance Wouters et al. 2017.

effects of eHealth are on the existing patients' rights and how they should be interpreted to remain the same level of protection as was originally intended when the WGBO was drafted. In other words, how patients' rights should be applied in eHealth care provision. Each chapter opens with a description of the eHealth application, illustrated with examples from health care practice. These examples will be used as stepping stones throughout the chapters. Each chapter will elaborate on these questions for one type of eHealth care provision, respectively e-consultation (chapter 4), tele-expertise (chapter 5) and telemonitoring (chapter 6).

Based on the outcomes of the previous chapters, the central question will be answered in part three of the study (chapter 7). An answer will be given to the question of how eHealth care provision can contribute to realising the right to health for everyone and whether the existing patients' rights in the Netherlands can be maintained, or if a different interpretation is required to protect patients during eHealth care provision. Finally, recommendations will be made on how to interpret existing patients' rights legislation and how to possibly adjust it to enhance the protection of patients' rights in the changing context of digital health care.

2



A golden scale of justice is shown against a white background. A blue banner with a wavy top edge is positioned across the upper half of the image. The scale's beam is visible on the left, and one of its pans hangs from a chain on the right. The text "On eHealth" is centered on the blue banner.

On eHealth

1. INTRODUCTION

“Stamping a definition on something like e-health is somewhat like stamping a definition on ‘the Internet’: It is defined how it is used – the definition cannot be pinned down, as it is a dynamic environment, constantly moving.”¹

This citation indicates that eHealth is hard to define, as Eysenbach stated in his article on eHealth in the *Journal of Medical Internet Research* in 2001.² eHealth, as mentioned in the first chapter, is the use of information and communication technologies for health and health care. This is a very broad description that does not provide us with an answer to the question of what eHealth exactly is. It even invokes another question: the question of what can be understood as ‘health’.

In this chapter the concept of eHealth will be clarified, the various forms of eHealth will be categorised and a definition will be proposed. This can only be done when a definition of health is given first.

It is necessary to clarify what eHealth is, because patients’ rights can only be understood in this context when it is clear exactly what it encompasses. In politics in the Netherlands³ as well as in Europe⁴, eHealth is a major item on the agenda. However, what is precisely meant by eHealth is not always made clear in these documents. Providing a clear definition of eHealth is not only required to give an answer to the main question of this study and therefore provide a framework for the research, but will be helpful for health care practice in general as well. Health care practitioners report a willingness to utilise eHealth.⁵ Patients, too, seem to be willing to contact their health care providers online.⁶ Yet, it is not evident to them which way their health care professionals have incorporated ICT in their work and what eHealth precisely contains.⁷ This use of eHealth seems to be behind;⁸ the lack of clarity could possibly be one of the reasons why. Furthermore, a clear definition of eHealth and its

1 Cited by Eysenbach in: Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/.

2 Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/.

3 See, for example *Kamerstukken II* 2019/20, 27529, no. 194.

4 This can be seen by the establishment of the eHealth Network based on Art. 14 of Directive (EU) 2011/24 of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare (*OJEU* 2011, L88) (hereafter: Patient Mobility Directive). The eHealth network is established by Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU (*OJEU* 2019, L 270).

5 Krijgsman et al. 2014, p. 34.

6 Krijgsman et al. 2015a, p. 76.

7 Krijgsman et al. 2014, p. 39 and Krijgsman et al. 2015a, p. 73.

8 See, for instance Nictz, NIVEL & Zorgimpuls, *ICT&health* 2017, issue 4, p. 15-17; Wouters et al. 2017, p. 44, 46-47; Krijgsman 2017, p. 12-13; Vroom 2017, p. 11-12 and RIVM, ‘Data-gedreven technologie in de zorg’, vtv2018.nl. Source: vtv2018.nl/data-gedreven-technologie.

meaning and objectives might contribute to a better understanding of the concept among academics and can improve communication about the concept.⁹

After a short introduction on several proposed definitions of eHealth (section 2), the concept of health will be analysed (section 3) because health is an inseparable component of eHealth, followed by a short description of ICT and ICT devices used to carry out health care over distance (section 4). Subsequently, in order to understand the development and growth of eHealth a brief summary of the history of eHealth, telemedicine and telehealth will be given (section 5). Based on recent as well as past developments an analysis of the meaning of eHealth will be carried out. Finally, to properly explain what eHealth can do, eHealth applications will be divided into categories and in each category examples will be given (section 6). The chapter will end with concluding remarks on eHealth and will propose a definition (section 7).

2. DEFINING EHEALTH: A SHORT INTRODUCTION TO COMMONLY USED DEFINITIONS

As presented in section 1, it is not always clear what eHealth is. Obviously, the ‘e’ stands for electronic, similar to the ‘e’ in e-banking and e-commerce.¹⁰ Other than that, the precise definition of eHealth has not been agreed upon. This section will elaborate on a number of definitions that have been given for ‘eHealth’.

In doctrine, various definitions have been drafted.¹¹ The definition formulated by Eysenbach became one of the most cited definitions of eHealth:¹²

“e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally and worldwide by using information and communication technology.”¹³

This definition explains the complexity of eHealth as a broad and comprehensive concept very well, for it includes all use of information and communication technologies (ICT) in

9 Also in this respect, see Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

10 Meier, Fitzgerald & Smith, *Annu. Rev. Biomed. Eng.* 2013, p. 360.

11 See, for instance the literature review by Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

12 According to Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/. Eysenbach's definition is one of the most cited definitions of eHealth. According to Google Scholar, Eysenbach was cited 3092 times (30 July 2020).

13 Cited by Eysenbach in: Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/.

health care. While taking a closer look at Eysenbach's definition, it can be concluded that eHealth not only encompasses the use of the Internet in the process of care giving as such, but the use of the Internet for the health system as a whole. The definition by Mitchell is also cited at times;¹⁴ his definition is "a new term needed to describe the combined use of electronic communication and information technology in the health sector - the use in the health sector of digital data-transmitted, stored and retrieved electronically-for clinical, educational and administrative purposes, both at the local site and at a distance."¹⁵ This is also one of the older definitions of eHealth. Another definition coined in academia is the one by Eng:

*"E-health is the use of emerging information and communications technology, especially the Internet, to improve or enable health and health care."*¹⁶

More recent definitions are often built on those definitions, such as the one coined by Pagliari et al.¹⁷ Another definition that can be found in academia is

*"eHealth encompasses many areas, including health records for professionals and patients, tele-health interventions, education and learning, mobile technologies and research."*¹⁸

This definition is also broad, but gives an indication of what is included in eHealth. A more concise definition can be found on the UN level. The World Health Organization (WHO), defines eHealth as:

*"the use of ICT for health."*¹⁹

Instead of the term 'health care', the term 'health' is used in this definition. Considering that the WHO defines health as

14 According to Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

15 Mitchell 1999.

16 Eng 2001, cited by Pagliari et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e9/.

17 Pagliari et al., *J Med Internet Res* 2005, available at jmir.org/2005/1/e9/. They endorse the definition by Eng, and building on the definition coined by Eysenbach, their definition is as follows: "e-health is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology" (adapted from Eysenbach).

18 Cunningham et al. 2014, p. 17.

19 WHO 2011, p. vi.

*“a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity,”*²⁰

this is an even more extensive description of eHealth than Eysenbach’s, which refers only to health care. That is to say, WHO’s definition of eHealth includes the element ‘health’ which is a broader concept than health services and information, which is included in the definition by Eysenbach.

On the European level, the European Commission formulated a definition of eHealth:

*“eHealth is the use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals.”*²¹

In the Netherlands, the KNMG and the RVS provided definitions of eHealth. According to the KNMG eHealth is about

*“digital applications in health care: the use of information and communications technology with the aim of supporting or improving health and healthcare.”*²²

According to the NHG, eHealth is

*“an umbrella term for a multitude of diverse applications. The denominator is more or less the use of internet (technology) and the use of multimedia applications.”*²³

The RVS²⁴ defines eHealth as

20 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth, and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively. *Basic Documents*, Forty-fifth edition, Supplement, October 2006.

21 COM (2012) 736 final, p. 3.

22 ‘eHealth’, knmg.nl. Source: knmg.nl/advies-richtlijnen/dossiers/ehealth.htm.

23 ‘NHG-Standpunt: e-health voor huisarts en patiënt’, nhg.nl. Source: nhg.org/nhg-e-health.

24 Until 2014 known as the *Raad voor de Volksgezondheid en Zorg* [Council for Public Health and Health Care] (RVZ).

“the use of new information and communication technologies, mainly Internet technology, to support or improve health and healthcare.”²⁵

This definition is utilised by the centre of expertise for standardisation and eHealth (Nictiz) and the Netherlands Institute for Health Services Research (NIVEL) in their annual eHealth-monitor as well.²⁶ In 2012, Klein Wolterink and Krijgsman (Nictiz) defined eHealth as follows:

“eHealth is the use of new information- and communication technologies, and especially Internet technology, to support or improve health and health care.”²⁷

In March 2019, Van Lettow, Wouters and Sinnige (Nictiz) coined a new definition of eHealth:

“E-health is the application of digital information as well as communication to improve and/or support health and health care.”²⁸

When comparing these two definitions by Nictiz, several changes attract attention such as the word ‘new,’ which can be seen in the 2012 definition but not in the definition of 2019. According to Van Lettow, Wouters and Sinnige, this was not necessary because not all technology used for eHealth is new, nor will new technology always be ‘new’.²⁹ Another difference is the use of the words ‘Internet’ and ‘technology.’ While these words can be seen in the 2012 definition, the 2019 definition does not mention them as elements of eHealth. The authors explain that the use of eHealth itself is more important than the means that are used to carry out eHealth.³⁰

The definition I will use in this study, building on the definitions formulated by the WHO, the KNMG and the RVS, is:

eHealth is the use of modern information- and communication technology (ICT) to support and improve health and health care.

This definition is chosen because it is comprehensive and acknowledges that eHealth is not just about supporting health care but also aims to improve it. Moreover, this definition underlines eHealth’s multiple functions: supporting health care provision and actual health care provision. Furthermore, this definition encompasses both eHealth’s function within and

25 RVZ 2002, p. 13 and Van Rijen, de Lint & Ottes 2002, p. 10-11.

26 See, for example Krijgsman et al. 2014, p. 18 and Krijgsman et al. 2015a, p. 18.

27 Krijgsman & Klein Wolterink 2012, p. 2. Translation IB.

28 Van Lettow, Wouters & Sinnige 2019, p. 11. Translation IB.

29 Van Lettow, Wouters & Sinnige 2019, p. 11 and 13.

30 Van Lettow, Wouters & Sinnige 2019, p. 11 and 12.

outside health care provision: as this chapter will argue, eHealth is of importance in the field of health care provision but plays a role outside that field as well. It enables individuals to manage their health before they even need health care provision. Finally, the definition excludes more old-fashioned ways of information and communication technology such as telegraphy and telephony, by indicating that eHealth is about modern information and communication technology. Such a limitation is necessary because eHealth already is a very broad concept.

This section mentions various definitions of eHealth. The definitions made clear that eHealth is the use of ICT for health and health care but they do not, however, clearly explain exactly what eHealth is and how it is utilised. They neither contribute to reaching a clear understanding of the concept, nor do they provide clarity about concrete eHealth care situations. The following sections of this chapter will elaborate on several elements included in the definition of eHealth, starting with ‘health’. At the end of the chapter, examples of the use of eHealth will be given in order to enhance understanding of eHealth because it can best be understood by means of its actual use.³¹

3. ON HEALTH

3.1 Introduction

Having established that eHealth is the use of modern ICT to support health and health care, other important questions such as what exactly health is, arise. To be able to interpret the meaning of eHealth, the meaning of health has to be understood first, because eHealth has an effect on health according to its definition. Therefore, this section will elaborate on the notion of health by briefly discussing various definitions that have been given to this concept since 1946. The discussion on the definition of health will be briefly highlighted and a position will be taken.

The definitions of health can be subdivided into categories. The first and most important definition, and currently the only authorised definition of health, was developed by the WHO in 1946. This definition can be referred to as the broad well-being definition (section 3.2). Other definitions to be discussed in the underlying section are the considerably narrower biostatistical definition (BST), as opposed to the holistic welfare theory (Holistic Theory of Health – HTH), which places emphasis on the degree of welfare experienced (section 3.3), the human health theory (HHT), which differentiates between ‘great health’ and ‘small health’ (section 3.4), and finally, the concept of health capital (section 3.5), followed by some concluding remarks (section 3.6).

31 According to the quotation by Eysenbach in: Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/.

First, the broad well-being definition will be discussed. This definition is currently the only authorised definition of health.

3.2 Broad well-being definition of health

The WHO describes health as

*“a state of complete physical, mental and social well-being and not merely the absence of disease.”*³²

Being healthy under this definition entails a general feeling of well-being and it does not exclusively involve not being ill; mental and social aspects are involved as well. That would make eHealth the use of ICT to support and improve complete physical, mental and social well-being.

In academia it is argued that a definition as broad as the WHO's has the potential to inspire and to lead to action.³³ Indeed, the WHO definition has broadened the view on health and has led it away from the traditional view of health as the absence of disease.³⁴ Those who are in favour of this definition state that the word 'health' is derived from the word 'whole' and that health therefore should entail more than solely the well-being of mind and body. A person's entire situation determines their health.³⁵ Nevertheless, the WHO's definition has been challenged repeatedly. For instance, it was criticised for relating more to happiness than to health.³⁶ Moreover, the WHO definition has been said to rather disregard the fact that health is a subjective feeling instead of an objective notion.³⁷ Other criticism of the WHO definition relates to the word 'state'. The definition fails to recognise the capability of people to adapt themselves to specific situations when health is defined health as 'a state'.³⁸ Furthermore, it has been argued that, under the WHO definition of health, people will find themselves unhealthy on a regular basis.³⁹ The WHO definition indeed seems slightly ambitious in this respect for no one will be in “a state of complete physical, mental and social well-being” all the time.⁴⁰ Therefore, Callahan provided a more narrow definition of health:

32 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth, and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively. *Basic Documents*, Forty-fifth edition, Supplement, October 2006. The definition has not been amended since 1948.

33 Van Spijk, *Med Health Care and Philos* 2015, p. 248.

34 Davies, *Perspectives in Biology and Medicine* 2007, p. 448.

35 *California Medicine* 1970, issue 4, p. 63.

36 Saracci, *BMJ* 1997, p. 1409.

37 Nieuwenhuijzen Kruseman, *Tsg* 2013, p. 137.

38 Smid, *Tsg* 2013, p. 132.

39 Nieuwenhuijzen Kruseman, *Tsg* 2013, p. 137.

40 Van Spijk, *Med Health Care and Philos* 2015, p. 248.

“health is a state of physical well-being.”⁴¹

He continues by explaining that this does not entail a state of complete physical well-being but rather a state of adequate physical well-being.⁴² While the WHO definition seems a little broad, Callahan’s definition seems too narrow as it excludes mental health. Mental health, however, is an important part of health and is interrelated with physical health.⁴³ Nevertheless, the idealistic approach to health by the WHO may, according to some, lead to unrealistic expectations in society such as the expectation that health care can solve all cases where people suffer from a less than complete state of physical, mental and social well-being or where they simply feel unhappy. This, in turn, might lead to excessive demands on health care,⁴⁴ especially when happiness becomes a major part of health. Happiness is, in a way, limitless which would make health a limitless goal as well.⁴⁵ Health care systems might not always be able to respond to these demands because individual health needs should always be weighed against available resources.⁴⁶ In a way, this is in line with the notion of the right to health in international human rights law, namely that the right to health is subject to progressive realisation and depends on the country’s available resources.⁴⁷ This means that more is expected from countries that are more developed as opposed to developing countries. Therefore, health is never a limitless goal because it strongly depends on the level of development of the country. The availability of resources will automatically be the limit. Consequently, it is unlikely that the broad well-being definition will lead to excessive demands or limitless goals of happiness. The definition proposed by Callahan, on the other hand, is too narrow especially with respect to eHealth as well, which relates to more than physical health alone; as this chapter will show, eHealth includes many areas besides physical health, such as mental health and public health.

3.3 Alternative definitions of health: the biostatistical definition versus the holistic welfare theory, or normal functional ability versus capability

In doctrine, some consider the WHO’s broad well-being definition too broad. Therefore, they prefer to refer to health solely in the medical sense of the word: the absence of a pathological condition, or put in a more positive way: normal functional ability.⁴⁸ This has become known

41 Callahan, *The Hastings Center Studies* 1973, issue 3, p. 87.

42 Callahan, *The Hastings Center Studies* 1973, issue 3, p. 87.

43 WHO 2013, p. 7.

44 Saracci, *BMJ* 1997, p. 1410; Bircher, *Med Health Care and Philos* 2005, p. 340; and Huber et al., *BMJ* 2011, p. 235 and Smid, *Tsg* 2013, p. 132.

45 Saracci, *BMJ* 1997, p. 1410.

46 Bircher, *Med, Health Care and Philos* 2005, p. 338.

47 Art. 2 ICESCR. This applies to all the human rights within the ICESCR.

48 See, for example C. Boorse, ‘Health as a Theoretical Concept’, *Philosophy of Science* 1977, p. 555 and 562 and Boorse, *Journal of Medicine and Philosophy* 2014, p. 684 (slightly corrected definition from 1977).

as Boorse's biostatistical theory (BST) of health. According to Boorse, defining health is an empirical question and not a matter of thinking about the deeper philosophical questions about the purpose of human life.⁴⁹ In the BST, health is the absence of disease. Schramme⁵⁰ acknowledges the need of a distinction between the BST's medical point of view and a more subjective point of view on health, such as Nordenfelt's holistic welfare theory, at times referred to as the Holistic Theory of Health (HTH).⁵¹ Even though Schramme is in favour of the BST, he argues that the theory should be supplemented by the HTH because of the latter theory's subjective elements.⁵² According to the HTH, health is defined as follows:

*"A is completely healthy if, and only if, A has the ability, given standard circumstances, to reach all his or her vital goals."*⁵³

Or, in short,

*"One's ability to fulfill one's goals."*⁵⁴

In this view, a person is healthy when they feel good and can function in their own environment.⁵⁵ Hence, health is closely related to welfare in this concept.⁵⁶

Nordenfelt's HTH was criticised because of its vital goals element. It has been noted that the 'vital goals,' goals that are seemingly important to reach health, are not explicitly pointed out by Nordenfelt.⁵⁷ Building on – however slightly adjusting – Nordenfelt's definition, it is stated that health is

*"a person's ability to achieve or exercise a cluster of basic human activities or capabilities."*⁵⁸

These basic human capabilities are inspired by Nussbaum's capabilities approach. In this approach, capabilities are what a person can do and can be in order to live a life worthy of

49 Boorse, *Philosophy of Science* 1977, p. 572.

50 Schramme, *Med, Health Care and Philos* 2007, p. 15.

51 See Nordenfelt 1995, p. 35 and Nordenfelt, *Med, Health Care and Philos* 2007, p. 7.

52 Schramme, *Med, Health Care and Philos* 2007, p. 16.

53 Nordenfelt, *Med, Health Care and Philo* 2007, p. 7. After receiving comments, Nordenfelt revised his 1987 and 1995 definition ("A is in health if, and only if, A has the ability, given standard circumstances, to realize his vital goals, i.e. the set of goals which are necessary and together sufficient for his minimal happiness", in: Nordenfelt 1987, p. 90 and Nordenfelt 1995, p. 90) several times: "A is completely healthy, if and only if A is in a bodily and mental state which is such that A is able to realize all his or her vital goals, given accepted circumstances." (in: Nordenfelt 1995, p. 212).

54 Nordenfelt 1995, p. 88.

55 Nordenfelt 1995, p. 35.

56 Nordenfelt 1995, p. 79.

57 Venkatapuram, *Bioethics* 2013, p. 274.

58 Venkatapuram, *Bioethics* 2013, p. 272.

human dignity.⁵⁹ Nussbaum listed ten central human capabilities.⁶⁰ It is suggested that these capabilities can serve as a means to fill in the cluster of basic human activities or capabilities, which can lead to health.⁶¹

Another point of criticism of the HTH relates to the criterion of minimal happiness. Even though the HTH is narrower than the WHO's broad well-being definition, it still marks healthy people as unhealthy because in the HTH, aiming for health equals realising certain goals. This means that a healthy person can be unhealthy under this definition because they are unable to realise a goal they set for themselves. The goals that Nordenfelt means in his HTH are, as noted by Venkatapuram,⁶² not listed anywhere. This might lead to inconsequentialities because health can be achieved by simply adjusting one's goals.⁶³ Indeed this can lead to inconsistencies when one person is seen as healthy because they are able to realise their goals while another person is not considered healthy because they are unable to realise their goals, even though their circumstances might exactly be the same.⁶⁴ The fact that the goals between these two people differ makes health a subjective notion and moreover, gives us the idea that health is malleable.

Another definition is Birchers' definition:

*"Health is a dynamic state of wellbeing characterized by a physical, mental and social potential, which satisfies the demands of a life commensurate with age, culture, and personal responsibility."*⁶⁵

He argues that the experienced health relates to both biological and personal aspects.⁶⁶ This definition does justice to the fact that health is more or less a subjective feeling and is related to several elements of life. Others, such as Davies, seem to be in favour of the HTH too. He argues that the BST alone is an insufficient instrument to measure an individual's health. In his view, health is related to the way in which people can maintain themselves in society.⁶⁷ Therefore, he defines health as:

*"an ongoing outcome from the continuing process of living life well. "Living life well" would be defined in terms of wealth, relationships, coherence, fitness, and adaptability, with disease avoidance playing only a minor part."*⁶⁸

59 Nussbaum 2006, p. 70.

60 Nussbaum 2006, p. 76-78.

61 Venkatapuram, *Bioethics* 2013, p. 279.

62 Venkatapuram, *Bioethics* 2013, p. 274.

63 Schramme, *Med, Health Care and Philos* 2007, p. 14.

64 Accordingly, Schramme, *Med, Health Care and Philos* 2007, p. 15.

65 Bircher, *Med, Health Care and Philos* 2005, p. 336.

66 Bircher, *Med, Health Care and Philos* 2005, p. 336-337.

67 Davies, *Perspectives in Biology and Medicine* 2007, p. 449.

68 Davies, *Perspectives in Biology and Medicine* 2007, p. 450.

Thus, in this view, health is more than the absence of disease. Health is a constantly shifting balance between health, disease and external factors.⁶⁹ Similar to several other definitions mentioned in this subsection, adaptability is an important factor to enjoy health. However, Davies stresses that health is neither the sole responsibility of society, nor is it fully the responsibility of individuals.⁷⁰ Therefore, those who are not able to manage themselves should receive help in order for them to be able to fully enjoy health.⁷¹ Before Nordenfelt, a relation between health and personal abilities had already been made by Canguilhem in 1943. According to Canguilhem, the feeling of what is normal can vary between individuals.⁷² Being healthy does not equal being normal in a given situation but equals being or becoming normal in any situation. Health then becomes the ability to deal with and to adapt to changing circumstances.⁷³

The definition coined by Huber et al. received a fair amount of attention. They defined health as

*“the ability to adapt and to self manage.”*⁷⁴

Huber et al. referred to various declarations and charters while drafting this definition, such as the Ottawa charter.⁷⁵ This charter explains that personal capabilities and the ability to cope are important in order to be able to reach health as defined by the WHO.⁷⁶ In response to Huber et al., Pledger suggested a working definition of health:

*“The ability to work, love and sleep.”*⁷⁷

The definition by Huber et al., or concept as Huber et al. refer to it,⁷⁸ drew a considerable amount of criticism as well. Under this concept, people who can manage themselves in the given circumstances are healthy. This assumption might lead to the rather undesirable conclusion that a person with a severe illness can nevertheless be healthy because they have the ability to manage themselves in spite of their poor physical condition.⁷⁹ Furthermore, a person who can adapt themselves to a specific situation of disease or illness might still feel

69 Davies, *Perspectives in Biology and Medicine* 2007, p. 451.

70 Davies, *Perspectives in Biology and Medicine* 2007, p. 450.

71 Davies, *Perspectives in Biology and Medicine* 2007, p. 449.

72 Canguilhem 1943, p. 110.

73 Canguilhem 1943, p. 121 and 123.

74 Huber et al., *BMJ* 2011, p. 237. This paper is also published as chapter 3 of Hubers' dissertation: Huber 2014. For the definition see p. 50.

75 Huber et al., *BMJ* 2011, p. 236 and Huber 2014, p. 32 and 48.

76 Ottawa Charter on Health Promotion, adopted by the first International Conference on Health Promotion in Ottawa on 21 November 1986.

77 Pledger, *BMJ* 2011, p. 436.

78 Huber, *Tsg* 2013, p. 133.

79 For instance Nieuwenhuijzen Kruseman, in: Huber et al. 2013, p. 132.

physically or emotionally miserable.⁸⁰ In reaction to Huber et al., Shilton et al. state that a present-day definition of health should take the fact that health is a human right into account.⁸¹ Their proposed definition of health is:

*“Health is created when individuals, families, and communities are afforded the income, education, and power to control their lives; and their needs and rights are supported by systems, environments, and policies that are enabling and conducive to better health.”*⁸²

This is indeed a definition that reflects human rights. It includes elements necessary to realise the right to health⁸³ and it includes other human rights, such as the right to education as well.⁸⁴ The latter seems more in line with the definition as proposed by Saracci,⁸⁵ who also explicitly mentions the fact that health is a human right. He describes health as

*“a condition of well being free of disease or infirmity and a basic and universal human right.”*⁸⁶

The WHO emphasised the fact that health is a human right in the Declaration of Alma-Ata.⁸⁷ Health as a fundamental human right is laid down in several international treaties and regulations, such as Article 12 ICESCR.⁸⁸ In this covenant, the right to health is referred to as the highest attainable standard of physical and mental health. While the right to health in the ICESCR does not encompass health according to the WHO definition,⁸⁹ the CESCR explained that the right to health is not restricted to the right to health care but includes determinants as well, such as a healthy environment and access to safe drinking water.⁹⁰ This is comparable to the new approach to public health as instigated by the WHO in the Ottawa charter,⁹¹ continued by the ‘Health in All Policies’ (HiAP) approach.⁹² A definition of health

80 Nieuwenhuijzen Kruseman, *Tig* 2013, p. 137.

81 Shilton et al., *BMJ* 2011, p. 435. The right to health is recognised in several international treaties and regulations, such as Art. 12 ICESCR and Art. 11 RESC.

82 Shilton et al., *BMJ* 2011, p. 435.

83 CESCR General Comment no. 14 (2000) on Health, Para. 4.

84 Art. 13 ICESCR.

85 Saracci, *BMJ* 1997, p. 1410.

86 Saracci, *BMJ* 1997, p. 1410.

87 Declaration of Alma-Ata, adopted by The International Conference on Primary Health Care, in Alma-Ata, USSR, 6-12 September 1978, Art. I.

88 International Covenant on Economic, Social and Cultural Rights (ICESCR), 16 December 1966, 6 *ILM* 1967, p. 360.

89 CESCR General Comment no. 14 (2000) on Health, Para. 4.

90 CESCR General Comment no. 14 (2000) on Health, Para. 4.

91 Ottawa Charter on Health Promotion, adopted by the first International Conference on Health Promotion in Ottawa on 21 November 1986.

92 WHO 2014, p. 8-9.

should focus on health as a human right that should be progressively realised, in accordance with the available resources.⁹³ Building on both the WHO definition and the definition by Huber et al., Nieuwenhuijzen Kruseman suggests describing health as the

*“ability to adapt and to self manage resulting in physical, mental and social well-being.”*⁹⁴

In my opinion, this definition imposes a large responsibility for an individual’s health on the individual themselves because it implies that being healthy largely depends on the degree to which that individual can adapt and self-manage. An approach, that bears in mind that health is a human right and thus implies a responsibility for states to at least create preconditions for leading a healthy life, is desirable.

3.4 Human Health Theory

Inspired by Friedrich Nietzsche’s understanding of ‘great health’, Van Spijk proposes the Human Health Theory (HHT). According to Van Spijk,

*“Human health – also called ‘great health’ – is the ability to live a life that makes sense.”*⁹⁵

He distinguishes between great health and small health, a narrower notion. While great health refers to a general feeling of well-being, small health merely refers to the absence of illness, disease, injury and impairment.⁹⁶ The feeling that a person’s life makes sense refers to a general feeling about their life, rather based on various positive occurrences than on a constant experience.⁹⁷ Under the HHT, a diseased person lacks small health but still can enjoy great health if, in spite of their disease, at times, they have the feeling that their life makes sense. The distinction between small health and great health prevents a person who suffers from disease or illness being called healthy.⁹⁸ In this view, the WHO definition can be classified as a definition of great health and the BST can be classified as small health.⁹⁹ Under the HHT it is possible to enjoy small health and yet, at the same time lack great health. This avoids only classifying pathological conditions as health. Ideally, a healthy person possesses both small and great health; a good definition of health should reflect this. The broad well-being definition by the WHO and the definition by Huber et al., for instance, do so because they take into account other factors besides pathological conditions.

93 Art. 2 ICESCR.

94 Nieuwenhuijzen Kruseman, *Tsg* 2013, p. 137.

95 Van Spijk, *Med Health Care and Philos* 2015, p. 246.

96 Van Spijk, *Med Health Care and Philos* 2015, p. 247.

97 Van Spijk, *Med Health Care and Philos* 2015, p. 247-248.

98 Van Spijk, *Med Health Care and Philos* 2015, p. 249.

99 Van Spijk, *Med Health Care and Philos* 2015, p. 248.

3.5 Health capital

In a further effort to bring the discussion to the next stage, Bekker, inspired by Grossman¹⁰⁰ who first coined the concept, defined the term health capital in order to stress that health is not only of importance to the individual but is also of societal significance. She defined this concept as

*“Health capital consists of a combination of common resources for the communal social adaptability and the communal ability to cope independently in view of socio-economic as well as physical and spatial challenges.”*¹⁰¹

Helderman explains the concept as

*“Health is a capital good. Health enables us to employ meaningful private, societal and public activities.”*¹⁰²

This concept can contribute to defining health as a more societal concept instead of an individual concept. However, more explanation on the exact meaning and use of the notion of health capital is necessary.¹⁰³

Comments on the proposed concept of health capital include the fact that it stretches the meaning of health too much. Extending health or health capital to human adaptability stretches the concept because adaptability depends on many individual or external factors. This means that health becomes dependent on factors that are not per se all related to (pathological) health. The concept is too broad and therefore less practicable.¹⁰⁴

Kooiker conducted a study in the Netherlands in order to find out how people really feel about health and how they would define it.¹⁰⁵ In his study, Kooiker, based on the answers of his respondents, divided health into an external notion and an internal notion, which are interrelated. The external notion of health relates to how a person can behave and act in society. This includes freedom of movement, independence and freedom of choice. The internal notion of health refers to the way a person experiences their health i.e. what a person feels when they are healthy such as the feeling to be balanced or a general feeling of well-being.¹⁰⁶ This means that people seem to value great health as well and not only small health. Therefore, the definition of health should include both small health and great health.

100 Grossman, *Journal of Political Economy* 1972, p. 223-255.

101 Bekker, *Tsg* 2014, p. 57 (translated from Dutch).

102 Helderman, *Tsg* 2014, p. 60 (translated from Dutch).

103 Huber, *Tsg* 2014, p. 58-59.

104 Stronks, *Tsg* 2014, p. 59.

105 Kooiker 2011.

106 Kooiker 2011, p. 14-18.

3.6 Concluding remarks on health

Although the WHO definition – as this section shows – has been criticised repeatedly, no other definition has been agreed upon yet. Even though various new definitions have been proposed, the broad well-being definition remains the legitimate definition of health. The inventors of the proposed alternative definitions can be roughly divided into two groups: the group who feels that the WHO definition is too broad and therefore stresses that health needs to be regarded as a strictly medical condition (BST)¹⁰⁷ and the group who wishes to place more emphasis on the individual and their surroundings. This group is in favour of the HTH.¹⁰⁸ The HTH shows more similarities to the broad well-being definition than it does to the BST. Van Spijks' HHT does both of these views justice by distinguishing between small health, which is a strictly medical condition and great health, which is more related to well-being.¹⁰⁹ The study conducted by Kooiker shows that individuals perceive health as great health instead of small health.¹¹⁰ Therefore, they seem to be in favour of the broad well-being definition or the HTH. Indeed, health relates to more than entirely biological factors because it is imaginable that physical health and a corresponding feeling of health closely relate to how a person really feels and functions. In that way, the WHO definition still seems up to date. However, recent developments in society as well as in health care might indicate otherwise.¹¹¹

Societies and the way we live have changed significantly since 1946. Health care, too, has undergone significant developments in the last century and people live to an older age, resulting in a considerable amount of diseases having become chronic conditions. Rather than something to cure, disease has become something to learn to live with.¹¹² Health, therefore, has become interrelated to the way we can manage ourselves and lead a normal life despite our diseases and disabilities.

Changes in health care, such as eHealth, can contribute to this development. The use of modern technology in health care allows individuals to take a more active role in their health care process. Ideally, it will make them gain more control over their own health. The latter is often referred to as patient empowerment.¹¹³ The changes in both health care and society in the past

107 Boorse, *Philosophy of Science* 1977, p. 555 and 562 and Boorse, *Journal of Medicine and Philosophy* 2014, p. 684 (slightly corrected definition from 1977).

108 Such as Nordenfelt 1995, p. 35 and Nordenfelt, *Med, Health Care and Philos* 2007, p. 7.

109 Van Spijk, *Med Health Care and Philos* 2015, p. 246.

110 Kooiker 2011, p. 14-18.

111 For instance, Bircher, *Med Health Care and Philos* 2005, p. 335.

112 Huber et al., *BMJ* 2011, p. 236 and Huber 2014, p. 47.

113 COM(2012) 736 final, p. 5.

few years can clarify the amount of definitions relating to capabilities that have been proposed.¹¹⁴ Capabilities and abilities to live with certain impairments have become more important than living without any kind of disease as such. eHealth strongly depends on people's abilities to manage their own health and simultaneously helps them to do so. eHealth refers to more than just a cure; it includes prevention, well-being, lifestyle management, self-management and involvement in one's health care process. eHealth emphasises people's own abilities and, in a way, gives the health care process back to the patient. Lifestyle advice, prevention and cure have gained importance in the digital era. These developments might reflect a changing perspective on health. Therefore, the definition of health coined by Huber et al., that health is the ability for a person to adapt and to manage themselves,¹¹⁵ is a step in the right direction although it does not reflect the fact that health is a human right.¹¹⁶ It rather gives the impression that health is achievable only if the individual learns to adjust, or acquires certain abilities.

Health, however, cannot always be achieved by simply developing new abilities. Biological factors should be taken into account as well. Therefore, in accordance with Schramme, we should see health as a combination of a medical condition and subjective elements.¹¹⁷ The BST can be the starting point to determine an individual's health.

Nevertheless, it cannot be denied that a feeling of general well-being is part of health too. Although the concept of health as coined by Huber et al. seems to fit recent developments such as eHealth, the major drawback is the fact that this concept can refer to a person as healthy because they are able to cope with their disease. Therefore, the broad well-being definition is still preferable. However, it is necessary to look at it in view of the new era and its recent developments.

The WHO's definition remains the most accurate definition of health because it envisages achieving health goals and it reminds us to respect health as a human right. eHealth should be seen in this respect as well; the use of information and communication technologies to support and improve health should be aimed at realising the right to health for everyone.¹¹⁸ In this view, health consists of both small health and great health, according to the classification proposed by Van Spijk.¹¹⁹

114 Examples include Nordenfelt's HTH (Nordenfelt 1995, p. 35 and Nordenfelt, *Med, Health Care and Philos* 2007, p. 7); Venkatapuram's definition (Venkatapuram, *Bioethics* 2013, p. 272); Davies' definition (Davies, *Perspectives in Biology and Medicine* 2007, p. 450) and the definition by Huber et al. (Huber et al., *BMJ* 2011, p. 237 and Huber 2014, p. 50).

115 Huber et al., *BMJ* 2011, p. 237 and Huber 2014, p. 50.

116 Accordingly, Shilton et al., *BMJ* 2011, p. 435.

117 Schramme, *Med, Health Care and Philos* 2007, p. 16.

118 Just as health law has the role of realisation of the right to health care, See Buijsen, *Ars Aequi* 2004, p. 428 and Buijsen 2016, p. 45.

119 Van Spijk, *Med Health Care and Philos* 2015, p. 246.

4 ON ICT

After having established that eHealth is the use of ICT to support and improve health, one question remains: what devices are used in eHealth applications? Information and communication technologies include

“technologies that are used for collecting, saving, editing, processing and transmitting information in various forms, such as data, images and sound.”¹²⁰

This means that ICT refers to all kinds of devices that are based on information systems and can be used for communication in various ways. The development of such devices started with the invention of the telegraph, which enabled communication over long distances.¹²¹ In the twentieth century, the development of modern technology moved ahead quickly. Inventions such as the telephone and the computer were gradually made available to everyone. Since the emergence of the Internet in the last few decades of the twentieth century, information can be obtained and shared easily.¹²² This development was reflected in various sectors of society, such as banking. Where people in the beginning of the last century often paid in cash, it has nowadays become customary to transfer the money to and from their bank accounts. In more recent times, banking has shifted from filling in paper forms to Internet banking, or e-banking. Other daily life activities have also been shifted to the Internet; online shopping and online booking of trips and holidays for instance have become common practice,¹²³ while making phone calls by means of video with the help of apps such as Facetime, Skype and WhatsApp also seem to have gained popularity.

ICT is of major importance in health care as well. Since the first information and communication technologies were developed, they were used in health care to deal with long distances and to cross borders. Health care over distance has a long history. Even the earliest ICT devices have been used in health care, such as the telegraph.¹²⁴ This study, however, concentrates on eHealth care provision; and in the definition of eHealth as adopted in section 2, eHealth refers to modern ICT. Therefore, the use of older ICT such as the telephone for phone calls between health professionals between each other or between health professionals and patients is not considered eHealth, even though the telephone in itself is an ICT device. The use of smartphone applications such as chat or email are included in this study's definition of eHealth though.

120 SER 1996, p. 17.

121 For an explanation of the history and development of the various types of telegraphs, see Winston 1998, p. 19-29.

122 For instance Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

123 SER 1997, p. 24 and 25 already hinted that this would happen based on developments in ICT.

124 See, for instance: *South Australian Advertiser* 24 February 1874, p. 2 mentioned by Eikelboom 2012, p. 71 and Zundel, *Bull Med Libr Assoc* 1996, p. 72.

In order to understand the meaning and purpose of the use of ICT for health care a brief historical exploration is required. This exploration will take place in the following subsection, which will discuss the history of health care over distance in general, and the history of eHealth in particular.

5 EHEALTH, TELEMEDICINE AND TELEHEALTH: A SHORT HISTORY

5.1 General introduction on ICT in health care

eHealths' history and development can be characterised by the shift of health care provision from health care facilities to the patients' private sphere.¹²⁵ Historically, health care provision took place in the patient's home. Whenever a health problem occurred, a physician would come to the patient. He would perform a great deal of the medical procedure on location.¹²⁶ After developments in health care, the provision of health care would shift from the patients' home to hospitals and other medical facilities, where technology was present.¹²⁷ The use of information and communication technologies in health care enables the patient and the physician to contact each other over distance, leading to a shift backwards: health care provision is taken from the facilities to the patients' home again.¹²⁸

This subsection will discuss the history of the use of information and communication technologies in health care. The history and development of eHealth is related to the terms telemedicine and telehealth. Together eHealth, telemedicine and telehealth are sometimes called 'ICT health' even though they are three separate concepts.¹²⁹ The terms telemedicine, telehealth and eHealth are often used as interchangeable, although there are differences.¹³⁰ Fatehi and Wootton conducted a study on the use of the terms telemedicine, telehealth and eHealth and found that telemedicine is by far the most prevalent term in scholarly literature although the term eHealth seemed to be used more frequently at the time the study was conducted. Additionally, they concluded that some overlap between the three terms exists and that their precise meaning is not always clear.¹³¹

125 For instance, RVZ 2015a, p. 27.

126 Ladan describes in his dissertation on the late medieval health care system of Leiden that health care provision, at least for the rich, took place in the patient's home. Ladan 2012, p. 12 and p. 23-24.

127 See, for example Papazossos 2004, p. 190-199 and Merrell 2004, p. 4.

128 For instance Timmer 2011, p. 82; Van Rijen, appendix to *Kamerstukken II* 2007/08, 31200-XVI, 165, p. 5; *Kamerstukken II* 2013/14, 27529, no. 130 and Ministerie van Volksgezondheid, Welzijn en Sport 2014, p. 17, 54 and 61.

129 Fatehi & Wootton, *Journal of Telemedicine and Telecare* 2012, p. 461 and 463.

130 Fatehi & Wootton, *Journal of Telemedicine and Telecare* 2012.

131 Fatehi & Wootton, *Journal of Telemedicine and Telecare* 2012, p. 464.

Nevertheless, eHealth, telehealth and telemedicine do have several characteristics in common. According to the RVS in their 2002 study on eHealth, these concepts all relate to the provision of health services, such as providing information or monitoring a patients' health condition where distance is a critical factor and ICT is used.¹³² However, comments can be made on the aspect of distance as a critical factor in all three concepts. Distance is, indeed, a critical factor in telemedicine and telehealth. In 2002, this might have been the case for eHealth as well but recently numerous eHealth inventions are being designed to be used by the patient on their own, referred to as consumer eHealth (as opposed to professional eHealth)¹³³ by the RVS in 2015.¹³⁴ These applications do not necessarily involve contacting a health professional and can be used by patients or consumers independently. Distance is not a part of such applications, unless this distance entails the distance between patients/consumers and developers of applications for consumer eHealth. Hence, the use of distance as a criterion to describe eHealth seems a little outdated. Moreover, professional eHealth does not always take place over distance. Electronic patient records, for instance, are a type of professional eHealth. Even though they can be shared over distance, this is not necessarily always the case. To conclude, while distance is an important factor in telemedicine, which refers to health care provision over distance, eHealth is much broader than that.

In this study, telemedicine and telehealth will be considered as types of eHealth. This subsection will show that eHealth is an umbrella term that encompasses both telemedicine and telehealth, and that the development of telemedicine and the broader concept of telehealth eventually led to the emergence of eHealth as we know it today. The subsequent subsections will respectively discuss telemedicine (section 5.2), telehealth (section 5.3) and eHealth (section 5.4), followed by some concluding remarks on the history and development of the concept (section 5.5).

5.2 Telemedicine

As briefly mentioned in the previous subsection, eHealth originates from other, earlier, forms of health care over distance, although no consensus exist about the exact commencement of this type of health care. While some argue that health care over distance was developed from the 1960s until the 1990s when modern technology began to emerge,¹³⁵ others state that it originates from the Civil War in the USA in the 1860s and from Australia around the same time, where distance always played a crucial role.¹³⁶ In both the USA during the Civil War and in Australia in the late 19th century, the telegraph was utilised in order to provide health

132 Van Rijen, De Lint & Ottes 2002, p. 10.

133 RVZ 2015a, p. 19.

134 RVZ 2015a, p. 20-23.

135 See, for example: Iakovidis, Wilson & Healy 2004, p. vi-vii.

136 See, for example: *South Australian Advertiser* 24 February 1874, p. 2 mentioned by Eikelboom 2012, p. 71 and Zundel, *Bull Med Libr Assoc* 1996, p. 72.

care over great distance. By the clicking of the telegraph, information on the health and well-being of a patient could be transferred from one area to another. Furthermore, the telegraph could be used to order health care supplies and to notify the home front on the situation of the wounded or ill during the American Civil War.¹³⁷ From Australia, a case is known in which the telegraph was used to obtain instructions on treatment of the wounded after a stabbing. The stabbing took place in Australia's outback, with the nearest physician located at the south coast, a distance of approximately 1800 kilometres. Because of the recently opened telegraph station, advice could be given in Morse code.¹³⁸

Obviously, these are very early forms of (analogue) telemedicine. After the invention of the telephone in the end of the 19th century, health care provision via the telegraph was replaced by health care provision over the telephone.¹³⁹ Telemedicine by means of a telephone originates from the Netherlands. Willem van Einthoven, a Dutch physician, is said to be one of the first physicians to have practised telemedicine the way we know it nowadays.¹⁴⁰ Van Einthoven measured and recorded electrocardiograms over distance, using the telephone wire.¹⁴¹ This was followed by the radio. For instance, the radio has been used for emergencies on ships at sea¹⁴² and by the Australian Flying Doctor Service.¹⁴³

The invention of television and video broadcasting, again, led to significant developments in telemedicine.¹⁴⁴ Nowadays, telemedicine includes photos, multimedia, the Internet and web-based apps as well.¹⁴⁵ It has been argued that telemedicine as we know it began to develop around 1950 along with the introduction of closed-circuit telecommunications systems.¹⁴⁶ In this point of view, health care via the telephone is not seen as telemedicine. Others, however, do recognise the use of the telephone as an early form of telemedicine, although they, too, recognise the 1950s as the starting point of telemedicine.¹⁴⁷ Sometimes, a distinction is made between two phases: the analogue phase and the current phase. The analogue phase includes telemedicine over telegraph and analogue telephone lines, whereas the current phases refers to the use of contemporary technology, such as digital telephone lines, computers and digital

137 Zundel, *Bull Med Libr Assoc* 1996, p. 72.

138 *South Australian Advertiser* 24 February 1874, p. 2 mentioned by Eikelboom 2012, p. 70-71 and Zundel, *Bull Med Libr Assoc* 1996, p. 72.

139 Zundel, *Bull Med Libr Assoc* 1996, p. 72.

140 Bashshur & Shannon 2009, p. 6, about Einthoven (1906), *American Heart Journal* 1957, issue 4 p. 602-615 (Translation by H.W. Blackburn, from *Archives Internationales de Physiologie* 4:132, 1906).

141 Einthoven (1906), *American Heart Journal* 1957, issue 4 p. 602-615 (Translation by H.W. Blackburn, from *Archives Internationales de Physiologie* 4:132, 1906).

142 Higgs, Dunn & Conrath, *Telecommunications Policy* 1984, p. 308.

143 Royal Flying Doctor Service, 'History', *flyingdoctor.org.au*. Source: flyingdoctor.org.au/about-the-rfdds/history/.

144 See, for example Benschoter, *Annals New York Academy of Sciences* 1967, p. 471-478.

145 Moore, *Future Generation Computer Systems* 1999, p. 245.

146 Coles 1995, p. 12.

147 See, for example: Sosa-Iudicissa, Wootton & Ferrer-Roca 1998, p. 2-3.

broadcasting systems.¹⁴⁸ Even though analogue telemedicine is a development that eventually led to eHealth as we know it nowadays, for the purpose of this study eHealth does not include analogue communication, such as phone calls.

As presented above, telemedicine is health care provision over distance and, like eHealth, has been defined by several actors in the field. According to the WHO, telemedicine encompasses

*“The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities.”*¹⁴⁹

The European Commission defines telemedicine as

*“The provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.”*¹⁵⁰

In literature, telemedicine is often referred to in a more concise way as

*“the provision of medical services across distance.”*¹⁵¹

Thus, telemedicine refers to health care provision over distance, where health care professionals use ICT in order to communicate with patients or with each other concerning the treatment of a patient.¹⁵² The goal is to improve individuals' health. Telemedicine always involves a health professional.¹⁵³ Consequently, patient-to-patient communication is not considered telemedicine.¹⁵⁴

The aforementioned examples show that the purpose of telemedicine used to be the support of rural and remote areas with little access to regular health care. Telemedicine was not

148 See, for example: Sosa-Iudicissa, Wootton & Ferrer-Roca 1998, p. 2-3.

149 WHO Group Consultation on Health Telematics 1998, p. 10.

150 COM(2008)689 final.

151 Fatehi & Wootton, *Journal of Telemedicine and Telecare* 2012, p. 460.

152 Delzell, 'Telemedicine technology propels diabetic foot care', *Lermagazine.com* April 2012. Source: lermagazine.com/article/telemedicine-technology-propels-diabetic-foot-care.

153 Huijbers, p. 1.

154 Delzell, 'Telemedicine technology propels diabetic foot care', *Lermagazine.com* April 2012. Source: lermagazine.com/article/telemedicine-technology-propels-diabetic-foot-care.

solely designed to enable patients in rural or remote areas to contact a health professional but also to enable health professionals in those areas to contact colleagues from a distance. Thus, telemedicine became a manner to deal with the shortage of certain types of health professionals in certain areas.¹⁵⁵ This explains why one of the earliest forms of health care over distance, as mentioned above, occurred in Australia,¹⁵⁶ a sparsely populated country.¹⁵⁷ Nowadays telemedicine applications are meant to increase the access to health care for everyone,¹⁵⁸ including the inhabitants of densely populated areas.

Examples of telemedicine are telemonitoring (the use of ICT to monitor a patient at home), e-consultation (consultation between a physician and a patient over distance), tele-expertise (consultation over distance between two or more health professionals about the diagnosis or treatment of a specific patient) and tele-assistance (remote assistance by a health professional relating to the treatment of a patient).¹⁵⁹ The latter is comparable to the type of telemedicine described in the example from Australia in 1874. Other resources add telecoaching to this list. Telecoaching refers to coaching over distance and is often used in mental health care.¹⁶⁰

5.3 Telehealth

Telehealth is a slightly broader concept than telemedicine. While the WHO does sometimes consider telemedicine and telehealth to be the same,¹⁶¹ it also refers to telehealth as a subtype of the broader concept of eHealth that is carried out by means of telecommunications.¹⁶² The WHO and the European Observatory on Health Systems and Policies together define telehealth as

*“The use of ICT applications to provide health and long-term care services over a distance.”*¹⁶³

In its Telehealth Code, the European Commission defines telehealth as

*“The means by which technologies and related services concerned with people’s health and well-being are accessed by them or provided for them, at a distance. A telehealth service may be staffed or automatic.”*¹⁶⁴

155 Zundel, *Bull Med Libr Assoc* 1996, p. 71- 72 and Moore, *Future Generation Computer Systems* 1999, p. 250.

156 *South Australian Advertiser* 24 February 1874, p. 2 mentioned by Eikelboom 2012, p. 71.

157 Also see Beuscart et al. 2014, p. 407.

158 Moore, *Future Generation Computer Systems* 1999, p. 246.

159 Beuscart et al. 2014, p. 410-411.

160 Huijbers, p. 2.

161 WHO 2010, p. 9.

162 Stroetmann et al. 2010, p. 3.

163 Stroetmann et al. 2010, p. 1.

164 TeleSCoPE Project, *European Code of Practice for Telehealth Services* 2014, Part C: Glossary of definitions, p. 14.

This definition indicates that telehealth is a broader concept than telemedicine for it not only encompasses prevention, diagnosis, treatment and follow-up of patients, but all services concerned with their health and well-being over a distance. In literature, telehealth is defined as follows:

*“the full array of technologies, networks and healthcare services provided through telecommunications, including delivery of educational programs, collaborative research, meeting, patient consultations and other services provided with the purpose of improving health.”*¹⁶⁵

Another concept that can be heard in this field is health telematics. Sometimes, telehealth and health telematics are understood as being the same:

*“Telehealth (also known as health telematics) covers the activities, services and systems performed remotely using ICT with respect to worldwide needs in health promotion, disease management and control, health management and health-related research.”*¹⁶⁶

However, at times health telematics is defined as a different concept, that is to say, as

*“a composite term for health-related activities, services and systems, carried out over a distance by means of information and communications technologies, for the purposes of global health promotion, disease control and health care, as well as education management, and research for health.”*¹⁶⁷

Health telematics includes telemedicine, tele-education, telematics for health research and telematics for health services management.¹⁶⁸ Based on these definitions it can be concluded that telehealth includes both telemedicine and public health over distance. I agree with the WHO where it is stated that the difference between telehealth and eHealth is that the latter is a wider concept.¹⁶⁹ Where telehealth includes telemedicine, eHealth includes telehealth and telemedicine. This will be presented in the following section.

5.4 eHealth

As presented already, eHealth is a broad concept that encompasses both telemedicine and telehealth. It is sometimes referred to as an evolution of telemedicine.¹⁷⁰ According to the Telehealth Code, eHealth is

165 Moore, *Future Generation Computer Systems* 1999, p. 245.

166 Beuscart et al. 2014, p. 410.

167 WHO Group Consultation on Health Telematics 1998, p. 10.

168 WHO Group Consultation on Health Telematics 1998, p. 10.

169 Stroetmann et al. 2010, p. 3.

170 Glinkowski 2006, p. 23.

*“the range of devices and services (based on information and communication technologies) used to assist and enhance the prevention, diagnosis, treatment, monitoring and management of people’s health and lifestyles.”*¹⁷¹

Similar to the definitions the European Commission and the WHO provided, as mentioned in section 2, this definition is very broad. It is made clear that both telemedicine and telehealth are a part of the umbrella term of eHealth. This broader term encompasses both health care over distance and services concerned with health and well-being in general. For instance, eHealth applications can be used to obtain lifestyle advice; in fact, eHealth embraces all use of ICT related to health and health care. Besides telemedicine and telehealth, it also includes consumer eHealth for example.¹⁷² In this respect, it has been said that the difference between eHealth and telemedicine can be established based on their focus. Whereas telemedicine is focused on the health professional, eHealth is focused on the patient – at times referred to as the consumer.¹⁷³ This statement is supported by the fact that the term ‘consumer eHealth’ (eHealth directly aimed at the consumer, without the involvement of a health professional) has been mentioned recently as well.¹⁷⁴ Some descriptions of eHealth stress that all eHealth applications should include the use of the Internet,¹⁷⁵ while others describe eHealth as the use of all ICT applications for health.¹⁷⁶ As presented in section 2, in this study eHealth refers to the use of modern ICT for health and health care, which is highly likely to include the Internet.

As stated in the introduction to this chapter, eHealth is defined many times and yet no consensus seems to exist. Two studies found 36¹⁷⁷ and 51 definitions.¹⁷⁸ One of these studies also concluded that eHealth is generally understood in the context in which it is used. Therefore, the precise meaning of the concept differs given its application.¹⁷⁹ The more narrow definitions of eHealth exclude patient–patient contact and any use of ICT without the involvement of a health professional.¹⁸⁰ Another study describes eHealth as

*“information and communication technology applications in direct patient care.”*¹⁸¹

171 TeleSCoPE Project, European Code of Practice for Telehealth Services 2014, Part C: Glossary of definitions, p. 12.

172 RVZ 2015a, p. 20-23.

173 See, for instance, Della Mea, *J Med Internet Res* 2001, issue 2, available at jmir.org/2001/2/e22/.

174 See, for instance, RVZ 2015a, p. 20-23 and RVZ 2015b, p. 12, referring to Weiner, Yeh & Blumenthal, *Health Affairs* 2013, where the term consumer eHealth is mentioned at p. 2001.

175 See, for instance, Watson, *BMJ* 2004, p. 1155.

176 See, for instance, Ontario Hospital eHealth Council December 2001, p. 5.

177 Pagliari et al., *J Med Internet Res* 2005, available at jmir.org/2005/1/e9/.

178 Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

179 Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

180 Pagliari et al., *J Med Internet Res* 2005, available at jmir.org/2005/1/e9/.

181 Eland-de Kok et al., *Journal of Clinical Nursing* 2011, p. 2997-2998.

A distinction is made between eHealth and telemedicine by the kind of technology that is used, where eHealth would refer to the use of modern means of communication, such as the Internet, while video and telephone are used for telemedicine.¹⁸² For this, the study refers to several other studies and reports, none of which seem to state this¹⁸³ although one study stresses that this used to be the case but that it changed due to developments in technology.¹⁸⁴ Objections to the view that telemedicine is only dependent on telephone or video technology and that eHealth uses more different kinds of technology can be made anyway because of the confusion it might cause. If telemedicine would refer to health care provision via the telephone alone and eHealth would refer to the use of the Internet, it would be clear. However, since telemedicine in this view refers to telephone and video consultation it is unclear whether telemedicine would include video consultation via the Internet, such as a Skype consultation. The relevant distinction seems to be that telemedicine relates to treatment and diagnosis.¹⁸⁵ The broader concept of eHealth includes telemedicine but can include the education of medical professionals as well¹⁸⁶ along with public health and consumer eHealth.¹⁸⁷ As presented earlier, eHealth relates to the use of modern ICT and does not include regular phone calls.

It is important to note that eHealth is meant to supplement health care by health professionals rather than to replace it, nor is it a new medical field. eHealth is a new way to practise medicine. eHealth care provision is usually offered in combination with regular, face-to-face health care provision. This is referred to as blended care.¹⁸⁸ In conclusion, eHealth is a broader term that includes telemedicine as well as telehealth, but also other aspects related to the use of ICT for health and health care, such as consumer eHealth.¹⁸⁹

5.5 Concluding remarks on the history and development of eHealth

As mentioned earlier, the term itself was coined for the first time in the 1990s when the emergence of the Internet caused a rapid development of eHealth.¹⁹⁰ In the past 25 years an ongoing and fast development of eHealth has taken place because of the rapid development and numerous new inventions in ICT, such as increased access to the Internet and the emergence of smartphones. Along with these developments, eHealth is no longer only useful in rural areas

182 Eland-de Kok et al., *Journal of Clinical Nursing* 2011, p. 2997-2998.

183 These are RVZ 2002; Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/ and Sood et al., *Telemedicine and e-health* 2007, p. 573-590.

184 Sood et al., *Telemedicine and e-health* 2007, p. 576.

185 RVZ 2002, p. 15.

186 Eland-de Kok et al., *Journal of Clinical Nursing* 2011, p. 2998.

187 RVZ 2002, p. 16-18; RVZ 2015a, p. 12 and RVZ 2015b, p. 20.

188 See, for instance Van Duivenboden 2015, p. 31; Voorham et al., *Tsg* 2, 2015, p. 41 and Baardman, *Tsg* 2015, p. 44.

189 Section 6.3 will elaborate on this.

190 Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

but in highly populated areas as well. A few of these advantages are the possibility of contact with a physician at any time, and the opportunity to contact any physician instead of the nearest one. Additionally, eHealth provides people with the possibility to live independently for a longer time because it enables monitoring them over distance.

This section shows that the development of health care over distance started as soon as early information and communication technologies were invented. Even the earliest ICT devices, such as the telegraph and the analogue telephone line, were used to provide access to health care to populations in rural or remote areas. Early records of telemedicine include Australia¹⁹¹ and several thinly populated areas of the United States.¹⁹² This illustrates that the first applications of telemedicine were designed according to need. Later, telemedicine aimed at providing access to health care for everyone. The development of telemedicine was followed by the development of telehealth. Telehealth includes telemedicine, but encompasses health education and health information as well.

eHealth is an all-encompassing term that includes telemedicine and telehealth. eHealth does not only concern health care provision but also other health-related aspects, such as prevention and lifestyle advice. Moreover, eHealth does not always include contact with a health professional. As presented earlier, this is referred to as consumer eHealth. In conclusion, eHealth is an umbrella term that encompasses the smaller concepts of telemedicine and telehealth, but other aspects such as consumer eHealth as well.

Consequently, eHealth does not only refer to health care and the Internet, as is often thought. Some devices that were used to carry out telemedicine, such as the telegraph, are nowadays hardly used anymore; contemporary technology took their place. In this study, eHealth is understood to refer to the use of modern information and communication technology.

Because eHealth is very broad, it is best explained how it is used.¹⁹³ Therefore, this chapter will proceed by categorising eHealth in the following section. Examples of what kind of eHealth applications exist will be provided. The different categorisation of eHealth will be explicated by listing several eHealth applications for each of these categories.

191 *South Australian Advertiser* 24 February 1874, p. 2 mentioned by Eikelboom 2012, p. 71.

192 Beuscart et al. 2014, p. 407.

193 Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/.

6 EHEALTH IN PRACTICE

6.1 Introduction

This section will illustrate what eHealth is. In order to be able to grasp the exact meaning of this concept, categorising the various possibilities of its use and identifying each type's stakeholders is recommended. As presented earlier, eHealth is best defined how it is used.¹⁹⁴ As a result, the best approach for this chapter is an exploration of the concept of eHealth by describing its various forms and providing examples. This section will describe differentiations as proposed in academia (section 6.2) and will provide examples of each category (section 6.3). A position will be taken as to which categorisation will be applied in the continuation of this study.

6.2 Categorising eHealth

A complex and comprehensive concept such as eHealth exists in various forms while the stakeholders can vary in relation to the application concerned. eHealth may have multiple stakeholders, depending on the situation. It can take place between two physicians, between a physician and a patient, and even by patients individually. When, for instance, a GP wants to consult a specialist regarding the status of the patient, they can do so by sending a picture to a colleague via a secured Internet or email application.¹⁹⁵ Second, eHealth can take place between a physician and a patient. An example of such eHealth care provision is e-consultation. These consultations are characterised by the physician and the patient not being in the same physical location.¹⁹⁶ An e-consultation can be held by email, live chat or video.¹⁹⁷ Finally, the patient can practise eHealth on their own, for instance by measuring and recording blood levels in a medical app. This information can be forwarded to a physician.¹⁹⁸ If this is not the case, the patient can show the results of the self-test during their next visit.¹⁹⁹ This type of eHealth enables the patient to be more involved in their own health care process, which is one of the main goals of eHealth.²⁰⁰

194 In accordance with the quotation Eysenbach took in: Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/.

195 In 2015, for instance, it became known that Dutch physicians were using WhatsApp to send pictures of patients to colleagues in order to ask for a second opinion. As presented in chapter 1, this led to questions about privacy. For instance Van Noort, *NRC Next* 8 July 2015, p. 7 and Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809.

196 Van Meersbergen 2012, p. 99-100.

197 For instance Meijnckens 2016, p. 71.

198 Krijgsman et al. 2016a, p. 104.

199 Krijgsman et al. 2016c, p. 39.

200 Meier, Fitzgerald & Smith, *Annual Review of Biomedical Engineering* 2013, p. 360.

A first important differentiation in eHealth types is the differentiation between professional eHealth and consumer eHealth. Professional eHealth refers to all eHealth applications where at least one health professional is involved.²⁰¹ Consumer eHealth refers to eHealth applications which are offered by commercial companies and do not involve contact with health professionals. Examples of consumer eHealth include apps for lifestyle and prevention. Consumer eHealth can be used for self-diagnosis and self-treatment.²⁰² As already briefly mentioned in chapter 1, professional eHealth is further categorised into e-care, e-care support and e-Public Health.²⁰³ Because e-care, in turn, is subdivided in three categories – one of which is e-care – for the purpose of this study e-care will be referred to as eHealth care provision. Not only will this avoid confusion, it will also enhance understanding of what is meant by this category: actual health care provision by means of eHealth. eHealth care provision includes physician–patient contact as well as physician–physician contact and can be used for consultation, diagnosis and therapy.²⁰⁴ This is what has been mentioned earlier as telemedicine:²⁰⁵ health care provision over distance with the goal of improving an individual's health. eHealth care provision can, in turn, be subdivided into e-diagnosis (for instance, e-consult), e-therapy (for instance medication over distance) and e-care (for instance monitoring the patient's health status over distance).²⁰⁶ The second category of eHealth as distinguished by the RVS is e-care support. E-care support refers to, among other things, electronic medical records and decision support systems.²⁰⁷ The last subcategory of eHealth as identified by the RVS is e-Public Health. This includes online prevention, the online provision of health information and other types of health education.²⁰⁸

In doctrine, another distinction has been made between three ways to employ eHealth. First, eHealth care systems can facilitate clinical practice. These systems are usually exclusively utilised by the health care provider – the electronic medical record is an example of such a system.²⁰⁹ This category is comparable with the RVS's e-care support. The second type of eHealth system identified in literature is the institutional system. These systems serve the health system as a whole, such as disaster management.²¹⁰ This is comparable to, but not similar to the RVS's e-Public Health. This includes online health education, while this particular distinction classifies health education under the third type of eHealth system:

201 RVZ 2015a, p. 19.

202 RVZ 2015a, p. 12; Boersma & Vermunt 2015, p. 8 and RVZ 2015b, p. 20.

203 RVZ 2002, p. 16-18. At the time of this advice, the differentiation between professional eHealth and consumer eHealth had not been made. However, the advice elaborates on eHealth in the sense of professional eHealth. Therefore, it can be stated that the RVZ makes is categorising eHealth care provision, even though the advice only mentions a subdivision of eHealth applications.

204 RVZ 2002, p. 16-17.

205 Accordingly, RVZ 2002, p. 16-18.

206 RVZ 2002, p. 16-17.

207 RVZ 2002, p. 17.

208 RVZ 2002, p. 18.

209 Piette et al., *Bull World Health Organ* 2012, p. 365.

210 Piette et al., *Bull World Health Organ* 2012, p. 365.

the system facilitating health care over distance. This includes monitoring of patients over distance, health education and communication between health professionals over distance.²¹¹ This is comparable with, but not similar to the RVS's e-care because it includes actions related to the patient, including actions that the RVS classifies as e-Public Health.

Another distinction that has been made in academia is a distinction between four types of eHealth. These are: consumer eHealth and mHealth tools (mHealth relates to the use of mobile devices to support and improve health); consumer-provider digital communication; telemedicine or remote care; and digital clinical workflow.²¹² In this categorisation, consumer eHealth is put on a par with mHealth, which, in my opinion, is broader because it can also be used for professional eHealth, for instance when mobile applications are used to monitor a patient at home. In the remainder of this study, mHealth will not be referred to as a separate category of eHealth. When it is discussed, it will be considered a component of either professional eHealth or consumer eHealth, depending on the situation. Consumer-provider digital communication, telemedicine or remote care together refer to the RVS's eHealth care provision, and digital clinical workflow is comparable to the RVS's e-care support. This refers to the use of ICT to support the work process in health care facilities, such as electronic patient records.²¹³

In their 2015 eHealth-monitor, Nictiz and NIVEL provided a subdivision of eHealth applications based on their goal. This subdivision contains six categories. First, Nictiz and NIVEL describe applications designed to provide a more smooth and customer-friendly service, such as applications that simplify contact between patients and physicians, including applications for online consultation. As a second category, Nictiz and NIVEL describe applications designed to support self-management and online treatment, such as apps for conducting self-measurements. Online treatment in this category refers to more long-term online contacts between patients and their health professionals. The next applications that Nictiz and NIVEL mention are those that enable care and support at home, for instance by monitoring the patient over distance, followed by applications that provide patients with online access to their medical files. Finally, the eHealth-monitor 2015 mentions the group of applications that support health care provision such as electronic medical records and applications for exchange of information between health professionals related to the care for a patient.²¹⁴ Many more ways to categorise a broad concept such as eHealth exist.²¹⁵

The following subsections will describe various eHealth applications, illustrated by some examples. The eHealth applications have been divided according to the distinctions made

211 Piette et al., *Bull World Health Organ* 2012, p. 365.

212 Weiner, Yeh & Blumenthal, *Health Affairs* 2013, p. 2001.

213 Weiner, Yeh & Blumenthal, *Health Affairs* 2013, p. 2001.

214 Krijgsman et al. 2015a, p. 19.

215 For an overview of other categorisations please consult Van Lettow, Wouters & Sinnige 2019, p. 17-19. The authors mention various other ways to categorise eHealth they found in academia.

by the RVS.²¹⁶ Although health care in general and eHealth in particular are undergoing constant developments,²¹⁷ such a classification is necessary to provide guidance. However, other distinctions remain possible and some applications could have been placed in multiple categories, choices have to be made, however; this shows how comprehensive eHealth really is.

6.3 Professional eHealth

6.3.1 eHealth care provision

6.3.1.1 E-consultation

E-consultation is an online physician–patient consultation where the physician gives advice in reaction to specific question posed by a patient. Additionally, a health professional can prescribe medication.²¹⁸ During e-consultation, a patient asks a health professional for help or advice and uses a type of ICT to do so.²¹⁹ E-consultation can take place via live (video) chat (synchronous) or email (asynchronous). Both e-consultation within an existing physician–patient relationship as well as e-consultation outside the scope of an existing physician–patient relationship are possible. For instance, it might be beneficial for patients who would like to discuss delicate matters or they wish to discuss in a relatively²²⁰ anonymous way. Moreover, contact hours are not per se limited to office hours any more. Finally, e-consultation can take place anywhere, without the need for the patient or the physician to travel for the consultation.²²¹ This can especially be an advantage for those with limited mobility.²²²

However, e-consultation has some disadvantages as well, such as the distance. Because of this distance, the physician might not be able to diagnose the patient very well. This can be caused by the impossibility of a physical examination but a language barrier can be a complicating factor too.²²³ Another disadvantage of this type of consultation is that it is not suitable for every patient. Whether e-consultation is an appropriate means to treat a certain patient also depends on the patient’s capabilities with ICT, and language skills in case of chat without video or email.²²⁴ ICT-related problems can decrease the quality and reliability of the

216 RVZ 2002, p. 16-18; RVZ 2015a, p. 19; RVZ 2015b, p. 20 and Boersma & Vermunt 2015, p. 8

217 Van Lettow, Wouters & Sinnige 2019, p. 15.

218 Van Meersbergen 2012, p. 99-100.

219 Van Meersbergen 2012, p. 99-100.

220 Relatively, because the chapter will show that although initiatives for anonymous mental health care exist, services that offer e-consultations to patients unknown to them after these patients register themselves and provide their citizen service number, exist as well.

221 Timmer 2011, p. 77-78.

222 See, for instance, Timmer 2011, p. 77 and Schalken et al. 2010, p. 42.

223 Meijman & Den Ouden, *Medisch Contact* 2014, p. 1585. Cunningham et al. 2014, p. 26 mention a language barrier within multilingual countries.

224 See, for example, Meijman & Den Ouden, *Medisch Contact* 2014, p. 1585.

e-consultation as well because of inferior Internet connections or poor image quality. In the worst possible case, the disadvantages presented here can lead to a missed diagnosis.

In the Netherlands, a number of health care institutions use a portal on their website through which they offer e-consultations. Some use a secured email application and others offer online consultations through their own patient portals,²²⁵ or patient portals administered by third parties such as *mijngezondheid.net* [myhealth.net]. This is a patient portal secured by means of DigiD where patients can see lab test results, a summary of their medical record, order medication that was prescribed to them before, make appointments with their health professionals or pose questions online in the secured environment of the portal.²²⁶ *Mijngezondheid.net* only facilitates online contact between health professionals and their own patients.²²⁷

An example of a patient portal of a health facility that can be used for e-consultation is the portal of the Leiden University Medical Center. Patients can use this portal – among other things – to contact their health professional. The portal is secured by means of DigiD.²²⁸

However, e-consultation between a health professional and a patient they have never met is also possible. Chapter 4 will discuss to what extent. An example of an e-consultation service which used to offer e-consultations between health professionals and patients who have never met each other, is the website and app that was presented in chapter 1: Constamed.²²⁹ This service enabled patients to pose a non-urgent question to a health professional of a certain specialism, for instance a GP, a dietician or a psychologist. Constamed, as a platform for patients and health professionals, used to facilitate e-consultations between patients and physicians who had not met before.²³⁰ Constamed does not exist anymore in 2020.

A special type of e-consultation is the Twitter consultation hour. During this consultation hour, which is – for instance – held weekly or monthly, patients are able to pose questions of a general nature to their health care providers. Such a Twitter consultation can be held by one or more GPs, or, for example, multiple medical specialists with the same expertise. Due

225 Patient portals will be described in section 6.3.1.4 below.

226 'Functionalliteiten', *mijngezondheid.net*. Source: home.mijngezondheid.net/functionaliteiten/.

227 'Home', *mijngezondheid.net*. Source: home.mijngezondheid.net/.

228 'mijnLUMC', *lumc.nl*. Source: lumc.nl/org/mijnlumc/.

229 Constamed stopped facilitating e-consultations between patients and professionals who never met before when they were subject to a lot of criticism. For instance 'NHG voorstander van e-consult met eigen huisarts', *nhg.nl* 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts and 'Constamed: Snel antwoord van je huisarts', *consumentenbond.nl* 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.

230 For instance, described here: 'NHG voorstander van e-consult met eigen huisarts', *nhg.nl* 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts and 'Constamed: Snel antwoord van je huisarts', *consumentenbond.nl* 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.

to the 140-character limit²³¹ patients will have to ask their questions as concisely as possible. However, it is possible to add photos, hyperlinks or other digital media to the tweet.²³² When the patient wants to use the Twitter consultation, they use a hashtag (#), indicating the Twitter consultation and the ‘at’ sign (@) with the name of the health care institution or the physician, for the right person to see and reply to the message. In general, the messages as well as the replies by the physician are public and can therefore at least be read by the followers of the patient and the physician and in some cases even by everyone. When a question is posed during the Twitter consultation hour, a patient can quickly obtain an answer to their general question. The questions and answers are published online and can therefore be useful to others with a similar question.²³³ This openness represents a disadvantage of this type of eHealth at the same time. With regard to more specific or serious questions, a private e-consultation or a visit to the regular, face-to-face consultation hour is still required. The sole possibility of posing a general question can be regarded as a downside of the Twitter consultation hour as well.²³⁴ An example of a Twitter consultation is the Dutch @tweetspreekuur, which ceased to exist in 2013. On this social medium, people could pose questions to two GPs. Most of the questions were published on Twitter and thus accessible to everyone but @tweetspreekuur also answered questions which were sent through the Twitter account’s private Direct Message function.²³⁵ While @tweetspreekuur does not exist anymore, it is likely that individual health professionals at times answer patients’ questions on Twitter.²³⁶

6.3.1.2 Tele-expertise

Tele-expertise is a type of consultation that shows similarities with e-consultation. The difference is that this consultation takes place between two health professionals. GPs for instance can consult medical specialists with specific questions regarding the treatment of a certain patient but two medical specialists can consult each other as well. Tele-expertise refers to consultation over distance, by means of ICT, between two or more health professionals with regard to the treatment of a specific patient. In doctrine, the word ‘teleconsultation’ is sometimes used to describe this type of eHealth care provision.²³⁷ The RVS mentions “consultations between colleagues”²³⁸ but such an expression is hardly specific enough because it does not distinguish between a face-to-face consultation and a consultation over distance by means of eHealth. Therefore, the prefix ‘tele’ is needed to describe this type of eHealth care provision. Sometimes, a distinction is drawn between the situation where the consultation

231 Kwak et al. 2010, p. 591.

232 ‘How to Tweet’, *help.twitter.com*. Source: help.twitter.com/en/using-twitter/how-to-tweet.

233 KNMG Guide for Physicians and Social Media 2020, recommendation 3, p. 11.

234 See, for example Nouwt & Hooghiemstra, *Computerrecht* 2011/152.

235 Brandenburg & Jansen, *Bijblijven* 2011, issue 8, p. 62.

236 KNMG Guide for Physicians and Social Media 2020, recommendation 3, p. 11. The KNMG refers to the Maxima Medical Center (Maxima MC). The Maxima MC does not seem to offer Twitter consultations as such, but they offer webcare on Twitter and they post health care-related news.

237 For instance Van der Heijden & Schepers, *Bijblijven* 2011, issue 8, p. 8.

238 RVZ 2002, p. 17.

takes place while the patient is present and situations where the patient is not present. The former is then referred to as teleconsultation,²³⁹ and the latter is referred to as tele-expertise.²⁴⁰ However, for the purpose of this study, tele-expertise will be assumed to include consultation over distance, by means of ICT, between two or more health professionals about the treatment of a specific patient. The patient can be present but does not necessarily have to be. It is unclear why different expressions are needed to describe the situation where the patient is present and the situation where they are not present. In both cases, after all, two (or more) health professionals consult each other about a patient. They request for each other's expertise either way. Whether the patient is present or not is irrelevant. The word 'teleconsultation' will not be used in this study to prevent confusion with e-consultation.²⁴¹

When a GP consults a specialist before referring, the number of referrals to medical specialists can decrease. This will improve the efficiency of the health care process.²⁴² An example can be found in dermatology in the Netherlands. Tele-expertise is commonly used in dermatology and has been proved to make the treatment faster and, at times, to prevent referral to a specialist. Experience with tele-expertise in dermatology in the Netherlands shows that GPs who use tele-expertise experienced a decrease in referrals to the dermatologist compared to the GPs who did not use this type of eHealth. It has been established that the decrease in referrals was 27.3% after five years.²⁴³ When the number of referrals to medical specialists decreases, the costs of the health care process will decrease too. Furthermore, an efficient handling of the patients' complaint will decrease their waiting time. When tele-expertise is used, an answer can often be given within a short period of time as opposed to a visit to a medical specialist, for which patients are usually placed on a waiting list before a specialist can examine them. Moreover, the patient can save travel time and will lose less work time.

Nevertheless, there are disadvantages in using tele-expertise as well. The impossibility for the consulted specialist to carry out a physical examination can lead to a missed diagnosis. As discussed in chapter 1 of this study, WhatsApp has been used for tele-expertise in the Netherlands. This is an example of tele-expertise. Physicians exchanged information and questions concerning the treatment of their patients over WhatsApp.²⁴⁴ On the one hand, communication via WhatsApp might be the fastest option but on the other hand, WhatsApp is not the most secure application and ways to communicate that provide the patient with

239 Beuscart et al. 2014, p. 413.

240 Beuscart et al. 2014, p. 411 and 414.

241 Since teleconsultation literally means consultation over distance, this might include e-consultation as well. For that reason alone, tele-expertise is a better term to describe consultation between two health professionals over distance in order to be able to distinguish between consultations between health professionals on the one hand, and consultations between health professionals and patients on the other.

242 Krijgsman et al. 2014, p. 124.

243 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539.

244 Van Noort, *NRC Next* 8 July 2015, p. 7.

better protection certainly do exist.²⁴⁵ This will be elaborated on in chapter 5, which will present the legal implications of tele-expertise.

6.3.1.3 Telemonitoring and home telecare (domotics)

Home telecare and telemonitoring are two kinds of eHealth that are closely related. Telemonitoring, as mentioned above, refers to the use of ICT to monitor a patient over distance. The results are transferred to and analysed by a physician.²⁴⁶ The data can be gathered through an implantable medical device (wearable), an external medical device or a non-medical device, such as a smartphone.²⁴⁷ An example of telemonitoring is a pacemaker that sends data on the patient's cardiac activity to a health professional from time to time. The pacemaker sends these data via a logger in the patient's home. The logger forwards the information to the health professional's secure server. In case of an emergency, an email or text message is sent to the physician.²⁴⁸ Another example of telemonitoring is when a patient measures their health values, such as blood pressure or weight, and then transfers the results to the physician. The health professional only contacts the patients when the results indicate that this is necessary.²⁴⁹

Home telecare, or domotics, on the other hand, refers to technology and services integrated in the habitat with the purpose of improving the quality of life.²⁵⁰ Domotics can monitor the patient to support the health professional or can replace a health professional by taking over certain tasks.²⁵¹ Examples include motion sensors or alarm buttons. Motion sensors can signal a health professional when a patient starts walking around during the night. An alarm button can be used by the patient when they need care, for example when they fall down and are unable to get up without help. This type of eHealth care provision typically notifies the health professional when care is needed and replaces regular visits of the health professional.²⁵² The purpose of home telecare is to support people to live independently at home for as long as possible by constantly monitoring them.²⁵³ Home telecare is thus the type of domotics that is related to health care. Telecare is defined as

*“the continuous, automatic and remote monitoring of real time emergencies and lifestyle changes over time in order to manage the risks associated with independent living.”*²⁵⁴

245 ‘Mag een arts patiëntgegevens uitwisselen via WhatsApp?’, knmg.nl Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm

246 Beuscart et al. 2014, p. 411.

247 Krijgsman & Klein Wolterink 2012, p. 6-7 and 10.

248 Beuscart et al. 2014, p. 412.

249 Wouters et al. 2017, p. 74.

250 Timmer 2011, p. 45.

251 Van der Velde, Cihangir & Borghans 2008, p. 13.

252 Timmer 2011, p. 48.

253 Timmer 2011, p. 47-48.

254 ‘What is Telecare?’ *telecareaware.com* last updated July 2012. Source: telecareaware.com/what-is-telecare/.

Domotics in themselves are broader than eHealth in that sense that they not always necessarily relate to health care.²⁵⁵ An advantage of home telecare is that the patient will receive assistance when they need it and is not dependent on the prearranged times for a health professional to visit. Unfortunately, the use of domotics is subject to risks as well; this is shown in case law. An elderly lady who had an alarm system installed in her house had to wait for five days to receive help because of a defect in the alarm system.²⁵⁶ This example shows that the patient can suffer severe damage when the technology used is malfunctioning and the patient does not get medical assistance on time – the consequences can be fatal. Another disadvantage of the use of domotics is that it might lead to loneliness. While people are enabled to live independently in their own home for longer, they might miss the human contact they have when a health professional visits them on a regular basis.²⁵⁷

In summary, telemonitoring refers to distant monitoring by a physician while domotics refers to monitoring risks and emergencies; home telecare is the type of domotics that refers to health care. Telemonitoring involves a physician constantly, although they only act while necessary,²⁵⁸ while domotics only send an alarm to the health professional in case of emergencies; there is no constant monitoring.²⁵⁹

6.3.1.4 Patient Portals

Patient Portals are a common eHealth application in the Netherlands. Various health care facilities are operating a portal.²⁶⁰ A patient portal is an online gateway that empowers patients by giving them access to their health information and providing them with the opportunity to share this information.²⁶¹ Patient portals can differ but in general, the portal offers several of the following functionalities: view lab test results, view a medication list, schedule appointments with a health professional, request an online consultation with their own health care practitioner, and at times take notes and add results of self-tests.²⁶² Because of these functionalities, multiple types of eHealth care provision are usually combined in a patient portal. While online consultation is typically eHealth care provision, electronic patient records are e-care support. However, since patients play the principal role in patient portals, they are included under eHealth care provision.

255 Meijnckens 2016, p. 79-80.

256 Rb. Noord-Nederland 19 September 2014, ECLI:NL:RBNNE:2014:4489, *NTHR* 2014, issue 6, m.nt. Ernes, p. 301.

257 Timmer 2011, p. 48.

258 Wouters et al. 2017, p. 74.

259 Meijnckens 2016, p. 80-81.

260 On 31 July 2020 the count was 61 for hospitals. Nictiz, 'Hoe online is jouw ziekenhuis?' *hoeonlineisjouwziekenhuis.nl*. Source: hoeonlineisjouwziekenhuis.nl/. These are just hospitals. Numerous other portals exist as well.

261 Heldoorn, Van Herk & Veereschild 2011, p. 15.

262 See the various portals listed in Heldoorn, Van Herk & Veereschild 2011, p. 16-26.

Patient portals can be of three types. First, a portal can be related to a specific institution, the so-called facility-specific portals. This includes all medical information about a certain patient, regarding their treatments within that specific health care facility.²⁶³ An example is the portal by the UMC Utrecht, which allows patients – once logged in – access to treatment reports, treatment goals, letters related to the particular patient, use of medication, results of measurements and lab test results.²⁶⁴ Second, a patient portal can contain all medical information concerning a specific patient. On this type of portal, the patient can add health care providers and authorise them to view their medical record. Usually, these type of portals concern a specific (chronic) disease.²⁶⁵ These are the so-called target group portals. An example of such a portal is parkinsonnet.nl, which connects patients with Parkinson specialists.²⁶⁶ The third type of portal is called the Personal Health Record (PHR). The patient can record their own medical information in this file and add data provided by health professionals. A PHR can, but does not have to be, shared with one or more health professionals.²⁶⁷ The PHR is thus a portal managed by the patient themselves. Health professionals are not authorised to enter medical data into the PHR; the patient has to add this information. At first sight, this type of portal seems to have the potential to make a positive contribution to the collection of all medical files at one, central point. However, the responsibility to add and edit the data rests with the patient. Even when the patient maintains their PHR well and all the data added are correct, the file still has to be shared with all health professionals if the patient wants them to have the information.²⁶⁸

All types of patient portals have in common that their purpose is to empower the patient by giving them more control over their own health care process.²⁶⁹ Patient portals have been said to improve the efficiency of the health care process because the patient can download their own lab test results after which they can call the health care provider and perhaps immediately schedule an appointment. Without the patient portal, the health care provider would have to call the patient first in order to inform them about their lab test results. Furthermore, experience with patient portals in the Netherlands has shown a decrease in no-shows when the patient is able to schedule the appointment with their physician by themselves.²⁷⁰

One of the main goals of the patient portal is to provide the patient with an overview of their medical information, where they used to collect this from health professionals such as the GP, the physiotherapist, the psychologist and the medical specialist, and perhaps another medical

263 Timmer 2011, p. 65.

264 'Patient portal My UMC Utrecht', *umcutrecht.nl*. Source: umcutrecht.nl/en/Hospital/Patient-portal-My-UMC-Utrecht.

265 Timmer 2011, p. 66.

266 Example mentioned by Timmer 2011, p. 66. See 'ParkinsonNet', *parkinsonnet.nl*. Source: parkinsonnet.nl.

267 Hooghiemstra & Ippel 2011, p. 14.

268 Hooghiemstra & Ippel 2011, p. 14.

269 Timmer 2011, p. 60-61.

270 Heldoorn, Van Herk & Veereschild 2011, p. 16.

specialist, who all practise in another health care facility.²⁷¹ However, the facility-specific portal does not solve this issue²⁷² and the PHR can only partially solve it. A facility-specific portal only provides an overview of the patient's medical history within that particular facility. The patient still has to share this information with other health professionals and with a PHR they have the responsibility to add their own health information. A patient portal that combines all medical information concerning a specific patient, on the other hand, can contribute to giving the patient a clear overview of all their medical data. Instead of being scattered over various health care providers, the data will be concentrated in one portal to which the patient can grant health professionals access. Only the combined patient portal really has added value in counteracting the spread of medical data across different health care providers. An example of such a portal is the *Persoonlijke gezondheidsomgeving* [Personal health environment] (PGO), which should enable patients to collect all their health information and share it with health professionals as they wish.²⁷³ In June 2020, 29 PGOs had received the *medmij* qualification (a qualification for safe exchange of health information), and more are being reviewed.²⁷⁴ An example is the PHR on the website www.quli.nl. On this website, patients can record their health information and share it.²⁷⁵

Apart from the fact that not all types of patient portals can fully contribute to collecting all patient information in one central portal, patient portals are subject to other challenges as well. Patient portals, especially the combined patient portal and the facility-specific portal, provide the patient with a lot of information. This might lead to an information overload at some point. Besides the fact that too much information can be confusing, we can wonder whether all this information is understandable to the patient. Results of lab tests, for example, are published in the portal without adjusting them. A patient might not know how to interpret these results and in the end they might be more confusing to them instead of clarifying the situation. Some patient portals provide a link to a website that contains an explanation of these results.²⁷⁶ It can be questioned whether and to what extent such an explanation contributes to understandability. Instead of waiting for the next appointment, a patient might become concerned and might consult the health care professional directly. In this instance, the efficiency of the health care process will decrease rather than increase.

271 Heldoorn, Van Herk & Veereschild 2011, p. 5 and 11.

272 Timmer 2011, p. 65.

273 Herderscheë, 'Medische gegevens in eigen beheer op je computer of telefoon: vanaf volgend jaar is het mogelijk', *Volkskrant.nl* 19 March 2018. Source: volkskrant.nl/binnenland/medische-gegevens-in-eigen-beheer-op-je-computer-of-telefoon-vanaf-volgend-jaar-is-het-mogelijk-a4582289/, Bruins: in Herderscheë, *de Volkskrant* 19 maart 2018, p. 12-13 (interview B. Bruins, Minister for Medical Care), Bouma, 'Vanaf volgend jaar medische gegevens in eigen beheer', *nrc.nl* 19 March 2018. Source: nrc.nl/nieuws/2018/03/19/vanaf-volgend-jaar-medische-gegevens-in-eigen-beheer-a1596187 and Van Steenberghe 'Alle medische informatie in één map op de tablet', *nrc.nl* 19 March 2018. Source: nrc.nl/nieuws/2018/03/19/alle-medische-informatie-in-eeen-map-op-de-tablet-a1596207.

274 'Persoonlijke gezondheidsomgevingen', *medmij.nl*. Source: medmij.nl/pgol/.

275 'Quli voor jou', *quli.nl*. Source: quli.nl/.

276 The patient portal by the LUMC does this.

6.3.2 e-Care support

6.3.2.1 Electronic medical records

An important development since the emergence of the Internet and related networks in health care is the electronic patient record (EPD). When asked about eHealth, most people will mention the EPD. At least in the Netherlands, this is the most well-known application of ICT in health care. This might be caused by the intense debate it sparked. The discussion on the Dutch EPD started in 2008 when the Dutch Minister of Health and Welfare submitted a legislative proposal on the implementation of a national EPD.²⁷⁷ The purpose of the EPD was to enable health professionals to request information from medical records kept by other health professionals when necessary. The location of specific medical files – not the files themselves – would be stored in a central location in the Netherlands. Health care providers would be enabled to contact each other through that central point.²⁷⁸ This would improve the exchange of information between health professionals.

For physicians to have faster access to a patients' medical history would improve the quality of health care as well. Health professionals will have the opportunity to obtain more and faster information at any time about, for instance, what kind of medication a patient uses. This would have prevented avoidable errors in the health care process. These errors are more likely to occur when patients receive health care from multiple health professionals, employed in multiple facilities, who do not have adequate information about the patients' medical history. Furthermore, the EPD was said to be responsive to the patients' needs because it is likely for people to be involved with several health professionals, at various locations.²⁷⁹ The legislative proposal would establish a national contact point (LSP).²⁸⁰ The LSP would contain an overview of the locations of patients' medical records, while the records themselves would remain stored and managed by the health professionals involved.²⁸¹

In November 2008, the Minister sent a letter to all Dutch households, informing them about the upcoming EPD and the opportunity to object to the recording of their medical history into the EPD. In 2010, a large proportion of the Dutch population had objected to the EPD.²⁸² Even though the national EPD provided several safeguards to the patient, such as the opportunity to delete or hide certain data,²⁸³ the EPD led to concerns related to the privacy,

277 *Kamerstukken II* 2007/08, 31466, no. 2.

278 *Kamerstukken II* 2007/08, 31466, no. 3, p. 1.

279 *Kamerstukken II* 2007/08, 31466, no. 3, p. 4-5.

280 Art. 13a of the legislative proposal on the use of the citizen service number in health care with regard to electronic exchange of information in health care, *Kamerstukken II* 2007/08, 31466, no. 2, p. 2.

281 *Kamerstukken II* 2007/08, 31466, no. 3, p. 6.

282 *Kamerstukken II* 2009/10, 27529, no. 61, p. 6.

283 Art. 13e Para. 2 sub a and b of the legislative proposal on the use of the citizen service number in health care with regard to electronic exchange of information in health care, *Kamerstukken II* 2007/08, 31466, no. 2, p. 4.

safety and trustworthiness of such a system. Furthermore, questions arose about liability in case of incorrect or incomplete information.²⁸⁴ Another problem was the name of the EPD. Confusion was caused because the term *dossier* [record] was used to refer to the EPD while the EPD in fact was an overview of the location of patients' medical records and was not supposed to contain the medical record as such.²⁸⁵ Therefore, after earlier critical comments of the *Raad van State* [Council of State] (RvS),²⁸⁶ the *Autoriteit Persoonsgegevens* [The Dutch Data Protection Authority] (Dutch DPA)²⁸⁷ and the KNMG,²⁸⁸ the legislative proposal was declined in 2011 because of a lack of trust in its efficiency, safety and proportionality.²⁸⁹

Immediately after this decline, the EPD made a turn-around. The *Landelijke Huisartsen Vereniging* [National General Practitioners Association] (LHV), the *Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie* [Royal Dutch Pharmaceutical Association] (KNMP) and the *Vereniging Huisartsenposten Nederland* [Association Out-of-hours General Practice Service] (VHN), in collaboration with the *Nederlandse Vereniging van Ziekenhuizen* [Dutch Hospitals Association] (NVZ) and the *Patiëntenfederatie Nederland* [Dutch Patients' Congress]²⁹⁰ proposed an EPD with a different design.²⁹¹ They proposed to divide the LSP into 42 different regions. Under this design, medical files can be exchanged regionally instead of nationally, that is, unless the patient did not give their permission to exchange the files (opt-in).

The LSP is now managed by the *Vereniging van Zorgaanbieders voor Zorgcommunicatie* [Health Care Providers for Communication in Health Care Association] (VZVZ) instead of the government. VZVZ was established by the LHV, the KNMP, NVZ and *Ineen*, the association for organisations in primary care.²⁹² Physicians and pharmacists record and store their patients' medical files. The LSP shows the patients' citizen service number (BSN) and at which GP or pharmacist their medical information is located. In order to use the LSP, the physician and the pharmacist need to ask the patient permission to save the location of their medical information into the LSP.²⁹³ Health professionals who are connected to the LSP are entitled to request access to a specific person's medical information if this person has given

284 Dekker & Hendriks, *NJB* 2009, p. 2759 and 2761-2762.

285 Keizer 2011, p. 364.

286 *Kamerstukken II* 2007/08, 31466, no. 4.

287 College Bescherming Persoonsgegevens [Dutch Data Protection Authority (now: Dutch Data Protection Authority)] (CBP), appendix to the letter of 14 June 2007 (*Advies van het College bescherming persoonsgegevens (CBP) over het voorstel tot wijziging van de Wet gebruik BSN in de zorg*) CBP 2007, available at: autoriteitpersoonsgegevens.nl/sites/default/files/downloads/adv/z2007-00577_2.pdf.

288 'Eerdere bezwaren tegen het wetsvoorstel EPD', *knmg.nl*. Source knmg.nl/Dossiers-9/Eerdere-bezwaren-KNMG.htm.

289 *Kamerstukken I* 2010/11, 31466, X.

290 Known as *Nederlandse Patiënten en Consumenten Federatie* [Netherlands Patients and Consumers Federation] (NPCF) until July 2016.

291 Appendix to *Kamerstukken II* 2011/12, 27529, no. 102-149602.

292 'Over VZVZ', *vzvz.nl*. Source: vzvz.nl/over-vzvz.

293 Art. 15a Para. 1 Wabvpz.

permission to their health care providers to share this information. GPs can access the so-called professional summary made by the patient's own GP. Pharmacists, GPs and medical specialists can request access to information, located at the patient's pharmacist, about the medication this patient uses.²⁹⁴ Based on Article 15a Paragraph 2 Wabvpz, which has yet to enter into force, patients can specify exactly which health professionals can have access to which data; in other words, they can give their specified consent.²⁹⁵

An association of GPs, together with several individual GPs and a patient, initiated a procedure against the LSP. They argued that the LSP violated the right to privacy, the obligations following from the *Wet bescherming persoonsgegevens* [Personal Data Protection Act] (Wbp)²⁹⁶ (the predecessor of the GDPR) and the right to medical confidentiality as laid down in Article 7:457 BW. The courts in all instances, however, rejected their claim and ruled that the LSP was not unlawful or contrary to the Wbp and the right to medical confidentiality, especially because of the system of specified consent.²⁹⁷ In March 2020 the *Concept Wetsvoorstel Elektronische Gegevensuitwisseling in de Zorg* [Draft Legislative Proposal on Electronic Data Exchange in Health Care] was published for consultation.²⁹⁸ The draft proposal aims to harmonise electronic exchange of data between health care providers and to solve problems that slowed down the development of electronic exchange thus far, such as a lack of interoperability. According to the draft explanatory memorandum, better and faster exchange of data in health care will benefit the quality of health care.²⁹⁹

6.3.3 e-Public Health

Increasing access to health information is one of eHealth's goals, and e-Public Health can assist in reaching that goal. Online collection and provision of health information can be considered e-Public Health.³⁰⁰ In the Dutch eHealth-monitor, an annual publication by

294 Nouwt, *P&I* 2014, p. 31-34.

295 This provision was supposed to enter into force in July 2020. However, this was not feasible according to the Minister for Medical Care. *Kamerstukken II* 2019/20, 27529, no. 192 and *Kamerstukken I* 2019/20 27529, K. The minister refers to the advice of the *Adviescollege toetsing regeldruk* [Dutch Advisory Board on Regulatory Burden] (ATR), appendix to *Kamerstukken II* 2019/20, 27529, no. 192-903663 and KPMG 2019.

296 *Stb.* 2000, 302.

297 HR 1 December 2017, ECLI:NL:HR:2017:3053, *NJ* 2018/166, m.nt. Legemaate. In Belgium, a comparable system has existed since 2008. See *Wet van 21 augustus 2008 houdende oprichting en organisatie van het eHealth-platform en diverse bepalingen* (*Belgisch Staatsblad* van 13 oktober 2008) [Gewijzigd bij wet van 19 maart 2013 (*Belgisch Staatsblad* van 29 maart 2013) en bij wet van 10 april 2014 (*Belgisch Staatsblad* van 30 april 2014)] and Heijlen 2014, p. 1.

298 Concept Wetsvoorstel Elektronische Gegevensuitwisseling in de Zorg [Draft legislative proposal on Electronic Exchange of Data in Health Care], internetconsultatie.nl/gegevensuitwisseling.

299 Concept Memorie van Toelichting Wetsvoorstel Elektronische Gegevensuitwisseling in de Zorg [Draft Explanatory Memorandum to the Draft Legislative Proposal on Electronic Exchange of Data in Health Care, p. 2-6.

300 RVZ 2002, p. 18 and Van Rijen, De Lint & Ottes 2002, p. 52-56.

Nictiz and NIVEL, the health information search is considered a form of eHealth as well.³⁰¹ The RVS refers to this as e-education.³⁰² I support these views by agreeing that evidence-based health information on the Internet is a type of e-Public Health. e-Public Health includes online health information search when the purpose of the information is to educate or inform the population with regard to prevention.

In the Netherlands, several accepted websites exist. The website *thuisarts.nl* [homedoctor.nl] is an example of such a website. This website is initiated, supported and maintained by the NHG.³⁰³ A study showed a decrease in visits to consultation hours after the website was published; the fastest decrease could be seen in telephone consultations.³⁰⁴ Health information on the Internet can also consist of blogs. According to the authors of a study on this topic, medical bloggers write their blogs because they want to share their knowledge and influence others in the way they think. According to this study, these kind of blogs often attract the media's attention.³⁰⁵ An example of a blog that used to provide health and lifestyle information in the Netherlands is the blog Green Happiness.³⁰⁶ In 2016, this blog received a substantial amount of criticism because following the suggested diet for too long could result in harmful effects.³⁰⁷

e-Public Health can also consist of smartphone applications that contain health information, such as the *GGD Op Reis* app. This travel-related app provides information about vaccinations required for each travel destination. This is official information obtained from the *Landelijk Coördinatiecentrum Reizigersadviesing* [National Coordinating Centre for Travel Advice] (LCR). Therefore, this app is a good example of e-Public Health and the user can also maintain a list of vaccinations already received.³⁰⁸

The corona apps which were under development in the spring of 2020, which inform users of potential contact with an infected person,³⁰⁹ fall within the scope of e-Public Health as well.

301 Krijgsman et al. 2014, p. 19.

302 RVZ 2002, p. 18.

303 For more information, consult *thuisarts.nl*. A comparable website exists in the United Kingdom. See 'About us', *patient.info*. Source: *patient.info/about-us*. This website bears the National Health Service England's (NHS England) quality mark.

304 Spoelman et al., *BMJ open* 2016; 6: e013166.

305 Kovic, Lulic & Brumini, *J Med Internet Res* 2008, issue 3, available at: jmir.org/2008/3/e28/.

306 'The Green Happiness', *thegreenhappiness.com*. Source: thegreenhappiness.com/.

307 'Your 50 Days of Green Happiness', *voedingscentrum.nl/encyclopedie*. Source: voedingscentrum.nl/encyclopedie/your-50-days-of-green-happiness.aspx.

308 'Nieuwe reis-app voor reizigers', *ggdreisvaccinaties.nl*. Source: ggdreisvaccinaties.nl/actueel/nieuwe-reis-app-voor-reizigers#:~:text=De%20app%20GGD%20reist%20mee,daadwerkelijk%20in%20dar%20land%20bent.

309 For a description of the development regarding such apps in the spring of 2020, please consult *Kamerstukken II* 2019/20, 25295, no. 277. Also see 'Coronavirus-apps', *rijksoverheid.nl*. Source: rijksoverheid.nl/onderwerpen/coronavirus-app/, 'Digitale ondersteuning bestrijding covid-19', *rijksoverheid.nl*. Source: rijksoverheid.nl/onderwerpen/coronavirus-app/documenten/publicaties/2020/05/19/digitale-ondersteuning-covid-19 and Wassens, 'Ministerie test corona-app regionaal', *nrc.nl* 29 May 2020. Source nrc.nl/nieuws/2020/05/29/ministerie-test-corona-app-regionaal-a4001318.

6.4 Consumer eHealth

6.4.1 mHealth

Over the past decennia, smartphone utilisation has become widespread. Therefore, it is not surprising that the field of eHealth has opened up to the smartphone as well. Using health-related applications on a smartphone is called mobile health, or, in short, mHealth.³¹⁰ According to the Telemedicine Code, mHealth can be defined as

*“The use of mobile devices to help in people’s management of their health.”*³¹¹

Applications include self-measurement, lifestyle advice, support for independent living and apps reminding people of appointments or medication.³¹² mHealth allows people to measure their health and to monitor their own health. This is consumer eHealth as long as a health professional is not involved.

Some mHealth applications do allow the patient to share their findings with a medical professional making it eHealth care provision, which falls under the scope of professional eHealth. ‘Eppy’ is an example of such an app. In this app, epileptic patients can record their health and the occurrence of attacks in a diary. This diary can be shared with a physician. Furthermore, Eppy provides patients with the opportunity to order their medication online.³¹³ With apps like this, patients are enabled to take control over their own health as they are provided with information about their health and managing their life in a better way.³¹⁴ Furthermore, health care-related apps that can support people during emergencies exist. An example of such an application is the ‘AED4.eu’ app, developed by Max.nl in collaboration with the Radboud University Medical Center. This app, and the corresponding website, contains a map with the location of automated external defibrillators (AED) in the Netherlands. By means of GPS, the app will show the location of the nearest AED.³¹⁵

An example of a mobile application for health that allows individuals to monitor themselves is the UV coach. This app allows the user to monitor the amount of UV radiation they are exposed to. The app provides advice based on information provided by the user, such as age, skin and eye colour, hair colour, skin type and the sun protection factor of the applied sunscreen. The UV coach will determine what length of time it is safe for a person to sunbathe. The UV coach calculates

310 Van Rijen, de Lint & Ottes 2002, p. 11.

311 TeleSCoPE Project, European Code of Practice for Telehealth Services 2014, p. 11.

312 COM(214) 219 final, p. 3.

313 Epilepsiefonds, ‘Epilepsie-app’, *epilepsie.nl*. Source: epilepsie.nl/leven-met-epilepsie/pagina/70-2/smartphone-applicatie-eppy/and Majoie, *Medisch Contact* 2012, p. 1476-1479.

314 Majoie, *Medisch Contact* 2012, p. 1476-1479.

315 AED4, *aed4.eu*. Source: aed4.eu/.

the amount of UV radiation the user can be exposed to in a year. The app uses the location to determine the UV index; it is able to distinguish between natural sunlight and solarium.³¹⁶

Various sleep and activity trackers also exist. These apps can be used to monitor and change sleep patterns or help the individual to achieve the daily recommended amount of exercise. An example of such an application is the *Sleep Cycle* app. This application monitors your sleep cycle by using the microphone of a mobile device. The microphone will measure movements and based on these movements *Sleep Cycle* will wake you up in the lightest sleep phase.³¹⁷ Other well-known activity trackers are Samsung's *S-Health*, which contains a walking mate but can measure blood pressure too³¹⁸ and Apple's *Health app*, which has multiple functionalities such as a sleep tracker, a weight monitor and heart rate measurement.³¹⁹ *Healthkit* can combine this information with information obtained from the fitness app or the information in the *Health app* can be sent to a health professional.³²⁰ In that case, this becomes a type of mHealth that falls under the scope of professional eHealth.

Another example of mHealth is the *Moet ik naar de dokter?* [Should I consult a physician?] app. Whenever someone experiences pain, they can enter this in the app. The app will pose questions such as where you feel the pain, in how much pain you are on a scale from one to ten and if you feel ill. Based on this information, the app will tell you whether you should consult a medical professional.³²¹

As the aforementioned examples show, mHealth exists in a great variety of forms. They offer different functionalities and each of them works in its own way. An important question is whether mHealth applications can be qualified as medical devices. Whenever a certain application is a medical device, they are subject to a number of requirements. The Medical Device Regulation³²² lists the requirements for applications to qualify as a medical device.³²³

Whenever mHealth applications qualify as a medical device and what requirements applications are subject to under this directive is an interesting topic for further investigation, and will not be discussed in this thesis.

316 Sunworld UVCoach app by Sunworld UV Health Center, Sunworld UVcoach, *sunworld.nl*. Source: sun-world.nl/uvcoach/ and A. Jacobs, 'Summer Apps & Wearables', *smarthealth.nl* 16 July 2015. Source: smarthealth.nl/review/2015/07/16/summer-apps-wearables-uv-coach/.

317 *Sleepcycle.com*, sleepcycle.com/howitworks.html.

318 *S-health.info*, s-health.info/s-health-application/.

319 'Ios Health' *apple.com*. Source: apple.com/ios/health/.

320 'Healthkit' *developer.apple.com*, Source: developer.apple.com/healthkit/.

321 'Moet ik naar de dokter?', moetiknaardedokter.nl.

322 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Medical Device Regulation) (*OJEU* 2017, L 117).

323 Art. 2 Para. 1 Medical Device Regulation.

6.4.2 Wearables

Wearables are another type of consumer eHealth, closely related to mHealth. They do share some characteristics with mHealth applications, since they include devices to monitor health. A great amount of the aforementioned mHealth applications are available as a wearable, too. An example of a wearable is the ‘smart plaster’. This plaster is placed on the skin and is comparable to an ordinary plaster but contains sensors which can measure data such as heart rate, bodily temperature and breathing. These data can be sent to a smartphone or an iPad, which can forward these data to a health professional. This will enable health professionals to monitor their patients 24 hours a day.³²⁴ However, it is possible to apply wearables for private use only. Otherwise, they must be classified as professional eHealth.

6.5 Special category of eHealth: e-mental health

E-mental health is a specific field of eHealth, referring to eHealth services in mental health care. E-mental health is the use of ICT to support and improve mental health and mental health care.³²⁵ In other words, e-mental health refers to all kinds of eHealth applications varying from eHealth care provision to e-Public Health and consumer eHealth, all related to care for mental health. This is another way to categorise eHealth: by the field of health care that a particular eHealth application plays a role in. However, that approach is not taken in this study. Insofar as e-mental health will be discussed in the remainder of the research, it will be qualified according to the categorisation presented in section 6.2 above; this means that e-consultations related to mental health care will be discussed together with e-consultations in other fields, telemonitoring in mental health care will be presented next to telemonitoring in other fields of health care (eHealth care provision) and e-mental health applications that are used without the involvement of a health professional will be considered consumer eHealth.

E-mental health is discussed separately because it received attention in academia and in the field,³²⁶ and it is – up until now – the only type of eHealth that has a legal provision in Dutch law aimed at it.³²⁷ In the Netherlands, it is possible to receive anonymous e-mental health care.³²⁸ The reason behind the statutory regulation to finance anonymous e-mental health is to provide care to people who would otherwise avoid seeking health care, for instance because they feel uncomfortable discussing their mental health. The legislator’s rationale for financing anonymous e-mental health is that prevention and early/earlier recognition can limit adverse (mental) health effects.³²⁹

324 A. Jacobs, ‘Wearables in de zorg: het land in met een slimme pleister’, *smarthealth.nl* 14 August 2014. Source: smarthealth.nl/2014/08/14/wearables-de-zorg-het-land-met-een-slimme-pleister/.

325 Riper et al., *J Med Internet Res* 2010, issue 5, available at jmir.org/2010/5/e74/.

326 Cavanagh & Shapiro, *Journal of Clinical Psychology* 2004, p. 239-251; Perle, Langsam & Nierenberg, *Clinical Psychology Review* 2011, p. 1247-1258 and Kayrouz et al., *Internet Interventions* 2015, p. 32-38.

327 Art. 70a Para. 1 Zvw. Elaborated in chapter 6, Para. 2 of the Health Insurance Regulation.

328 Art. 70a Para. 1 Zvw. Elaborated in chapter 6, Para. 2 of the Health Insurance Regulation.

329 *Kamerstukken II* 2012/13, 33675, no. 3, p. 1 and 3.

This group of patients may benefit from additional support. Furthermore, e-mental health might lead to earlier recognition of problems, resulting in early intervention and prevention of deterioration.³³⁰ Examples of e-mental health include online self-tests, e-consultation and online treatment programmes.³³¹

7. CONCLUSION: DEFINING EHEALTH

This chapter described eHealth along with examples of its use and tried to contribute to the understanding of this broad and comprehensive phenomenon. A short history of eHealth showed that the earliest kinds of health care over distance were carried out in Australia's outback and in the American Civil War in the end of the 19th century. Early ICT inventions such as the telegraph were used to deliver health care over enormous distances.³³² Later, telephone, radio and video broadcasting were used to provide telemedicine, health care over distance.³³³ Because of an ongoing development of ICT applications, telemedicine ceased to be used to provide health care over distance alone; well-being in general became important. The slightly broader term telehealth was used to refer to this kind of usage of ICT for health.³³⁴ With the emergence of the Internet in the 1990s, the term eHealth was coined.³³⁵ eHealth includes both telemedicine and telehealth and encompasses all use of ICT for health. The definition that is chosen for this study is:

eHealth is the use of modern information- and communication technology (ICT) to support and improve health and health care.

This definition, as the other definitions of eHealth, contains the elements 'health' and 'ICT'. Therefore, these elements were presented in this chapter, starting with the term health. In 1946, the WHO defined health as "a state of complete physical, mental and social well-being

330 Riper et al., *J Med Internet Res* 2010, issue 5, available at jmir.org/2010/5/e74/. For an in-depth analysis of e-mental health and its possible effects on the right to health see Kokabisaghi, Bakx and Zenelaj, *ELR* 2016, p. 146-160.

331 *Kamerstukken II* 2012/13, 33675, no. 3, p. 2.

332 Zundel, *Bull Med Libr Assoc* 1996, p. 72 and *South Australian Advertiser* 24 February 1874, p. 2 mentioned by Eikelboom 2012, p. 71.

333 Benschoter, *Annals New York Academy of Sciences* 1967, p. 471-478; Higgins, Dunn & Conrath, *Telecommunications Policy* 1984, p. 308; Zundel, *Bull Med Libr Assoc* 1996, p. 72 and Royal Flying Doctor Service, 'History', flyingdoctor.org.au. Source: flyingdoctor.org.au/about-the-rfds/history/.

334 TeleSCoPE Project, European Code of Practice for Telehealth Services 2014, Part C: Glossary of definitions, p. 14.

335 Oh et al., *J Med Internet Res* 2005, issue 1, available at jmir.org/2005/1/e1/.

and not merely the absence of disease.³³⁶ This definition can be referred to as the broad well-being definition. This definition, which has been discussed and challenged since its formulation but nevertheless no other definition has been agreed on yet. The other proposed definitions can be subdivided into two main categories: the biostatistical definition (BST)³³⁷ and the holistic welfare theory, or holistic health theory (HTH).³³⁸ Recent developments in health care, such as eHealth, led to a changing perspective on health. This is reflected by the definition coined by Huber et al., which focuses on personal abilities rather than pathological conditions.³³⁹ However, the BST should remain the starting point to determine health because health is not always realisable with personal abilities. The broad well-being definition still seems to give the most accurate description of health because it reminds us that health is a human right as well.

eHealth is a complex and comprehensive concept and is, comparable to health, not easily captured by a definition. By means of explanation of the concept, several examples were provided in section 6. Because of the great diversity in applications of eHealth and their stakeholders, multiple classifications of eHealth types have been made in both academia and in the field. This study supports the categorisation made by the RVS. eHealth consists of professional eHealth on the one hand, and consumer eHealth on the other hand. Professional eHealth refers to applications which are applied and developed by, or in association with health care professionals.³⁴⁰ Consumer eHealth refers to applications offered by (international) commercial companies, without involvement from a health professional.³⁴¹ Examples include apps and wearables, related to lifestyle and prevention. Professional eHealth, in turn, is divided into three further categories by the RVS, namely e-care, e-care support and e-Public Health.³⁴² E-care (I will refer to this as eHealth care provision) refers to eHealth applications that are utilised in the health care process as such.³⁴³ Examples include e-consultation, tele-expertise and patient portals. E-consultation refers to online physician–patient contact,³⁴⁴ while tele-expertise refers to physician–physician communication over distance. Patient portals are

336 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth, and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively. *Basic Documents*, Forty-fifth edition, Supplement, October 2006. The definition has not been amended since 1948.

337 Boorse, *Philosophy of Science* 1977, p. 555 and 562 and Boorse, *Journal of Medicine and Philosophy* 2014, p. 684 (slightly corrected definition from 1977).

338 Nordenfelt 1995, p. 35 and Nordenfelt, *Med Health Care and Philos* 2007, p. 7.

339 Huber et al., *BMJ* 2011, p. 237 and Huber 2014, p. 50.

340 RVZ 2015a, p. 19.

341 RVZ 2015a, p. 20; Boersma & Vermunt 2015, p. 8 and RVZ 2015b, p. 12.

342 RVZ 2002, p. 16-18.

343 RVZ 2002, p. 16-17.

344 Van Meersbergen 2012, p. 99-100.

online portals where a patient has access to multiple functionalities, which differ for each portal but usually include the opportunity for a person to view their own medication list, to view lab test results and to schedule appointments with health professionals. Sometimes, a teleconsultation can be requested on the portal.³⁴⁵ E-care support refers to systems supporting the health care process;³⁴⁶ the electronic patient record is an example.³⁴⁷ e-Public Health refers to prevention and health education of the population.³⁴⁸

345 See the various portals listed in Heldoorn, Van Herk & Veereschild 2011, p. 16-26.

346 RVZ 2002, p. 16-18.

347 RVZ 2002, p. 17.

348 RVZ 2002, p. 18.

3



A golden scale of justice is shown against a white background. A blue banner with a wavy top edge is positioned across the middle of the scale. The text "On patients' rights" is written in white on the banner. The scale's beam is on the left, and the pans are on the right. The right pan is empty and hangs lower than the left pan.

On patients' rights

1. INTRODUCTION

For as long as we can remember, people have been falling ill. Every now and then, we find ourselves in need of a health professional in order to help us deal with illness, disease and inconveniences that affect our physical or mental well-being. As stated in the previous chapter, health, a fundamental human right, is of major importance to our functioning. Without it, we cannot function in society and we are unable to fully enjoy our other rights and freedoms. For a long time, the relationship between the person falling ill, the patient, and the person who is asked for their advice, the health professional, has been predominated by inequality. Historically, this inequality was related to the social status physicians enjoyed and the inevitable knowledge gap that usually exists between doctors and patients.¹ In the second half of the 20th century, an evolution in thinking about the patient took place, while at the same time, patients became increasingly assertive.² These changes in society led to international as well as national movements to codify patients' rights in treaties, statutes and regulations in order to deal with the inequality and to provide the patient with greater protection in their relationship with health professionals.

This chapter will discuss patient's rights in international and national law. The right to health, as a fundamental human right, should be a part of a study concerning the application of a new way of health care provision.³ As a fundamental right, the right to health should be realised for all human beings in an equal way.⁴ Because of this obligation, the question should be addressed whether eHealth care provision can contribute to realising this right. The right to health is included in various international and national legal documents and this chapter will elaborate on them (section 2). Subsequently, human rights in health law as well as some international declarations and principles on patients' rights will be presented (section 3), followed by an elaboration of the importance of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)⁵ for health law (section 4). Furthermore, the GDPR, an EU regulation that is of particular importance for health care will be discussed (section 5). To illustrate the developments in thinking about patients' rights, the WHO declaration on the Promotion of Patients' Rights in Europe⁶ and the Ljubljana

1 *Kamerstukken II* 1989/90, 21561, no. 3, p. 6.

2 For instance *Kamerstukken II* 1987/88, 16771, no. 31, p. 7.

3 The right to health, as a social right, has been subject to discussions about its justiciability. It can be stated that the right to health does include several elements which are, in fact, justiciable, such as the principle of non-discrimination. See CESCR General Comment no. 14 (2000) on Health, Para. 1. For a thorough analysis of the justiciability of the right to health, please consult San Giorgi 2012.

4 This applies to states that have endorsed this right as a human right.

5 Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms* (ECHR), 4 November 1950, ETS No. 5.

6 WHO, Regional Office for Europe 1995a, p. 29-32.

Charter⁷ will be presented (section 6). Finally, the WGBO, which contains the majority of Dutch patients' rights, will be discussed (section 7). The chapter will end with several concluding remarks on patients' rights (section 8).

2. THE RIGHT TO HEALTH

2.1 General introduction: the right to health

As presented in chapter 1, eHealth is subject to many expectations, a large number of which directly or indirectly aim at enhancing the right to health.⁸ Moreover, the right to health is connected with many patients' rights, such as the right to medical confidentiality.⁹ This right, on the one hand aims to protect the individuals' privacy but on the other hand, aims to ensure equal access to health care for everyone without the fear of having their personal information disclosed.¹⁰ Since equal access to health care is an element of the right to health,¹¹ the right to health and the right to medical confidentiality are interrelated. Furthermore, the extent of enjoyment of the right to health also affects how people feel about all other fundamental rights and freedoms they enjoy.¹² A healthy person is able to exercise and enjoy other fundamental rights such as freedom of religion or freedom of speech.¹³ As stated in the previous chapter, health is a broader feeling of general well-being that depends on numerous factors.¹⁴ This section presents the right to health in detail by discussing it in international (section 2.2) and European treaties and regulations (section 2.3) as well as in the Dutch Constitution (section 2.4).

7 WHO, European Member States, *The Ljubljana Charter on Reforming Health Care* 19 June 1996, EUR/ICP/CARE 94 01/CN01 Rev. 1 (Ljubljana Charter).

8 For instance when it is expected that eHealth will enhance accessibility of health care. See for example: 'eHealth: Digital health and care, overview', *ec.europa.eu*. Source: *ec.europa.eu/health/ehealth/home_en*; COM(2012) 736 final, p. 3 and 5 and, for instance, *Kamerstukken II* 2013/14, 27529, no. 130, p. 1 and 9-10. Accessibility is an element of the right to health, following from CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

9 Art. 7:457 BW.

10 Hof Den Bosch, 13 October 1998, *TvGR* 1999/13, p. 125-127.

11 CESCR General Comment no. 14 (2000) on health, Para. 12(b) and Para. 43.

12 CESCR General Comment no. 14 (2000) on Health, Para. 1.

13 WHO & OHCHR 2008, p. 6. In the Vienna declaration it is stated that human rights all depend on each other. Vienna Declaration and Programme of Action, adopted by the World Conference on Human Rights, held in Vienna, 14-25 June 1993, *A/CONF.157/23*, I, Para. 5.

14 WHO definition. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth, and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively. *Basic Documents*, Forty-fifth edition, Supplement, October 2006. The definition has not been amended since 1948.

2.2 The right to health in international treaties and regulations

Internationally, the right to health is laid down in several treaties and regulations. As seen in chapter 2, the WHO gave its definition of health (“*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*”) in the preamble to its constitution. In the same preamble, the WHO stressed that health is a fundamental human right that should be realised for everyone without discrimination.¹⁵ That health is a human right is also stated in the Declaration of Alma-Ata, the declaration signed during the international conference on primary health care in 1978.¹⁶ In its first paragraph, the declaration endorses the WHO’s definition of health and states that health is a human right. The declaration also mentions that other factors play an important part in realising the right to health for all.¹⁷

Another international regulation which includes the human right to health is the Universal Declaration on Bioethics and Human Rights (UDBHR),¹⁸ which includes a clause related to social responsibility and health, stating that the promotion of health and social development should be a major purpose of governments for all sectors in society.¹⁹ Moreover, the clause provides additional information on the right to health, emphasising that the right to the highest attainable standard of health is a fundamental right and stating that progress in science and technology should include access to health care of good quality, access to adequate nutrition and water, improvement of living conditions and the environment, elimination of marginalisation and exclusion, and the reduction of poverty and illiteracy.²⁰ The right to health can found in specific international conventions, such as the International Labour Organization (ILO) convention on Medical Care and Sickness Benefits 1969,²¹ as well. This convention urges its members to protect the health of people at work and contains various provisions related to the protection of health.²²

15 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth, and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively. *Basic Documents*, Forty-fifth edition, Supplement, October 2006. The definition has not been amended since 1948.

16 Declaration of Alma-Ata, adopted by The International Conference on Primary Health Care, in Alma-Ata, USSR, 6-12 September 1978.

17 Declaration of Alma-Ata, adopted by The International Conference on Primary Health Care, in Alma-Ata, USSR, 6-12 September 1978, para I.

18 *Universal Declaration on Bioethics and Human Rights* (UDBHR), adopted by UNESCO’s 33rd General Conference on the report of Commission III at the 18th plenary meeting, on 19 October 2005.

19 Art. 14 Para. 1 UDBHR.

20 Art. 14 Para. 2 UDBHR.

21 *ILO Medical Care and Sickness Benefits Convention 1969 (No. 130)*, Geneva, 53rd ILC session (25 June 1969), entry into force: 27 May 1972.

22 Art. 7 Subparagraph a, Art. 8, Art. 9, Art. 10 and Art. 13 ILO Convention 130.

Various UN treaties and declarations mention a right to health. The right to health can be derived from Article 55 Paragraph a and b of the UN charter,²³ which states – among other things – that the UN shall promote a higher standard of living and solutions of international health problems. Furthermore, the right to a standard of living adequate for health and well-being can be found in Article 25 Paragraph 1 UDHR.²⁴ According to the UN, good health will enhance economic and social progress as well.²⁵ Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) includes the right to the highest attainable standard of health, commonly referred to as the right to health. This is probably the most well-known provision pertaining to the right to health. Therefore, section 2.2.1 below will thoroughly elaborate on it. Even though the ICCPR does not contain a right to health as such, several provisions related to the right to health can be found in this convention. Some rights directly relate to the right to health because refraining from actions that might harm a person's health can influence their health. The right to freedom from torture as provided for in Article 7 ICCPR is an example of such a right.²⁶

The International Convention on the Elimination of all forms of Racial Discrimination (CERD) contains a provision related to the right to health as well.²⁷ Article 5(e) Subparagraph iv CERD explicitly says that States parties have to guarantee the right of everyone to equal enjoyment of the right to public health, medical care, social security and social services.²⁸ Another convention which includes the right to health is the International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families (ICRMW).²⁹ According to this convention, migrant workers and their families have a right to emergency health care and equality of treatment with nationals concerning emergency health care.³⁰ Moreover, the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW)³¹ contains several provisions pertaining to the right to health, such as a right to education about health,³² a right to a healthy work environment,³³ a right to access to

23 *Charter of the United Nations*, United Nations, 1 UNTS XVI (24 October 1945).

24 *Universal Declaration of Human Rights*, UN Doc A/RES/217(III) (10 December 1948).

25 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt (31 January 2008), *Promotion and protection of all human rights, civil, political, economic, social and cultural rights*, UN Doc A/HRC/7/11, Para. 12 and Roscam Abbing *European Journal of Health Law* 2004, p. 13.

26 Jamar, *Southern University Law Review* 1994, p. 28.

27 *International Convention on the Elimination of all forms of Racial Discrimination* (CERD), 660 UNTS 195; G.A. res. 2106 (XX), Annex, 20 U.N. GAOR Supp. (No. 14) at 47, UN Doc A/6014 (21 February 1965, entry into force: 4 January 1969).

28 Art. 5(e)(iv) CERD.

29 *International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families* (ICRMW), UN Doc GA/RES/45/158 18 December 1990.

30 Art. 28 ICRMW.

31 *International Convention on the Elimination of all forms of Discrimination Against Women* (CEDAW), UN Doc A/RES/34/180 (18 December 1979, entry into force: 3 September 1981).

32 Art. 10(e) CEDAW.

33 Art. 11(f) CEDAW.

health care without discrimination³⁴ and access to health care for women in rural areas.³⁵ Provisions related to the right to health are also included in the Convention on the Rights of the Child (CRC).³⁶ The CRC contains a general clause with respect to the child's right to health in Article 24 CRC. Furthermore, the convention contains several provisions related to the right to health in specific situations. Examples include access to information about health,³⁷ realising the right to health for children with disabilities,³⁸ rights of children who are placed in care³⁹ and the right to protection from work that is detrimental to their health.⁴⁰ Finally, the Convention on the Rights of Persons with Disabilities (CRPD)⁴¹ includes clauses related to the right to health as well. The right to health is protected in Article 25 CRPD. Furthermore, the CRPD states that people with disabilities have a right to safe and healthy working conditions without discrimination.⁴²

2.2.1 Article 12 ICESCR: the right to the highest attainable standard of health

Article 12 ICESCR, briefly known as the right to health, is the best-known provision containing the right to health. Based on this provision, everyone has a right to an equal enjoyment of the highest attainable standard of physical and mental health. The rights in the ICESCR, including the right to health, are subject to progressive realisation.⁴³ Progressive realisation entails that states should take measures to gradually but steadily reach a realisation of the rights in the covenant, according to their own economic situation and progress. However, maximum use of the available resources is required.⁴⁴ Retrogressive measures will lead to a violation of the rights in the covenant.⁴⁵ Even though the realisation of the rights in the covenant are subject to progressive realisation, certain minimum requirements must be met.⁴⁶ Furthermore, states have the obligation to protect, respect and fulfil the rights in the ICESCR.⁴⁷ These duties include that states should not interfere with the right to health,

34 Art. 12 Para. 1 CEDAW.

35 Art. 14 Para. 2(b) CEDAW.

36 *Convention on the Rights of the Child (CRC)*, UN Doc A/RES/44/25 (20 November 1989, entry into force: 2 September 1990).

37 Art. 17 CRC.

38 Art. 23 CRC.

39 Art. 25 CRC.

40 Art. 32 Para. 1 CRC.

41 *Convention on the Rights of Persons with Disabilities (CRPD)*, UN Doc A/RES/61/106 (24 January 2007, entry into force: 3 May 2008).

42 Art. 27 Para. 1(a) and (b) CRPD.

43 Art. 2 ICESCR.

44 Art. 2(1) ICESCR: UN Committee on Economic, Social and Cultural Rights (CESCR), *The Nature of States Parties' Obligations (Art. 2, Para. 1)*, General Comment no. 3 (1990) on the Nature of States Parties Obligations; 23/01/1991. UN Doc E/C.12/1990/3 (hereafter: CESCR General Comment no. 3 (1990) on the Nature of States Parties' Obligations), Para. 1, 9 and 10.

45 *The Maastricht guidelines on Violations of Economic, Social and Cultural Rights* 22-26 January 1997, UN Doc E/C.12/2000/13, p. 16-24, Para. 14(e).

46 Art. 2(1) ICESCR and CESCR General Comment no. 3 (1990) on the Nature of States Parties' Obligations, Para. 1, 2, 9 and 10.

47 CESCR General Comment no. 14 (2000) on Health, Para. 33 and 50-52.

should prevent violations of the right to health and should aim to progressively realise the right to health.

2.2.2 The Committee on Economic, Social and Cultural Rights

National bodies, UN treaty bodies and other international bodies have a role in interpreting the rights in the ICESCR.⁴⁸ The committee in charge with monitoring States parties' obligations relating to the ICESCR, is the Committee on Economic, Social and Cultural Rights (CESCR). The CESCR was established by the United Nations Economic and Social Council (ECOSOC) in 1985.⁴⁹ Up until 1985, the ECOSOC itself was responsible for monitoring States parties' compliance with the obligations resulting from the ICESCR.⁵⁰ The CESCR has three supervisory instruments at its disposal: concluding observations in response to the state reports, views or decisions on individual complaints, and general comments or general recommendations.⁵¹

The CESCR expresses its views on the interpretation of economic, social and cultural rights (ESC rights) in its general comments. General comments are interpretations of the treaty provisions in the ICESCR. General comments, in contrast to concluding observations and views on individual communications, contain the committee's view on one right in general and are not related to a specific country or a specific situation within a country, although the general comment might be based on problems earlier encountered by the CESCR under another treaty monitoring procedure.⁵² General comments aim to define the nature and obligations of the provision – or part of the provision – they describe.⁵³ General comments, comparable to the other UN treaty body output, are soft law and although some perceive them as authoritative,⁵⁴ no consensus on their exact legal role exists.⁵⁵

Because this study will take General Comment no. 1⁵⁶ as a starting point to evaluate the (potential) effects of eHealth on the right to health, it is important that the status and role of general comments is described at this point. Because this part concerns the nature and status of general comments, materials on general comments by UN treaty monitoring bodies other than the CESCR are studied for this purpose as well.

48 Steiner, Alston & Goodman 2008, p. 358.

49 ECOSOC Res 1985/17 (28 May 1985) *UN Doc E/RES/1985/17*.

50 This obligation was laid down in Art. 16 Para. 1 in conjunction with Para. 2 under a ICESCR. For further reading, see Steiner & Alston 2000, p. 248 and Nowak, *Netherlands Quarterly of Human Rights* 2013, p. 3-4.

51 International Law Association (Committee on International Human Rights Law and Practice) 2002, p. 3.

52 Rodley 2013, p. 631.

53 McGrogan, *Netherlands Quarterly of Human Rights* 2014, p. 365.

54 See, for instance, Rodley 2013, p. 639 as quoted by Michalowski & Martin 2014 and Steiner & Alston 2000, p. 265.

55 McGrogan, *Netherlands Quarterly of Human Rights* 2014, p. 365.

56 CESCR General Comment no. 14 (2000) on Health.

2.2.2.1 Importance of UN treaty body output and general comments in particular

In 2002, the Committee on International Human Rights Law and Practice issued the 'Interim report on the impact of the work of the United Nations human rights treaty bodies on national courts and tribunals'.⁵⁷ In this interim report, the effects of the concluding observations in response to the state reports, views or decisions on individual complaints as well as general comments and general recommendations by the various UN treaty bodies were studied. Although most of these findings relate to the work of the Human Rights Committee, the committee in charge with monitoring States parties' compliance with the ICCPR, the general findings can be applied to other treaty monitoring bodies too. First, the interim report discussed the impact of the work of UN treaty bodies in domestic courts and found that in particular, the views and decisions on individuals' complaints and general comments are applied by national courts.⁵⁸ The final report, issued two years after the interim report, gives an overview of cases before national courts in which the work of the UN treaty bodies was applied.⁵⁹ The report mentions various cases where general comments and general recommendations are used.⁶⁰ This is a first indication of the perceived weight of general comments.

Despite the fact that the work by the UN treaty bodies is not binding under international law in the same way as decisions by supra national courts such as the ECtHR, States parties cannot disregard UN treaty bodies' decisions.⁶¹ The work of UN treaty bodies possesses a certain convincing power and is therefore useful for interpreting treaty provisions as well as national legislation on the same issue.⁶² The exact status of this work, however, is rarely mentioned.⁶³ The final report of the Committee on International Human Rights Law and Practice concludes that national courts perceive general comments as relevant in interpreting treaty provisions.⁶⁴ An example of the use of the work of a UN Committee in Dutch case law is a case before the *Centrale Raad van Beroep* [Central Appeals Tribunal] (CRvB) in which the CRvB referred to the decision on the individual complaint that appellant brought to the UN

57 International Law Association (Committee on International Human Rights Law and Practice) 2002.

58 International Law Association (Committee on International Human Rights Law and Practice) 2002, p. 6.

59 International Law Association (Committee on International Human Rights Law and Practice) 2004, p. 7-28.

60 International Law Association (Committee on International Human Rights Law and Practice) 2004, p. 20-25.

61 See, for instance, Dommen 1998, *Georgetown International Environmental Review*, p. 21, as quoted by the International Law Association (Committee on International Human Rights Law and Practice) 2002, p. 9.

62 International Law Association (Committee on International Human Rights Law and Practice) 2002, p. 10.

63 International Law Association (Committee on International Human Rights Law and Practice) 2002, p. 10.

64 International Law Association (Committee on International Human Rights Law and Practice) 2004, p. 43.

Human Rights Committee. According to the CRvB, decisions by the UN Human Rights Committee are not legally binding, yet authoritative. Therefore, derogation of such decisions is only possible in case of compelling reasons.⁶⁵ The procurator general of the *Hoge Raad* [Supreme Court of the Netherlands] (HR) discussed two decisions of the UN Human Rights Committee, endorsing this CRvB's judgement and stating that such a position with respect to the work of the UN Human Rights Committee must be adopted in criminal proceedings as well.⁶⁶

Much has been written about general comments. It has been agreed upon that they are not legally binding.⁶⁷ This does, however, not mean that they should be ignored;⁶⁸ they are often seen as authoritative.⁶⁹ General comments can be helpful in interpreting States parties' commitments under a treaty.⁷⁰ Often, they explain provisions of the covenant, which can give States parties insight on how to realise a specific right.⁷¹ Such explanations are useful because the provisions in the covenant sometimes tend to be open norms and States parties' obligations derived from these rights are not always clear.⁷² General comments, provided by the treaty bodies established by the respective treaties, can at least be considered a means that offers states suitable guidance and casts light on how states are supposed to act with respect to specific human rights.⁷³ Even though general comments provide an explanation of the right they discuss, it is up to States parties to decide what to do with these comments.⁷⁴ That being said, since they reflect expectations pertaining to the rights in the covenants and provide points of departure for implementing these rights, they must not be disregarded.

Although general comments elaborate on the contents of specific rights, they do so in a manner such that States parties have a certain margin of appreciation to take their own

65 CrvB 21 July 2006, ECLI:N:CRVB:2006:AY5560, AB 2007/97, m.nt. Barkhuysen & Van Emmerik, as quoted by Procurator General Spronken, in: ECLI:NL:PHR:2020:162.

66 ECLI:NL:PHR:2020:162 (advisory opinion Procurator Spronken, to HR 7 April 2020, ECLI:NL:HR:2020:626, NJ2020/264, m.nt. Vellinga), Para. 8.2.

67 For instance Hunt 2003, p. 2; Blake, *Center for Human Rights and Global Justice Working Paper*, no. 17, NYU School of Law 2008, p. 3; Rodley 2013, p. 639, McGrogan, *Netherlands Quarterly of Human Rights* 2014, p. 367; Donders, *PER/PELJ* 2015, p. 211 and the literature cited in International Law Association (Committee on International Human Rights Law and Practice) 2002, p. 8.

68 Rodley 2013, p. 639; Ando 2013, p. 708 and McGrogan, *Netherlands Quarterly of Human Rights* 2014, p. 367.

69 For example general comments on the Convention on the Rights of the Child (CRC) are regarded as authoritative in the advisory opinion of Solicitor-General Spronken, ECLI:NL:PHR:2015:1295, on HR 30 June 2015, ECLI:NL:2015:2465, NJ 2016/40, m.nt. Mevis.

70 McGrogan, *Netherlands Quarterly of Human Rights* 2014, p. 367.

71 Hunt 2003, p. 2; Blake, *Center for Human Rights and Global Justice Working Paper*, no. 17, NYU School of Law 2008, p. 11; Mechlem, *Vanderbilt Journal of Transnational Law* 2009, p. 927; Rodley 2013, p. 631; Medina 2013, p. 668; McGrogan 2014, *Netherlands Quarterly of Human Rights*, p. 367 and Donders, *PER/PELJ* 2015, p. 211.

72 Mechlem, *Vanderbilt Journal of Transnational Law* 2009, p. 927.

73 Rodley 2013, p. 639 and McGrogan, *Netherlands Quarterly of Human Rights* 2014, p. 367.

74 Ando 2013, p. 712.

country's situation and culture into account.⁷⁵ General comments aim to set standards that can be reached by rich as well as poor countries.⁷⁶ This implies that standards are usually higher for countries with a higher level of economic welfare. An example can be found in the CESCR's General Comment no. 14,⁷⁷ which mentions that states must use the "maximum of their available resources" to realise the right to health.⁷⁸ The same is expressed in Article 2 Paragraph 1 ICESCR, which states that countries should use the maximum of their available resources to realise the rights in the covenant.⁷⁹

The UN treaty bodies formulate their general comments building on matters that gained their attention through individual reports or individual complaints.⁸⁰ Likewise, because general comments contain information on treaty bodies' notion of the right in the treaties or covenants, they can be useful for states to successfully fulfil their reporting duties.⁸¹ The latter is also mentioned as one of the purposes of general comments by the CESCR, the committee responsible for general comments about the rights in the ICESCR.⁸² On the other hand, general comments can be useful for the committees themselves while handling individual complaints,⁸³ and in carrying out their other responsibilities.⁸⁴

2.2.3 General Comment no. 14

The CESCR has given its views on the contents and applications of the right to health in General Comment no. 14.⁸⁵ The meaning of the right to health as laid down in Article 12 ICESCR, along with the state obligations arising from this provision, is further explicated in this general comment.⁸⁶ Although citizens cannot derive a right to be healthy from Article 12 ICESCR,⁸⁷ this provision entails obligations for states to progressively realise this right.⁸⁸

Furthermore, the CESCR explains in General Comment no. 14 that the right to health does not entail the right to be healthy. Such a right would be hardly enforceable because no state can guarantee its citizens a life free of all possible disease and illness.⁸⁹ According to the

75 Donders, *PER/PELJ* 2015, p. 211.

76 Hunt 2003, p. 2.

77 CESCR General Comment no. 14 (2000) on Health.

78 CESCR General Comment no. 14 (2000) on Health, Para. 47.

79 Art. 2 Para. 1 ICESCR.

80 Medina 2013, p. 656; Rodley 2013, p. 631 and Donders, *PER/PELJ* 2015, p. 186-187

81 Mechlem 2009, p. 927; Rodley 2013, p. 631 and Medina 2013, p. 668-669.

82 Report on the third session (6-24 February 1989) of the Committee on Economic, Social and Cultural Rights, *Un Doc E/1989/22* and *E/C.12/1989/5*.

83 Mechlem 2009, p. 927; Rodley 2013, p. 632 and Michalowski & Martin 2014, p. 3.

84 Rodley 2013, p. 632.

85 CESCR General Comment no. 14 (2000) on Health.

86 CESCR General Comment no. 14 (2000) on Health.

87 CESCR General Comment no. 14 (2000) on Health, Para. 8.

88 Art. 2 ICESCR.

89 CESCR General Comment no. 14 (2000) on Health, Para. 8 and 9.

CESCR, the right to health has four separate though interconnected elements. In order to live up to the right to health, health facilities, goods and services should be available, accessible, acceptable and of good quality.⁹⁰

The CESCR is appointed with the task to monitor the implementation of the Economic, Social and Cultural Rights in the ICESCR. The CESCR regularly publishes general comments on ICESCR treaty provisions and relating state obligations. General Comment no. 14 provides an explanation on the right to health as laid down in Article 12 ICESCR. In this comment, the CESCR clarifies that the covenant aims at the highest attainable standard of health necessary to enable people to live a life in dignity.⁹¹ Remarkably, the highest attainable standard of health in Article 12 ICESCR does not refer to health as defined by the WHO – “health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”⁹² – as discussed in chapter 2.⁹³ However, this does not mean that Article 12 ICESCR refers to health as the absence of disease. The formulation of the provision alone shows that the ICESCR does not concern the absence of illness alone, nor does it solely cover the right to health care. The “highest attainable standard of health” does not imply not being ill, it means the highest attainable standard of health for each individual in their specific situation.

The fact that wealth, and economic and social development can differ between states is taken into account for states must take measures according to their available resources, with the condition that retrogressive measures are not allowed.⁹⁴ Whether states meet their obligations following from the right to health is usually measured according to the AAAQ framework as laid down in General Comment no. 14.⁹⁵ This framework, as mentioned in the first chapter, was developed by the CESCR and is used to determine if the right to health is realised, protected and fulfilled by a certain state by examining whether health systems, services, facilities, goods or programmes are available (A), accessible (A), acceptable (A) and of good quality (Q).⁹⁶

90 CESCR General Comment no. 14 (2000) on Health, Para. 12.

91 CESCR General Comment no. 14 (2000) on Health, Para. 1.

92 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

93 CESCR General Comment no. 14 (2000) on Health, Para. 4.

94 CESCR General Comment no. 3 (1990) on the Nature of States Parties' Obligations, Para. 9, the right to education (art. 13 ICESCR), UN Committee on Economic, Social and Cultural Rights (CESCR), *The right to Education*, General Comment no. 13 (1999) on the Right to Education; *UN Doc E/C.12/1999/10* (hereafter: CESCR General Comment no. 13 (1999) on the Right to Education), Para. 45 and CESCR General Comment no. 14 (2000) on Health, Para. 32.

95 CESCR General Comment no. 14 (2000) on Health, Para. 12.

96 CESCR General Comment no. 14 (2000) on Health, Para. 12.

Availability means that enough and adequate health services should be available within a country. If a state has met this obligation, is always measured according to that state's circumstances. However, countries have to offer their population certain essential elements without exception. These elements are clean drinking water, sanitation facilities, health care institutions with qualified health professionals and essential medicines.⁹⁷ These elements are referred to as the underlying determinants of health.⁹⁸ eHealth can have a positive impact on the availability of health services because it can increase the availability of health professionals by enabling health care over distance.

Accessibility can be divided in four types, to be guaranteed by countries. First, health facilities, goods and services must be offered without discrimination. Second, health facilities, goods and services should be physically accessible for everyone, including vulnerable groups such as people with disabilities and minorities. Physical accessibility also includes access to the underlying determinants of health throughout the country, i.e. not only in metropolitan areas. Third, health facilities, goods and services should be affordable. This entails that payment for health services should be equitable for all. Finally, accessibility entails the accessibility of health information. Everyone should be enabled to find and share information about health.⁹⁹ One of the points of discussion in this study is whether eHealth care provision leads to health care provision without discrimination or whether it leads to new types of discrimination. eHealth care provision seems to increase the physical accessibility at first sight, because in many cases of eHealth care provision travelling is not necessary. As for affordability, critical points can be made. For instance, whether the potential financial benefits of eHealth care provision balance the implementation costs. eHealth care provision will lead to more access to information about health, but questions can be raised about the quality and the origin of some of this health information.

Acceptability means that health facilities, goods and services should respect medical ethics and should be culturally appropriate for those receiving the service.¹⁰⁰ This means that health services, including eHealth care provision, should be offered in compliance with the relevant legislation and good practice guidelines. As for cultural acceptability, this means that eHealth care provision must be acceptable for patients in order to meet the criterion of acceptability.

The requirement of quality involves health facilities, goods and services that are scientifically and medically appropriate. This implies, among other things, qualified health personnel, scientifically approved medicines prescribed before their expiry date, appropriate medical

97 CESCR General Comment no. 14 (2000) on Health, Para. 12(a).

98 CESCR General Comment no. 14 (2000) on Health, Para. 11 and 12(a).

99 General Comment no. 14 (2000) on Health, Para. 12(b).

100 General Comment no. 14 (2000) on Health, Para. 12(c).

devices and, again, the underlying determinants of health.¹⁰¹ An important question in this respect is whether eHealth care provision can lead to health care of good quality.

Albeit a soft law instrument, the AAAQ framework is considered authoritative.¹⁰² In section 2.2.2.1 the authoritativeness of the UN treaty body output was presented, with examples of its application in Dutch case law.¹⁰³ It can be assumed that this prevails with respect to general comments.

2.3 The right to health in regional treaties and regulations in Europe

European treaties and regulations mention a right to health as well. Examples include Article 35 of the Charter of Fundamental Rights of the European Union (CFREU).¹⁰⁴ According to this provision, a high level of health protection should be attained in the determination and application of European Union policies and activities. Furthermore, the right to health is included in the European Social Charter (ESC)¹⁰⁵ and the Revised European Social Charter (RESC).¹⁰⁶ In this charter, the right to health is included in Article 11 as the right to protection of health. Based on this provision, states are assigned with the task of protecting people from causes of ill health, to take care in advising and educating people about health, and the responsibility to prevent the outbreak of epidemic and endemic diseases to the best of their ability. In Article 13 ESC and Article 13 RESC, the right to social and medical assistance is laid down.

The Revised European Code of Social Security¹⁰⁷ includes provisions on medical care as well, related to the costs of health care and what elements are included in medical care.¹⁰⁸

Another European document of relevance to the right to health is the directive on the application of patients' rights in cross-border health care (Patient Mobility Directive).¹⁰⁹

101 General Comment no. 14 (2000) on Health, Para. 12(d).

102 See, for instance Rodley 2013, p. 639 as quoted by Michalowski & Martin 2014.

103 CrVB 21 July 2006, ECLI:N:CRVB:2006:AY5560, AB 2007/197, m.nt. Barkhuysen & Van Emmerik, as quoted by Procurator General Spronken, in: ECLI:NL:PHR:2020:162 (advisory opinion to HR 7 April 2020, ECLI:NL:HR:2020:626, NJ2020/264, m.nt. Vellinga), Para. 8.2.

104 European Union, *Charter of Fundamental Rights of the European Union*, 7 December 2007, OJEU C/303.

105 Council of Europe, *European Social Charter*, 18 October 1961, ETS 35.

106 Council of Europe, *European Social Charter (Revised)*, 3 May 1996, ETS 163.

107 Council of Europe, *European Code of Social Security (Revised)*, Rome, 6 November 1990, ETS No. 139.

108 Art. 8 and Art. 10 European Code of Social Security (Revised).

109 Directive (EU) 2011/24 of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJEU 2011, L88) (hereafter: Patient Mobility Directive).

This directive, developed in response to case law,¹¹⁰ creates a framework for the delivery of cross-border health care.¹¹¹ The Patient Mobility Directive aims to improve access to safe cross-border health care of good quality.¹¹² The connection to the right to health can be seen in various provisions in the Patient Mobility Directive such as Article 5, which defines the responsibilities of the Member State where the treatment takes place, the Member State of treatment. According to this provision, the Member State of treatment should provide inhabitants of other Member States equal access to safe health care of good quality. Furthermore, the Patient Mobility Directive aims to regulate the reimbursement of health care provided in another Member State.¹¹³ The reimbursement of non-hospital care received in another Member State may not be subject to prior authorisation.¹¹⁴ As seen in section 2.2.3, affordability as a subcondition of accessibility, is an element of the right to health.¹¹⁵ Article 9 of the Patient Mobility Directive contains rules with respect to administrative procedures of cross-border health care.

The WHO Declaration on the Promotion of Patients' Rights in Europe contains a provision related to health protection as well.¹¹⁶ According to Paragraph 1.6 of this declaration, everyone has a right to protection of their health. The provision instructs countries to take measures in order to prevent disease, provide health care and give the population the opportunity to reach their highest attainable standard of health. Article 5.1 of this declaration contains the right to health as well.

The large number of international and European treaties, regulations and declarations that mention the right to health indicates its great importance. Dutch national law, too, contains a provision on the right to health. This provision can be found in the Dutch Constitution and will be discussed in the following subsection.

2.4 The right to health in the Dutch Constitution

The right to health is laid down in the *Grondwet* [Constitution] (Gw)¹¹⁷ in Article 22 Paragraph 1, stating that the government should take measures to promote public health. In

110 CJEU 28 April 1998, C-158/96, ECLI:EU:C:1998:171 (*Kohll*); CJEU 28 April 1998, C-120/95, ECLI:EU:C:1998:167 (*Decker*); CJEU 12 July 2001, C-157/99, ECLI:EU:C:2001:404 (*Smits and Peerbooms*); CJEU 13 May 2003, C-385/99, ECLI:EU:C:2003:270 (*Müller-Fauré and Van Riet*); CJEU 23 October 2003, C-56/01, ECLI:EU:C:2003:578 (*Inizan*) and CJEU 16 May 2006, C-372/04, ECLI:EU:C:2006:325 (*Watts*).

111 Art. 1 Patient Mobility Directive.

112 Art. 1 Para. 1 Patient Mobility Directive.

113 Art. 7 Patient Mobility Directive.

114 Art. 7 Para. 8 Patient Mobility Directive.

115 General Comment no. 14 (2000) on Health, Para. 12(b).

116 Declaration on the Promotion of Patients' Rights in Europe, WHO, European Consultation on the Rights of Patients, Amsterdam 28-30 March 1994.

117 *Stb.* 1840, 54.

comparison with Article 12 ICESCR, the provision in the Dutch Constitution seems rather concise, even though this right is derived from the international right to health as mentioned earlier.¹¹⁸ Furthermore, Article 21 of the Dutch Constitution states that the government should facilitate habitability of the regions and protect and enhance the living environment. This is, as shown in section 3.1, a component of the right to health. In this section, General Comment no. 14 was discussed, which states that the right to health includes other, related components as well, such as “access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information.”¹¹⁹ Habitability and a good and safe living environment would certainly fall under the scope of this citation. In the preparatory memorandum of the amendment of the Dutch Constitution in 1983, the government explained that the obligation to promote public health also includes the protection of people’s health.¹²⁰ The government should therefore abstain from violation of the population’s and the individuals’ health.¹²¹ The phrase that “health includes the protection of people’s health as well” is comparable to the phrase “protection of health” in Article 13 ESC and Article 13 RESC.

3. INTERNATIONAL LAW AND PATIENTS’ RIGHTS

3.1 Human rights in health care: introduction

International human rights are and have been important for patients’ rights. When the WGBO – the Dutch body of patients’ rights – was drafted, international human rights law was mentioned as detrimental to the idea of patients’ rights.¹²² However, besides some declarations and regulations on specific types of health care or on a particular group of patients, little specific international patients’ rights treaties exist. In this section, relevant international human rights treaty provisions and the views of Dutch health law scholars on these human rights in health care will be discussed (section 3.2), followed by an explanation of international declarations and guiding principles on the rights of (specific groups) of patients (section 3.3).

118 Vlemminx 2000, p. 240.

119 General Comment no. 14 (2000) on Health, paragraph 11.

120 *Kamerstukken II* 1975/76, 13873, no. 1-4, p. 14.

121 Vlemminx 2000, p. 241.

122 *Kamerstukken II* 1989/90, 21561, no. 3, p. 5.

3.2 Human rights and health law

As mentioned before, human rights treaties contain several rights that are considered especially important within the patient–health care provider relationship. Multiple human rights apply in this relation and they are laid down in several treaties and declarations. In academia as well as in practice, different principles are assigned to health law. Usually, self-determination and respect for the individual are mentioned, at least as the basis of patients' rights.¹²³

However, no consensus exists among Dutch health law scholars, over which human rights health law is meant to serve. Leenen stated that self-determination and equal access to health care are the core principles of health law.¹²⁴ Self-determination is often said to have had a significant influence on the thinking about patients' rights, both nationally – at least in the Netherlands – and internationally.¹²⁵ Self-determination as described by health law scholars is to be understood as autonomy.¹²⁶ It has been said that this is reflected in Dutch patients' rights legislation.¹²⁷ Buijsen contests this by mentioning that autonomy cannot always be guaranteed by patients' rights because sometimes exceptions are possible.¹²⁸

Leenen also assigns value to the right to privacy and inviolability of the human body as principles of health law, stating that self-determination is reflected in those rights.¹²⁹ Buijsen states that privacy and inviolability are indeed important within health law¹³⁰ but he relates them to human dignity, which is the basis of all human rights.¹³¹ The right to privacy is protected in both Article 12 UDHR and Article 17 ICCPR. Inviolability of the human body can be found in Article 5 UDHR and Article 7 ICCPR.

Sluijters opposed Leenen's view and stated that health law does not have its own principles but is rather based on principles derived from a wide variation of other, more established fields of

123 See, for instance, Asvall 1995, p. 8.

124 Leenen 1981, p. 13 and Leenen 1988, p. 20.

125 Hendriks 2005, p. 374.

126 For instance Hendriks, Frederiks and Verkerk, *TvGR* 2008, p. 4, who refer to self-determination as the principle of autonomy.

127 *Kamerstukken II* 2006/07, 30800 XVI, no. 183, p. 2 as cited by Hendriks, Frederiks & Verkerk, *TvGR* 2008, p. 4.

128 Buijsen 2017, p. 21. One of the examples that Buijsen mentions to illustrate this is the right to informed consent as laid down in Art. 7:448 in conjunction with Art. 7:450 BW. Based on this right the physician can only perform a medical procedure after they have received explicit consent. During emergencies, however, this explicit consent cannot always be awaited.

129 Leenen 1988, p. 21.

130 Buijsen 2003, p. 7.

131 Buijsen, *Cambridge Quarterly of Healthcare Ethics* 2010, p. 322. According to Buijsen, preambles of human rights treaties always refer to human dignity. An example of such a preamble is the preamble to the ICCPR: International Covenant on Civil and Political Rights (ICCPR), 16 December 1966, 6 *ILM* 1967, p. 36. Also see Buijsen 2017, p. 4-5.

law, such as criminal law, civil law, administrative law and the law governing legal persons.¹³² Such a notion is problematic according to Buijsen because health law deviates, for example, from the principles of contract law in several aspects such as the health insurer's obligation to accept clients for basic health insurance and the absence of freedom of contract for health professionals.¹³³

Next to self-determination, the right to health care is the other pillar of health law according to Leenen.¹³⁴ Leenen deliberately chose the phrase "right to health care" instead of the phrase "right to health" as used in section 2. The right to health, according to Leenen, is an incorrect wording because the government cannot prevent people from falling ill from time to time. Moreover, when formulated like this, the right would suggest immortality.¹³⁵ Chapter 2 stressed that the right to health does not imply a right to be healthy.¹³⁶ This study therefore used the phrase "the right to health" when referring to – among others – Article 12 ICESCR and Article 22 Paragraph 1 Gw. Buijsen recognises the realisation of the right to health care as the core principle of health law; according to Buijsen, health laws' purpose is the realisation of the right to health.¹³⁷ The AAAQ framework laid down in General Comment no. 14 on Health seems to reflect a similar view.¹³⁸

Hendriks recognises self-determination, protection and equality as the principles of health law.¹³⁹ Recent editions of Leenen's handbook of health law take these three principles as basic principles of health law as well. Other principles are mentioned but self-determination, protection and equality seem to stand out according to the editors.¹⁴⁰ As noticed by various scholars, self-determination has been given more attention in case law in recent years, both on national and European regional level.¹⁴¹

Equality, as the only right that is not yet discussed at this point, means that every act of health care should take place without discrimination. All patients within a country should receive equal treatment. In international human rights law, equality can be found in the rights with respect to non-discrimination, such as Article 2 UDHR, Article 7 UDHR, Article 2 ICCPR and Article 26 ICCPR.

132 Sluijters 1985, p. 149.

133 Buijsen 2003, p. 6-7 as quoted by Buijsen, *Ars Aequi* 2004, p. 427; Buijsen 2016, p. 43-44 and Buijsen 2017, p. 21-22.

134 Leenen 1981, p. 13 and Leenen 1988, p. 20.

135 Leenen 1988, p. 23-24.

136 General Comment no. 14 (2000) on Health, Para. 8 and 9.

137 Buijsen, *Ars Aequi* 2004, p. 428 and Buijsen 2016, p. 45.

138 General Comment no. 14 (2000) on Health, Para. 12.

139 Hendriks 2005, p. 372-373.

140 Leenen/Dute & Legemaate 2017, p. 55.

141 Legemaate, referring to relevant case law in Legemaate, *TvGR* 2004. Den Hartogh 2014, p. 17 and 50 cites relevant case law as well.

3.3 Declarations and principles on patients' rights

As mentioned in section 3.2, internationally, few actual patients' rights provisions exist in international law. Internationally, patients' rights are based on human rights and principles and declarations explaining what such a human right entails within the doctor–patient relationship. This section will list some of these principles and declarations.

An example of a declaration pertaining to patients' rights issued by a UN organ is the UNESCO Universal Declaration on the Human Genome and Human Rights of 1997. This declaration contains patients' rights related to scientific research and human dignity related to the human genome.¹⁴²

The international development regarding increased thinking about patients' rights can be seen in various actions undertaken by international organisations, such as the WHO and the World Medical Association (WMA). Several international codes of ethics define duties of health professionals in their relationship with their patients, such as the WMA International Code of Medical Ethics.¹⁴³ Additionally, the WMA drafted a document especially focused on patients' rights: the Declaration on the Rights of the Patient of 1981, stating in the preamble that physicians should act in accordance with their own principles and with patients' well-being in mind. Physicians should always defend patients' rights.¹⁴⁴ The declaration itself includes ten principles: the right to health care of good quality, the right to choose freely, the right to self-determination, rights for the patient who is not able to consent to a medical treatment due to unconsciousness or legal incompetency, a right for the patient to not be diagnosed or treated against their will, the right to information, the right to confidentiality, the right to education about health and the right to dignity.¹⁴⁵ Human dignity and human rights, such as the inviolability of the human body, the right to privacy and the right to health are reflected in these principles, once again demonstrating that patients' rights can be considered human rights in health care.

142 UNESCO Resolution 53/152 (9 December 1998), *Universal Declaration on the Human Genome and Human Rights*, UNESCO, 29th General Conference, 11 November 1997, *UN Doc A/RES/53/152*.

143 World Medical Association International Code of Medical Ethics, adopted by the 3rd General Assembly of the World Medical Association. London, England, October 1949 and amended by the 22nd World Medical Assembly Sydney, Australia, August 1968 and the 35th World Medical Assembly Venice, Italy, October 1983 and the WMA General Assembly, Pilanesberg, South Africa, October 2006.

144 World Medical Association (WMA) Declaration on the Rights of the Patient. Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981, and amended by the 47th WMA General Assembly, Bali, Indonesia, September 1995, and editorially revised at the 171st Council Session, Santiago, Chile, October 2005 and reaffirmed by the 200th WMA Council Session, Oslo, Norway, April 2015 (hereafter: WMA Declaration on the Rights of the Patient).

145 WMA Declaration on the Rights of the Patient, principles 1-10.

In 1981, building on earlier reports and strategies,¹⁴⁶ the WHO issued the Global Strategy for Health for All by the Year 2000.¹⁴⁷ This strategy emphasises the importance of equity in health care¹⁴⁸ and wishes to stimulate patients' involvement¹⁴⁹ in the health care process. Such developments can be seen in contemporary Dutch patients' rights as well since the legislator introduced shared decision-making in Article 7:448 BW in a recent amendment to the WGBO.¹⁵⁰ The 'Global strategy for Health for All by the Year 2000' was followed by the global health policy 'Health for all in the twenty-first century'.¹⁵¹ This included several new incentives for action to reach health for all, such as a gender perspective and the usage of modern technology for health. Furthermore, the strategy considers health a core value of sustainable human development and emphasises the increased importance of the civil society in health.¹⁵²

Because the goals of the Declaration of Alma-Ata had not been reached yet, the People's Health Assembly, which consists of various international organisations, civil society movements and academic institutions, issued the People's Charter for Health.¹⁵³ This charter stresses the importance of health as a human right and that health services therefore should be available to everyone and must not be dependent on income. According to the People's Charter for Health, health, equity and sustainable development should be high on the agendas of local, national and international authorities.¹⁵⁴

The WHO monitored the developments of patients' rights in different countries. The WHO genomic resource centre published a basic introduction to patients' rights in various countries. According to the genomic resource centre, patients' rights vary in different countries, based on their specific cultures and societies. Several patients' rights however, seem to be accepted by many countries. These are: the right to privacy, the right to confidentiality of medical information, the right to consent to or refuse treatment, and the right to be informed about relevant risks of medical procedures. Furthermore, the WHO genomic resource centre states that every medical intervention should at least be consistent with the following patients' rights:

146 Declaration of Alma-Ata, adopted by the International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978, Geneva: World Health Organization 1978, resolutions WHA 30.43, 19 May 1977, WHA 32.30, 25 May 1979 and WHA 33.24 Concerning Health for All by the Year 2000 and UN General Assembly Resolution 34/58, health as an integral part of development of 29 November 1979.

147 WHO 1981.

148 WHO 1981, p. 34, 36 and 75.

149 WHO 1981, p. 32 and 34.

150 *Kamerstukken II* 2017/18, 34994, no. 3, p. 4-6 and Art. 7:448 Para. 1 BW; entered into force 1 January 2020, *Stb.* 2019, 284.

151 WHO, Regional Office for Europe 1998.

152 WHO, Regional Office for Europe 1998, p. 17.

153 People's Health Movement, People's Charter For Health, adopted by the People's Health Assembly in Bangladesh on 4-8 December 2000 (hereafter: People's Charter For Health 2000).

154 People's Charter For Health 2000, p. 4.

equal access to health care of good quality, a right to privacy and medical confidentiality, the right to informed consent, and a safe clinical environment for the medical intervention to take place. Based on their research, the genomic resource centre identified four models of patients' rights found in Europe and North America. In the paternalistic model, the health professional decides according to the patient's best interest. This model does not necessarily involve the patient as a decision maker.¹⁵⁵ In the informative model, the physician provides information and the patient is considered the decision maker.¹⁵⁶ In the interpretive model the physician provides information to the patient. The patient makes decisions based on this information but the health professional assists in making their decision by advising them on the most appropriate medical intervention considering their personal circumstances. It is however the patient who makes their own decision in this model.¹⁵⁷ The last model, the deliberative model, focuses on a collaboration between the physician and the patient in the health care process. In this model, the emphasis is on discussion between the patient and the health professional.¹⁵⁸

4. THE EUROPEAN CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND FUNDAMENTAL FREEDOMS

Patients are protected by the international human rights as laid down in the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)¹⁵⁹ of the Council of Europe.

Whether the provisions in the ECHR are directly justiciable in front of national courts depends on the national state's approach to international law. This can be either the monistic or the dualistic view.¹⁶⁰ The Netherlands has a so-called partly monistic system, meaning that provisions in international law, such as the ECHR, have a direct effect when these provisions are "binding on all persons by virtue of their contents".¹⁶¹ It is well established in the Netherlands that the substantive rights in the ECHR have a direct vertical effect, meaning that they are applicable in the relationship between a government and its citizens.¹⁶²

155 Emmanuel & Emmanuel, *JAMA* 1992, p. 2221 and WHO Genomic resource centre, *Patients' rights*. who.int/genomics/public/patientrights/en/. Accessed 11 March 11 2016.

156 Emmanuel & Emmanuel, *JAMA* 1992, p. 2221 and WHO Genomic resource centre, *Patients' rights*. who.int/genomics/public/patientrights/en/. Accessed 11 March 11 2016.

157 Emmanuel & Emmanuel, *JAMA* 1992, p. 2221.

158 Emmanuel & Emmanuel, *JAMA* 1992, p. 2222.

159 Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms* (ECHR), 4 November 1950, ETS No. 5.

160 Lemmens 2018, p. 23-26.

161 Article 93 Gw, translation *The Constitution of the Kingdom of the Netherlands 2018*, Ministry of the Interior and Kingdom Relations 2018.

162 Van der Pot/Elzinga, de Lange & Hoogers, p. 144 (online edition).

These fundamental rights lack direct horizontal effect, i.e. applicability between individual citizens. Article 34 ECHR explicitly mentions that (groups of) persons or legal entities can bring a claim to the ECtHR when a States party has allegedly violated an ECHR obligation. Individuals can bring a case to the court, however, when a Member State did not adequately protect an ECHR right in the relation between citizens and thus breached a treaty obligation. This is referred to as an indirect horizontal effect.¹⁶³ The importance of the ECHR for health law will now be illustrated by means of examples from case law.

In *Vo vs. France*, Mrs Vo, who was pregnant, went to the hospital for a check-up. While she was there, she was mistaken for another Mrs Vo, who came in to have a coil removed. Due to this procedure, Mrs Vo could not keep her pregnancy. Her pregnancy was terminated a few days after the procedure.¹⁶⁴ The *Court de Cassation* [Supreme Court] did not want to convict the physician of involuntary homicide because the unborn child was not a person under French law. Vo stated that this results in a violation of the right to life of unborn children under Article 2 ECHR.¹⁶⁵ The Court judged that unborn children do not have an absolute right to life based on Article 2 ECHR, because they are not a 'person' in the sense of this article. Under certain circumstances unborn children can benefit from protection, but this right should be weighed against the mother's rights. States have a margin of appreciation.¹⁶⁶

In *Evans vs. the United Kingdom*, Mrs Evans had to undergo an ovariectomy. Before this procedure, she had some egg cells collected for an IVF procedure. Following this procedure, she had embryos stored in the clinic, with the intention to implant them after her recovery. When she recovered, however, she and her partner had unfortunately split up. Since the embryos contained his genetic material as well, he withdrew his consent to implant the embryos and requested the clinic to destroy them. Evans stated that this resulted in a violation of Article 2 ECHR (the right to life) and Article 8 ECHR (the right to respect for personal and family life).¹⁶⁷ According to the Court, embryos do not have a right to life based on Article 2 ECHR.¹⁶⁸ As for Article 8 ECHR, the Court judged that there was no violation

163 Van der Pot/Elzinga, de Lange & Hoogers, p. 169 (online edition). For an elaboration and examples, please consult Gerards 2019, p. 145-155.

164 ECtHR 8 July 2004, ECLI:CE:ECHR:2004:0708:JUD005392400, *AB* 2005/10, m.nt. Van Beers (*Vo v. France*), Para. 9-12.

165 ECtHR 8 July 2004, ECLI:CE:ECHR:2004:0708:JUD005392400, *AB* 2005/10, m.nt. Van Beers (*Vo v. France*), Para. 46.

166 ECtHR 8 July 2004, ECLI:CE:ECHR:2004:0708:JUD005392400, *AB* 2005/10, m.nt. Van Beers (*Vo v. France*), Para. 75-95.

167 ECtHR 10 April 2007, ECLI:CE:ECHR:2007:0410:JUD000633905, *NJ* 2007/459, m.nt. De Boer (*Evans v. United Kingdom*).

168 ECtHR 10 April 2007, ECLI:CE:ECHR:2007:0410:JUD000633905, *NJ* 2007/459, m.nt. De Boer (*Evans v. United Kingdom*), Para. 53-56.

of this provision. The right of Evans to become a mother and her ex-partner's right to not become a father should be weighed against each other. Neither of these rights, however, should prevail over the other. This means that states have a wide margin of appreciation to regulate this matter.¹⁶⁹

In the case of *D. vs. the United Kingdom*, D., who suffered from AIDS, was to be sent back to Saint Kitts by the UK government. D, however, stated that this constituted a violation of Article 3 ECHR. Because of the lack of opportunities for treatment in Saint Kitts, he stated that sending him to Saint Kitts would result in inhuman and degrading treatment.¹⁷⁰ The Court judged that, considering D's individual circumstances, sending him back would indeed be in violation of Article 3 ECHR.¹⁷¹

In *Tysiac vs. Poland*, Mrs Tysiac, who lived in Poland, wanted to terminate her pregnancy because it could result in health risks for her. In Poland, at the time, abortion was allowed if a physician could declare that the pregnancy constituted health risks for the mother. Her physicians, however, did not want to issue such a declaration. She stated that her rights under Article 3 and Article 8 ECHR were violated.¹⁷² The Court ruled that there was not violation of Article 3 ECHR. Article 8 ECHR was violated though, because the Polish government did not provide for an appropriate procedure for Tysiac to contest the physicians' decision.¹⁷³ The court noted that states have positive obligations with respect to Article 8 ECHR.¹⁷⁴

In *A, B and C vs. Ireland*, A, B and C, wanted to undergo an abortion for health reasons. In Ireland at the time this was only allowed when the pregnancy constituted a danger to the mother's life. This was not further elaborated in legislation. Therefore, many women went abroad for an abortion. In this case, A, B and C underwent an abortion in the UK. They stated that their rights in Articles 2, 3, 8 and 14 ECHR were violated.¹⁷⁵ The Court referred to *Vo vs. France* and *Evans vs. the UK* and stressed that that states have a margin of appreciation

169 ECtHR 10 April 2007, ECLI:CE:ECHR:2007:0410:JUD000633905, *NJ* 2007/459, m.nt. De Boer (*Evans v. United Kingdom*), Para. 81 and 90.

170 ECtHR 2 May 1997, ECLI:CE:ECHR:1997:0502:JUD003024096, *NJ* 1998/582 (*D. v. United Kingdom*), Para. 39-40.

171 ECtHR 2 May 1997, ECLI:CE:ECHR:1997:0502:JUD003024096, *NJ* 1998/582 (*D. v. United Kingdom*), Para. 46-54.

172 ECtHR 20 March 2007, ECLI:CE:ECHR:2007:0320:JUD000541003, *NTM/NJCM-bull.* 2007, p. 494, m.nt. Hendriks (*Tysiac v. Poland*), Para. 62 and 67.

173 ECtHR 20 March 2007, ECLI:CE:ECHR:2007:0320:JUD000541003, *NTM/NJCM-bull.* 2007, p. 494, m.nt. Hendriks (*Tysiac v. Poland*), Para. 114-130.

174 ECtHR 20 March 2007, ECLI:CE:ECHR:2007:0320:JUD000541003, *NTM/NJCM-bull.* 2007, p. 494, m.nt. Hendriks (*Tysiac v. Poland*), Para. 129.

175 ECtHR 16 December 2010, ECLI:CE:ECHR:2010:1216:JUD002557905, *NJ* 2011/216, m.nt. Alkema (*A, B & C v. Ireland*), Para. 154, 157, 160 and 167.

with respect to abortion and the beginning of life.¹⁷⁶ The Court judged that Articles 2 and 3 ECHR were not violated in this case.¹⁷⁷ As to Article 8 ECHR, this provision was only violated in the case of C. By not offering a procedure in which she could request an abortion, the government violated its positive obligations towards her based on the respect for private life.¹⁷⁸

In *Sentges vs. the Netherlands* the applicant, who suffered from Duchenne muscular dystrophy, was refused payment for a robotic arm. He stated that this was a violation of his right to respect for private life based on Article 8 ECHR. The court judged that while the state does indeed have positive obligations following from Article 8 ECHR, these obligations were met in this case. Even though a robotic arm will enhance Sentges' autonomy, not offering him a refund for a robotic arm was not in violation of Article 8 ECHR; he had sufficient access to health care.¹⁷⁹

In *Glass vs the United Kingdom*, the importance of self-determination in health care was brought to the fore.¹⁸⁰ In this case, medication was given to a child against his mother's wishes.¹⁸¹ This resulted in a violation of Article 8 ECHR.¹⁸²

These cases demonstrate the role of human rights and the ECHR in health law. It can be drawn from these cases that patients' rights come in all shapes and forms. The rights presented in the cases mentioned here are classic rights, but patients' rights can be derived from social rights as well. An example is the right to medical confidentiality, which not only aims to protect individual privacy but the right to access to health care as well.¹⁸³ In General Comment no. 14, confidentiality is mentioned as a condition for acceptable health care provision.¹⁸⁴ This demonstrates the connection between the right to health as a social right and the right to medical confidentiality as well. Moreover, these cases show the existence of positive (*Tysiak vs. Poland*, *A, B and C vs. Ireland* and *Sentges vs. the Netherlands*) as well as negative obligations (*Glass vs. United Kingdom*) with respect to human rights in health care.

176 ECtHR 16 December 2010, ECLI:CE:ECHR:2010:1216JUD002557905, *NJ* 2011/216, m.nt. Alkema (*A, B & C v. Ireland*), Para. 185.

177 ECtHR 16 December 2010, ECLI:CE:ECHR:2010:1216JUD002557905, *NJ* 2011/216, m.nt. Alkema (*A, B & C v. Ireland*), Para. 159 and 165.

178 ECtHR 16 December 2010, ECLI:CE:ECHR:2010:1216JUD002557905, *NJ* 2011/216, m.nt. Alkema (*A, B & C v. Ireland*), Para. 267-268.

179 ECtHR 8 July 2003, ECLI:CE:ECHR:2003:0708DEC002767702, *NJCM Bulletin* 2004, p. 54 (*Sentges v. The Netherlands*).

180 Wijne 2017b, p. 209.

181 ECtHR 9 March 2004, ECLI:ECHR:2004:0309JUD006182700, *NJ* 2005/14 (*Glass. v. UK*), Para. 1.

182 ECtHR 9 March 2004, ECLI:ECHR:2004:0309JUD006182700, *NJ* 2005/14 (*Glass. v. UK*), Para. 83.

183 HR 21 April 1913, *NJ* 1913, p. 958 and Leenen/Dute & Legemaate (eds.) 2017, p. 151.

184 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

The GDPR, a regulation that is not specifically aimed at health care but is nevertheless of great importance for this area will be discussed next. Article 8 ECHR is drawn up in more detail in this regulation.¹⁸⁵ Moreover, this right is protected in the Convention for the protection of individuals with regard to automatic processing of personal data,¹⁸⁶ in turn drawn up in more detail in Recommendation No. R(97)5 on the protection of medical data.¹⁸⁷

5. EU PRIVACY PROTECTION; THE GENERAL DATA PROTECTION REGULATION

5.1 The GDPR: introduction

In the context of health care, personal information is processed daily. Often, if not always, health information is very private and is considered even more personal and sensitive than some other private data, such as the information on a person's bank account.¹⁸⁸ Health information is protected by medical confidentiality.¹⁸⁹ However, patients can derive additional protection from several European regulations, of which the Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, GDPR) is the most important. This regulation was preceded by the European Commission's Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (the Data Protection Directive),¹⁹⁰ which followed shortly after the Strasbourg Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Strasbourg Convention). The GDPR, like the Data Protection Directive, was designed to both protect individuals' privacy and support the free movement of personal data.¹⁹¹ The Data Protection Directive was replaced by the GDPR, a regulation, because the European Parliament considered more harmonisation desirable.¹⁹² The GDPR instructs states to further elaborate some of its rules. In the Netherlands, the GDPR is further elaborated

185 GDPR, preamble Para. 1.

186 Council of Europe, *Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data* (Strasbourg Convention), 28 January 1981, ETS 108.

187 Council of Europe, Committee of Ministers, *Recommendation No. R (97) 5 on the Protection of Medical Data* 13 February 1997.

188 Kroes, *Medisch Contact* 2014, p. 1382-1383 and Keizer 2011, p. 377.

189 Art. 7:457 BW in Dutch law.

190 Directive 1995/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive), (*OJEU* 1995, L 281). In the Netherlands, the Data Protection Directive was implemented in the *Wet bescherming persoonsgegevens* [Personal Data Protection Act] (*Wbp*) (*Stb.* 2000, 302).

191 GDPR, preamble Para. 3 and 9, p. 1 and 2 and Directive 95/46/EC, preamble, Para. 8 and 10.

192 GDPR, preamble Para. 10, p. 2.

in the *Uitvoeringswet AVG* [Implementation Act GDPR] (UAVG).¹⁹³ The GDPR for instance instructs states to establish a supervisory authority.¹⁹⁴ In the Netherlands, this is the *Autoriteit Persoonsgegevens* [The Dutch Data Protection Authority] (Dutch DPA).¹⁹⁵

Although the GDPR does not focus on health information solely, several parts of it are relevant to the health care process. The additional protection provided by the GDPR can be desirable because eHealth may lead to new questions related to personal data and potential violations of privacy. This was for instance shown in the discussions relating to the corona app in the spring of 2020. During a press conference, the Dutch Minister for Health, Welfare and Sport spoke about the idea of an app that could show whether a person has been near someone who is infected with the corona virus.¹⁹⁶ The development of such smartphone applications led to concerns.¹⁹⁷ Privacy was one of the issues.¹⁹⁸ Based on the advice by experts from various fields, seven apps were selected for further testing.¹⁹⁹ However, none of these apps met the criteria set for such applications, including privacy protection.²⁰⁰

5.2 The GDPR in health care provision

The meaning of the GDPR for health care provision will be illustrated by means of the obligation to keep a medical record as imposed by Article 7:454 BW. The GDPR is directed at the person or authority who determines that and how personal data should be processed (the controller),²⁰¹ the person or authority who is processing the personal data on behalf of

193 *Uitvoeringswet AVG* [implementation Act] (UAVG), *Stb.* 2018, 144.

194 Art. 51 GDPR.

195 Art. 51 GDPR and Art. 57 GDPR in conjunction with Art. 6 Para. 2 UAVG.

196 'Text of the press conference of 7 April 2020', *rijksoverheid.nl*. Source: rijksoverheid.nl/documenten/mediateksten/2020/04/07/letterlijke-tekst-persconferentie-minister-president-rutte-en-minister-de-jonge-na-afloop-van-crisisberaad-kabinet and *Kamerstukken II* 2019/20, 25295, no. 219, p. 5-6.

197 Based on the categorisation of eHealth as described in chapter 2, such an app would qualify as e-Public Health although it shows characteristics of mHealth (not consumer eHealth though; this would only be the case when health professionals or (public) health organisations are involved). See chapter 2, para. 6.3.3 and 6.4.1.

198 For instance, C. Muller et al., 'Open letter to Prime Minister Mark Rutte, Minister De Jonge, Minister Van Rijn, Minister Grapperhaus and Mr Sijbesma,' 13 April 2020, Source: allai.nl/wp-content/uploads/2020/04/Online-versie-Brief-Minister-President-Rutte-Ministers-De-Jonge-Van-Rijn-Grapperhaus-de-heer-Sijbesma-inzake-COVID-19-tracking-en-tracing-en-gezondheidsapps.pdf and Gezondheidsraad, 'Verslag van de wetenschappelijke discussiebijeenkomst COVID-19: Apps als onderdeel van een exitstrategie, held at Sunday 19 April 2020 from 14.00 to 16.00 hrs,' [gezondheidsraad.nl](https://gezondheidsraad.nl/documenten/overige/2020/04/20/verslag-wetenschappelijke-discussiebijeenkomst-covid-19-apps-als-onderdeel-van-een-exitstrategie). Source: gezondheidsraad.nl/documenten/overige/2020/04/20/verslag-wetenschappelijke-discussiebijeenkomst-covid-19-apps-als-onderdeel-van-een-exitstrategie.

199 'Zeven apps doen mee aan publieke test komend weekend', *Rijksoverheid.nl*, newsmessag 17 April 2020 13.30 hrs. Source: rijksoverheid.nl/actueel/nieuws/2020/04/17/zeven-apps-doen-mee-aan-publieke-test-komend-weekend.

200 Appendix to *Kamerstukken II* 2019/20, 25295, no. 277-931540; KPMG 2020; Zwenne and Van Graafeiland 2020; Autoriteit Persoonsgegevens 2020 and *Kamerstukken II* 2019/20, 25295, no. 277, p. 34-35.

201 Art. 4 Para. 7 GDPR.

the controller (the processor)²⁰² and third parties who are authorised to process the personal data under the authority of the controller or the processor.²⁰³ In the case of a medical record, the health care institution or the health professional who holds their own surgery is the controller, whereas the health professional is the processor.²⁰⁴

According to the GDPR, personal data are “any information relating to an identified or identifiable natural person (‘data subject’)(...)”²⁰⁵ Data processing is defined as “any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.”²⁰⁶ Consequently, keeping a medical record, whether or not in electronic format, is considered processing of data under the GDPR.²⁰⁷ Because the data stored in the medical record are related to a particular patient, who is identifiable, medical data are personal data under the GDPR. Keeping a medical record is processing of personal data as meant by the GDPR since it includes recording a person’s medical data, as well as storing them. Furthermore, keeping a medical record entails retrieving, consulting and updating these data. When a physician sees their patient, they will have to retrieve the medical file, consult it and update it after each consultation with the patient. Moreover, keeping a medical file will at times entail destroying it because, as we will see further on, a patient has a right to destruction of their medical record.²⁰⁸ Finally, dissemination of the medical file can play a role too, for instance when a patient gives their consent to the transferring of the data to another health professional such as a locum tenens or a successor, or when the patient invokes their right to access their medical file.²⁰⁹

According to Article 9 Paragraph 1 in conjunction with Article 9 Paragraph 3 GDPR and Article 9 Paragraph 2(h) GDPR, medical data are a special category of data and processing such data is only possible under certain conditions. Processing the data should be necessary for health care provision and should be done by a health professional who has an obligation of medical confidentiality.²¹⁰ ECtHR case law confirmed that processing medical data is

202 Art. 4 Para. 8 GDPR.

203 Art. 4 Para. 10 GDPR.

204 Also in this respect: Leenen/Dute & Legemaate (eds.) 2017, p. 173.

205 Art. 4 Para. 1 GDPR.

206 Art. 4 Para. 2 GDPR.

207 Also in this respect: *Kamerstukken II* 2017/18, 34939, no. 3, p. 63.

208 Art. 7:455 BW.

209 Art. 7:456 BW.

210 Art. 9 Para. 1 in conjunction with Art. 9 Para. 3 and Art. 9 Para. 2(h) GDPR.

processing of sensitive information, for which additional safeguards should be provided.²¹¹ Under the WGBO, medical records are kept by the health professional who has a contract for provision of medical services²¹² with the person whose data they are gathering, recording and updating. Not only is processing personal data necessary for providing the care of a conscientious health professional,²¹³ the health professional is obliged to do so by the WGBO.²¹⁴ Health care providers in the Netherlands are bound by an obligation of professional secrecy as meant in Article 9 Paragraph 3 GDPR.²¹⁵ Even in situations where physicians are seeing patients without the establishment of a contract for provision of medical services – e.g. medical check-ups for labour relations²¹⁶ – health professionals are bound by the obligation of medical confidentiality. When the WGBO, for whatever reason, does not apply in a certain situation, this obligation arises from Article 88 *Wet op de beroepen in de individuele gezondheidszorg* [Individual Health Care Professions Act] (BIG Act)²¹⁷ which imposes the duty of professional confidentiality on everything the health professional is entrusted with while practising their profession. Moreover, breaching professional confidentiality is listed as a criminal offence in Article 272 of the *Wetboek van Strafrecht* [Dutch Penal Code] (Sr).²¹⁸

5.3 Relation between the WGBO and the GDPR

Because both the WGBO and the GDPR apply in the case of eHealth care provision, this section will elaborate on the relation between these regulations. The GDPR has a broader range than health care alone since it aims to regulate data protection in various areas. The WGBO, on the other hand, is not restricted to privacy alone but includes multiple patients' rights and is directed to health professionals. Consequently, the WGBO and the GDPR coexist and might sometimes overlap. In literature, however, it has been stated that the coexistence of the WGBO and the GDPR's predecessor, the *Wbp*, has not led to difficulties so far.²¹⁹ The chances for a conjunction of the WGBO and the GDPR are reduced by an amendment to several provisions of the WGBO, on the occasion of the entry into force of the GDPR.²²⁰ These provisions will be presented below.

211 ECtHR 4 December 2008, ECLI:CE:ECHR:2008:1204JUD003056204, *NJ* 2009/410, m.nt. Alkema (*Marper and S. v. United Kingdom*); ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*) and ECtHR 17 July 2008, ECLI:CE:ECHR:2008:0717JUD002051103 (*I. v. Finland*) as cited by Verhey & Raijmakers, *RegelMaat: Kwartaalblad voor wetgevingsvraagstukken* 2013, p. 186. The ECtHR bases its decision on Art. 6 of the Strasbourg Convention.

212 Based on Art. 7:446 BW.

213 Art. 7:453 BW.

214 Art. 7:454 BW.

215 Art. 7:457 BW.

216 See Art. 7:446 Para. 4 BW.

217 *Wet op de Beroepen in de Individuele Gezondheidszorg* (BIG Act), *Stb.* 1993, 655.

218 *Wetboek van Strafrecht* [Penal Code] (Sr), *Stb.* 1886, 6.

219 Leenen/Dute & Legemaate (eds.) 2017, p. 174.

220 *Kamerstukken II* 2017/18, 34939, no. 2; *Kamerstukken I* 2017/18, 34939, A and *Stb.* 2018, 247.

5.4 Access to personal data

Based on the GDPR, the data subject has a right to access their personal data.²²¹ This does not only include the medical record as such, but a right of access to the logging data as well.²²² These data include information on who accessed which part of the medical record and which health professional shared what information.²²³ A right to access the medical record can be found in the WGBO as well.²²⁴ Both the GDPR and the WGBO grant patients the right to request a copy of their data.²²⁵ Under the WGBO, the health professional could ask the patient for a small fee with respect to costs of printing. Since the GDPR entered into force, however, this was removed from Article 7:456 BW because Article 15 Paragraph 3 GDPR does not give data processors a right to claim a fee.²²⁶

5.5 Correction of personal data

Based on Article 16 GDPR, the data subject has the right to request the controller to adjust their personal data when these data are processed incorrectly or are incomplete. According to the KNMG Guidelines for dealing with medical data, this provision refers to incorrect information in the medical record. However, this right does not include the right to contest the diagnosis.²²⁷ If the patient wants to contest their diagnosis, they can do so by means of Article 7:454 Paragraph 2 BW, which gives the patient the right to have the health professional add information to the medical record.²²⁸ Examples of such information include a written declaration by the patient or a second opinion by another health professional.²²⁹ The physician must comply with such a request.²³⁰

5.6 Storage of personal data

Regarding storing personal data, the GDPR does not provide an exact term. The GDPR states that personal data should not be stored for a longer period than necessary.²³¹ In the case of a medical record, we can refer to the WGBO, which mentions in Article 7:454 Paragraph 3 that medical data should be kept for twenty years after the last data in the medical record were processed.²³²

221 Art. 15 GDPR.

222 Art. 15 Para. 1(c).

223 *Kamerstukken II* 2012/13, 33509, no. 3, p. 7.

224 Art. 7:456 BW.

225 Art. 7:456 BW and Art. 15, para 3 GDPR.

226 *Kamerstukken II* 2017/18, 34939, no. 3, p. 63.

227 KNMG Guidelines for dealing with medical data 2020, Para. 7.2, p. 125.

228 Art. 7:457 Para. 2 BW and KNMG Guidelines for dealing with medical data 2020, Para. 7.2, p. 125.

229 *Kamerstukken II* 1989/90, 21561, no. 3, p. 36.

230 Art. 7:454 Para. 2 BW.

231 Art. 5 Para. 1(e) GDPR.

232 Also see KNMG Guidelines for dealing with medical data 2020, Para. 6.4, p. 115-118.

5.7 Deletion and destruction of personal data

A remarkable new right in this regulation, is the right to be forgotten.²³³ This includes data where processing is no longer necessary,²³⁴ data that are processed against the law²³⁵ or data that have to be deleted in order to comply with a national statute or a European Union regulation.²³⁶ It is unclear, however, whether this right applies to the medical record. The government, in the explanatory memorandum to the amendments to certain national statutes with respect to the entry into force of the GDPR and the *Uitvoeringswet AVG* [Implementation Act GDPR] (UAVG), stresses that the period within which the health professional must comply with a patient's request to delete their medical record based on Article 7:455 BW will no longer be three months, but as soon as possible with a maximum of one month instead. The explanatory memorandum refers to Article 12 Paragraph 3 GDPR, which states the same period.²³⁷ This provision states that this is the period within which a response to a request by a data subject based on Articles 15 to 22 GDPR must be given, thus including the right to be forgotten in Article 17 GDPR. According to the KNMG, however, Article 17 GDPR does not apply in case of the medical record.²³⁸ When taking a closer look at Article 17 GDPR, this might stem from Article 17 Paragraph 3(h) GDPR, which states that Paragraph 1 (the right to destruction) does not apply in case the data are processed according to a legal obligation. Such an obligation can be found in Article 7:454 BW where the health professional is obliged to keep a medical record. Consequently, for deleting the medical record, it seems that the patient will have to use their right of destruction of the medical record as laid down in Article 7:455 BW instead of Article 17 GDPR.

Furthermore, Article 28 GDPR urges health care institutions, as the controller, to examine whether third parties who process data on behalf of the controller meet the standards for security. When health care providers, for instance, work with patient portals (portals that allow patients to access their health information – see chapter 2, paragraph 6.3.1.4) designed and maintained by third parties,²³⁹ they should check whether these parties meet the security standards for processing personal data. The health care provider, as the controller, remains responsible for the personal data.²⁴⁰

233 Art. 17 GDPR.

234 Art. 17 Para. 1(a) GDPR.

235 Art. 17 Para. 1(d) GDPR.

236 Art. 17 Para. 1(e) GDPR.

237 *Kamerstukken II* 2017/18, 34939, no. 3, p. 63.

238 KNMG Guidelines for dealing with medical data 2020, Para. 7.3, p. 128.

239 For instance MijnGezondheid.net, home.mijngezondheid.net/ Source: home.mijngezondheid.net/.

240 Art. 4 Para. 7 GDPR.

5.8 Personal data breaches

Article 32 GDPR states that the controller should take appropriate measures, both technical and organisational, to protect personal data. When, in spite of these measures, these data are deleted, changed or have fallen into the wrong hands, this is called a personal data breach.²⁴¹ The GDPR contains a provision on notification of such a personal data breach.²⁴² The so-called personal data breach notification obligation means that the controller should notify the supervisory authority of the breach.²⁴³ As mentioned in paragraph 5.4.1, in the Netherlands this is the Dutch DPA.²⁴⁴

In the example of the medical record, either the health care institution or the health professional should inform the Dutch DPA when the personal data breach is likely to have adverse effects.²⁴⁵ A breach of personal health data is highly likely to cause adverse effects, especially when it causes third parties to access these data. Personal health data are usually considered sensitive data, considering the fact that the GDPR list them as a special category in Article 9 Paragraph 1 GDPR. Moreover, the personal data breach notification obligation requires the controller to notify the data subject when their individual privacy is likely to be violated by the personal data breach.²⁴⁶ This seems to be the case when, for instance, personal health data risks being exposed to third parties. Medical records contain general information about the patient as well and therefore the contents of the medical file can easily be traced to a natural person, resulting in a violation of the data subjects' privacy. Often, a personal data breach will correspond with a violation of the obligation of medical confidentiality as laid down in Article 7:457 BW. This will be presented in detail in chapters 4 to 6.

The personal data breach notification obligation has drawn criticism in academia as well, for instance related to the lack of clarity regarding what exactly constitutes a personal data breach in health care. For example, does giving a password to a colleague or the visibility of a patients' data for others to see on a computer when the health professional is reading the medical record, constitute a personal data breach? It is stated that such a broad definition of personal data breach will result in a burden on health care provision.²⁴⁷ While this may

241 Art. 4 Para. 12 GDPR.

242 Art. 33 GDPR.

243 Art. 33 Para. 1 GDPR.

244 Art. 51 GDPR and Art. 57 GDPR in conjunction with Art. 6 Para. 2 UAVG.

245 Art. 33 GDPR.

246 Art. 34 GDPR.

247 Ploem, *TvGR* 2016, p. 287. Also in that sense: Hendriks, *NJB* 2017, p. 1079 about the implementation of the Data Notification Obligation in the Wbp. In anticipation of the GDPR's applicability from May 2018 onwards, in the Netherlands, the Data Breach Notification Obligation took effect in January 2016 (*Stb.* 2015, 230). The Data Breach Notification Obligation entailed an amendment to the Wbp. The most important amendment established an obligation to notify the Dutch DPA and – under certain circumstances – the data subject in case of a potential personal data breach.

be true, it is advisable to always close the medical record and lock the screen before walking away.

This section explained the role of the GDPR in health care provision. It has been mentioned that the overlap between the Wbp (the predecessor of the GDPR in Dutch law) and the WGBO did not seem to have presented problems in the past.²⁴⁸ Furthermore, certain provisions in the WGBO are amended in consideration of the entry into force of the GDPR.²⁴⁹ Nevertheless, should a conflict between a provision in the WGBO and a provision in the GDPR occur, the rules of European law dictate that the GDPR must prevail. In contrast to the Wbp, which is – as well as the WGBO – a national regulation, the GDPR is a regulation of the European Union. The regulations of the EU apply directly in Member States.²⁵⁰ According to settled case law, by becoming a member of the EU (in the present case, the European Economic Community (EEC)), states give up a part of their sovereignty and are therefore bound by this community's law. As a result, national statutes that conflict with EU law must be rendered inapplicable in that particular case.²⁵¹

5.9 Enforcement of privacy rights under the GDPR and the WGBO

Medical confidentiality and informational privacy are interconnected since they both concern personal information. At first sight, there seems to be little difference between a violation of the obligation of medical confidentiality and a personal data breach under the GDPR. However, a difference can be found in the consequences of each violation. The GDPR aims at protecting the individual's privacy and an offence carries a large fine in case of violations.²⁵² The obligation of medical confidentiality in the WGBO on the other hand, has another objective besides the protection of the individual's privacy, namely protecting the public interest of unrestricted access to health care for everyone.²⁵³ Thus, everyone has to feel free to contact a health professional for an e-consultation without fearing that the information they provide will be disclosed to third parties. In sum, the right to medical confidentiality protects a broader interest than the right to privacy in international law.

Another difference between the GDPR and the WGBO is the possibility of legal action. As mentioned, a fine will be imposed on offenders of the GDPR and this fine will be paid to the Dutch DPA. Should the victim wish for compensation for a violation of Article 7:457 BW, a civil suit can be brought against the offender. This will most likely be done based

248 Leenen/Dute & Legemaate (eds.) 2017, p. 174.

249 *Kamerstukken II* 2017/18, 34939, no. 2, p. 47-48; *Kamerstukken I* 2017/18, 34939, A and *Stb.* 2018, 247.

250 Art. 288 Treaty on the Functioning of the European Union (TFEU).

251 CJEU 15 July 1964, C-6/64, ECLI:EU:1964:66 (*Costa v. ENEL*).

252 Art. 58 Para. 2(i) in conjunction with Art. 83 Para. 4 and 5 GDPR.

253 Hof Den Bosch, 13 October 1998, *TvGR* 1999/13, p. 125-127.

on a violation of Article 8 ECHR. A quick glance at any database containing ECtHR judgements will provide numerous judgements about Article 8 ECHR in relation to medical confidentiality.²⁵⁴ The obligation of medical confidentiality is laid down in Article 88 BIG Act as well. Besides a fine or compensation, a violation of medical confidentiality as laid down in this provision can result in a disciplinary measure, varying from a fine to removal from the Dutch register of health care professionals.²⁵⁵ These measures, although they can feel as a punishment, are not meant to punish health professionals but instead are meant to protect the quality of health care provision.²⁵⁶

5.10 NEN standards

Several standards that can serve as a means to interpret the GDPR norms in health care are developed in the field of IT by the *Nederlands Normalisatie Instituut* [Netherlands Standardization Institute]. NEN7510, NEN7512 and NEN7513 are especially designed for data protection in health care. Although the NEN standards are not legally binding as such, they are appropriate as good practice guidelines. In the literature, these standards are called terms of reference.²⁵⁷ Their importance was confirmed by the *Hoge Raad*, which held that it can be assumed that statutory requirements are met if the NEN standards are met: they constitute a presumption of law.²⁵⁸ Moreover, these standards are referred to in Dutch regulations.²⁵⁹ Finally, the NHG Checklist explicitly refers to the NEN7510 as the national standard for data protection in health care.²⁶⁰ In conclusion, these standards are not legally binding in themselves nor will they guarantee that a personal data breach will never occur. However, they are minimum standards for security: once the NEN standards are complied with, it can at least be assumed that the safety and security of the health care institution is up to date as the law stands and according to the latest standards of technology.

When taking a closer look at these standards and what they entail, we see that NEN7510 relates to information security management in health care and contains provisions on authorisation

254 Examples include ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*); ECtHR 27 August 1997, ECLI:NL:XX:1997:AD4543, *NJ* 1999/464 (*M.S. v. Sweden*) and ECtHR 23 February 2016, ECLI:CE:ECHR:2016:0223JUD004037806, *NJ* 2016/1001 (*Y.Y. v. Russia*).

255 Art. 48 BIG Act.

256 For instance Kastelein 2009, p. 40.

257 Ekker 2012, p. 59.

258 HR 22 June 2012, ECLI:NL:HR:2012:BW0393 (advisory opinion of Solicitor-General Langemeijer, ECLI:NL:PHR:2012:BW0393), *NJ* 2012/397 (*Knooble/Staat*), Para. 4.10 and in the same case in the Court of Appeal: Hof Den Haag 16 November 2010, ECLI:NL:GHSGR:2010:BO4175, *JB* 2011/77, m.nt. Teunissen, legal ground 8. Even though this case did not relate to health care, but to the construction industry, this judgement is applicable to NEN standards related to health care as well.

259 For instance the Ministerial Regulation on Subsidizing the acceleration of information exchange in long-term care. Art. 5 Para. 1(g) and Art. 5 Para. 2(k) refer to NEN 7510, 7512 and 7513.

260 NHG Checklist e-consult 2014, Para. 4, p. 3.

and authentication. Clear rules regarding authorisation will also prevent unauthorised people from accessing a patient's medical record.²⁶¹

NEN7512 concerns electronic communication in health care, including communication between health professionals and their patients. This standard provides rules for exchanging data in a safe manner and serves as an addition to the NEN7510 standard.²⁶² This can serve to protect the patient's privacy and to make sure that personal medical information about a particular patient is not disclosed to an unauthorised party.

NEN7513 refers to electronic medical records and the logging of data. The standard discusses logging, stating that the system should record when a medical file was accessed and by who.²⁶³ This means that when a physician holds a consultation with their patient and therefore refers to the patient's medical record, this action will be recorded. This can help to detect attempts of illegal access to the data.

Another norm relevant for the protection of personal data against unlawful access is the ISO27001-norm. This norm relates to information security management and is not only relevant in health care but for all organisations that process personal data. The norm aims to help organisations with protecting information, such as personal data.²⁶⁴

6. WHO REGIONAL OFFICE FOR EUROPE

6.1 The WHO Declaration on the Promotion of Patients' Rights in Europe

In the end of the twentieth century, thinking about patients' rights increased in Europe. This is best illustrated by the WHO Declaration on the Promotion of Patients' Rights in Europe of 1995.²⁶⁵ This declaration was drafted at the consultation between the representatives of EU Member States and expert parties, initiated by the WHO Regional Office for Europe and has been an important incentive for countries to regulate patients' rights in their national legal order.²⁶⁶ Moreover, the declaration provides an insight into about what rights a consensus existed in Europe at the time.

261 'Achtergrondinformatie over NEN7510', Nen.nl, source: nen.nl/Alles-over-NEN-7510/Achtergrondinformatie-over-NEN-7510.htm. NEN7510 and its provisions are explained by Ekker 2012, p. 59.

262 'NEN 7512:2015 nl', nen.nl. Source: nen.nl/nen-7512-2015-nl-198046.

263 'NEN 7513:2018 nl', nen.nl. Source: nen.nl/nen-7513-2018-nl-245399.

264 'Informatiebeveiliging', nen.nl. Source: nen.nl/NEN-Shop/Informatiebeveiliging-1.htm.

265 WHO, Regional Office for Europe 1995a, p. 29-32.

266 WHO, Regional Office for Europe 1995c, p. 14.

The general idea of the patients' rights movement was to 'empower' the patient by providing them with adequate information which might involve them in their own health care process. This would enhance equity and ethical health care.²⁶⁷ At the same time, a larger role was given to the right to respect the individual and the freedom to make their own choices.²⁶⁸

Developments in health care as well as developments in society were mentioned as reasons for the patients' rights movement at the end of the twentieth century. Developments in health care that were mentioned are the increasing possibilities of health care in combination with the use of more advanced technologies.²⁶⁹ As for the developments in society, patients became increasingly articulate while physicians, at least in some parts of Europe, began to lose their traditional superior positions.²⁷⁰ The patient, however, still remains the weaker party. Patients' rights can offer protection to this weaker party.²⁷¹ At the end of the twentieth century, medical information became available to people to a greater extent as well, for instance via television shows.²⁷² These developments bear a resemblance to the developments relating to eHealth. Again, new technology leads to new possibilities and changes in health care, such as electronic consultations or self-management.²⁷³ Moreover, eHealth and the Internet in general contribute to an increase in the available information.²⁷⁴ This, again, requires thinking about patients' rights.

The declaration is meant to provide guidelines for regulation of patients' rights nationally as well as internationally²⁷⁵ and builds on existing human rights documents such as the UDHR, the ICCPR, the ICESCR, the ECHR and the ESC.²⁷⁶

One of the purposes of the declaration is "to reaffirm fundamental human rights in health care, and in particular to protect the dignity and integrity of the person and to promote respect of the patient as a person."²⁷⁷ This underlines that patients' rights are human rights.

The declaration consists of seven sections. The first section contains general human rights in health care, such as the right to respect for the individual, the right to self-determination, the right to privacy, the right to have personal moral and cultural values, and religious and

267 Asvall 1995, p. 9.

268 WHO, Regional Office for Europe 1995b, p. 32.

269 D'Ancona 1995, p. 2-3 and WHO, Regional Office for Europe 1995b, p. 32.

270 D'Ancona 1995, p. 2-3.

271 D'Ancona 1995, p. 4.

272 D'Ancona 1995, p. 2-3.

273 For instance *Kamerstukken II* 2013/14, 27529, no. 130, p. 1 and p. 9-10.

274 About online health information, see chapter 2 Para. 6.3.3. and the examples mentioned there.

275 D'Ancona 1995, p. 3 and Asvall 1995, p. 7 and WHO, Regional Office for Europe 1995c, p. 14-15.

276 WHO, Regional Office for Europe 1995b, p. 37.

277 WHO, Regional Office for Europe 1995b, p. 36.

philosophical convictions respected, and the right to protection of health.²⁷⁸ Second, the declaration encompasses information-related rights, such as the right to information about health services, information about personal health and the right to ask to not receive certain information.²⁷⁹ In particular, the information must also be comprehensible to each patient.²⁸⁰ Additionally, patients have a right to ask for a second opinion.²⁸¹ The declarations' third section contains rights related to consent;²⁸² section 4 elaborates on confidentiality and privacy.²⁸³ Furthermore, patients are given a right to access to their medical files²⁸⁴ and to correct unjust or outdated information.²⁸⁵ These rights can be seen in the GDPR and the WGBO as well.²⁸⁶ Patients also have a right to spatial privacy – no one is allowed to be present during the medical intervention, unless the patient has given their explicit consent.²⁸⁷ Section 5 contains rights regarding the process of care and treatment. Rights include the right to health,²⁸⁸ the right to health care of good quality,²⁸⁹ the right to continuity of care,²⁹⁰ the right to a choice of a health professional,²⁹¹ non-discrimination,²⁹² respect for human dignity and respect for the individual, including the patient's culture and values,²⁹³ the right to support and (spiritual) guidance²⁹⁴ and the right to die in dignity.²⁹⁵ Section 6 contains rules regarding the application of the rights in the declaration, information and advice to help patients to exercise their rights.²⁹⁶

6.2 The Ljubljana Charter

In 1996 the Ljubljana Charter on Reforming Health Care was published.²⁹⁷ This charter states that health care systems, among other things, should be focused on health, be of good

278 Para. 1.1-1.6 Declaration on the Promotion of Patients' Rights in Europe.

279 Para. 2.1, 2.2, 2.3 and 2.5 Declaration on the Promotion of Patients' Rights in Europe.

280 Para. 2.4 Declaration on the Promotion of Patients' Rights in Europe.

281 Para. 2.7 Declaration on the Promotion of Patients' Rights in Europe.

282 Para. 3.1 and 3.2 Declaration on the Promotion of Patients' Rights in Europe.

283 Para. 4.1 Declaration on the Promotion of Patients' Rights in Europe.

284 Para. 4.4 Declaration on the Promotion of Patients' Rights in Europe.

285 Para. 4.5 Declaration on the Promotion of Patients' Rights in Europe.

286 Art. 15 GDPR and Art. 7:456 BW for access to personal data and Art. 16 GDPR and Art. 7:454 Para. 2 BW for correction of personal data.

287 Para. 4.7 Declaration on the Promotion of Patients' Rights in Europe.

288 Para. 5.1 Declaration on the Promotion of Patients' Rights in Europe.

289 Para. 5.3 Declaration on the Promotion of Patients' Rights in Europe.

290 Para. 5.4 Declaration on the Promotion of Patients' Rights in Europe.

291 Para. 5.6 Declaration on the Promotion of Patients' Rights in Europe.

292 Para. 5.5 Declaration on the Promotion of Patients' Rights in Europe.

293 Para. 5.8 Declaration on the Promotion of Patients' Rights in Europe.

294 Para. 5.9 Declaration on the Promotion of Patients' Rights in Europe.

295 Para. 5.11 Declaration on the Promotion of Patients' Rights in Europe.

296 Para. 6.5 Declaration on the Promotion of Patients' Rights in Europe.

297 WHO, European Member States, *The Ljubljana Charter on Reforming Health Care* 19 June 1996, EUR/ICP/CARE 94 01/CN01 Rev. 1 (Ljubljana Charter).

quality and be centred on people.²⁹⁸ The charter lists human dignity, equity, solidarity and professional ethics as fundamental values of health care.²⁹⁹ These values have all contributed to the development of and the consideration of patients' rights. The Ljubljana charter stresses that patients should be involved in their own health care process.³⁰⁰ Moreover, patients have a right to information and education about health. In the charter, these rights are linked to 'choice' which is explicitly referred to as a patients' right.³⁰¹

7. THE WGBO

7.1 General introduction: WGBO

In the Netherlands, the majority of the legislation pertaining to patients' rights is laid down in the WGBO.³⁰² This statutory regulation is incorporated in the Dutch Civil Code, in book 7 (on specific contracts), more precisely in the title 7 (on services). The WGBO is a statutory regulation of the medical treatment contract between the health professional and the patient.

7.2 Situation in the Netherlands before the WGBO

7.2.1 Introduction to patients' rights prior to the WGBO

Several statutes and regulations were directly applicable in the physician–patient relationship. Two constitutional rights played a large role in medical treatment: the right to privacy and the inviolability of the human body.³⁰³ The right to privacy was further elaborated in the *Wet persoonsregistraties* [Dutch Privacy Act] (W.P.R.)³⁰⁴ Claims related to incorrect behaviour by health professionals could be sought out via either criminal law or disciplinary law.³⁰⁵ Because of the lack of a specific regulation for the relationship between physicians and their patients, this relationship was governed by the general rules on provision of services as laid down in Article 1637 BW. This has to be further elaborated by good practice, good faith and what parties agreed on. Good practice guidelines determined what was considered common practice in health care.³⁰⁶

298 Ljubljana Charter, cover page.

299 Art. 5.1 Ljubljana Charter.

300 Art. 6.2.2 Ljubljana Charter.

301 Art. 6.2.3 Ljubljana Charter.

302 *Stb.* 1994, 837.

303 Respectively Art. 10 and 11 GW.

304 *Wet persoonsregistraties* [Dutch Privacy Act] (W.P.R.), *Stb.* 1988, 655 as mentioned in *Kamerstukken II* 1989/90, 21561, no. 3, p. 4-5. The W.P.R. was replaced by the *Wbp* (*Stb.* 2000, 302), established to implement the Data Protection Directive. As of May 2018, the *Wbp* was replaced by the GDPR.

305 *Kamerstukken II* 1989/90, 21561, no. 3, p. 4.

306 *Kamerstukken II* 1989/90, 21561, no. 3, p. 5-6.

Although the Dutch legal system did not contain specific patients' rights legislation, patients did enjoy several rights, based on other statutes and case law as disciplinary law.³⁰⁷ Examples will be presented in section 7.2.2 and 7.2.3.

7.2.2 Medical confidentiality

An example of such a right is the right to medical confidentiality, although this right was not explicitly mentioned in a legal provision as such. As a matter of fact, it can be questioned whether medical confidentiality is a patients' right at all because it is usually formulated and explained as a physicians' duty. The subsection on the contents of the WGBO will show that this applies to numerous other patients' rights as well. The purpose of medical confidentiality is twofold. On the one hand, the duty of medical confidentiality aims to protect the individuals' privacy; on the other hand, this duty aims to protect the collective interest to equal access to health care for everyone, without the fear of certain information being publicly disclosed.³⁰⁸ Such fear can impose a threat to the equal accessibility of health care as discussed in section four of this chapter. This function of medical confidentiality was already mentioned by the *Hoge Raad* in 1913. In his judgement, the *Hoge Raad* provided clarity about which information is covered by the obligation of medical confidentiality. The *Hoge Raad* ruled that both the information the patient provides to their physician and the information the physician obtains by examination is subject to this obligation. Such is necessary to prevent people from not seeking health care because they fear that their information will be brought into the open.³⁰⁹ Prior to the WGBO, (medical) confidentiality could be found in Dutch criminal law. The Dutch Criminal Code contains a provision related to professional confidentiality in general. According to Article 272 Paragraph 1 Sr, violation of professional confidentiality is illegal and can result in a punishment. Article 272 Paragraph 1 Sr addresses those who are subject to an obligation of professional confidentiality based on statutory regulations or the nature of their profession. Currently, health professionals derive their obligation of medical confidentiality from Article 88 BIG Act.³¹⁰ This Act entered into force in 1994.³¹¹ The BIG Act replaced multiple statutes in relation to the medical profession.³¹² Before the BIG Act came into force, the profession of health care provider was governed by various statutes, such as the *Wet regelende de uitoefening de geneeskunst* [Medical Practice Act] (WUG),³¹³ the Act of 25 December 1878, *houdende regeling der voorwaarden tot verkrijging der bevoegdheid van arts, tandarts, apotheker, vroedvrouw en apothekersbediende* [regulating the professional qualification of physicians, dentists, pharmacists, midwives and pharmacy clerks]

307 See, for instance, Van der Heijden 1988, p. V.

308 HR 21 April 1913, *NJ* 1913, p. 958 and Leenen/Dute & Legemaate (eds.) 2017, p. 151.

309 HR 21 April 1913, *NJ* 1913, p. 958.

310 Nowadays this obligation can be derived from the WGBO as well, in Art. 7:457 BW.

311 *Wet op de Beroepen in de Individuele Gezondheidszorg* (BIG Act), *Stb.* 1994, 16.

312 These are listed in Art. 145 BIG Act and, except for the Medical Practice Act and the Medical Disciplinary Act, will not be further discussed in the present chapter.

313 *Wet regelende de uitoefening der geneeskunst* [Medical Malpractice Act] (WUG), *Stb.* 1865, 60.

(Professional Qualifications Act 1878)³¹⁴ and the *Medische tuchtwet* [Medical Disciplinary Act].³¹⁵ Physicians used to have a duty of medical confidentiality based on the Professional Qualifications Act 1878.³¹⁶

7.2.3 Informed consent

The right to information before being subject to a medical treatment and the right not to be subjected to such treatment without explicit consent were recognised in case law prior to the existence of the WGBO. The rights to information and the right to give explicit consent are now recognised together in the WGBO as the right to informed consent.³¹⁷

7.3 History of the WGBO

At the end of the twentieth century, providing patients with additional protection was considered necessary.³¹⁸ Before this time, the common thought was that an extensive Act which regulates the relationship between patients and physicians was not needed, because this relationship depended on mutual trust. The idea of legal rules governing this relationship seemed to contradict this.³¹⁹ The change in thinking about this topic was connected to national as well as international occurrences.³²⁰ The explanatory memorandum to the WGBO mentions, among other things, the fact that the patient holds a weaker position because they are mainly concerned with recovery and are strongly dependent on their physician for that reason,³²¹ and the growth in number of legal claims taken to the civil or the disciplinary courts.³²²

In 1973, Rang was the first to discuss the need for a separate framework of patient rights in the Netherlands. In his inaugural lecture, he pleaded for the inclusion of the medical treatment contract in the Dutch Civil law.³²³ He stressed that the patients' status was hardly addressed in the statutes and regulations with respect to health care that had come into existence up to that time. Patients were patronised rather than protected.³²⁴ Van Wijmen endorsed Rang's view and stated that the rights and obligations of patients and health

314 *Wet van 25 december 1878 houdende regeling der voorwaarden tot verkrijging der bevoegdheid van arts, tandarts, apotheker, vroedvrouw en apothekersbediende* [Professional Qualifications Act], *Stb.* 1878, 222.

315 *Medische Tuchtwet* [Medical Malpractice Act], *Stb.* 1928, 222.

316 Art. 21 Professional Qualifications Act 1878.

317 Art. 7:448 in conjunction with Art. 7:450 BW.

318 *Kamerstukken II* 1989/90, 21561, no. 3, p. 1 and 6.

319 *Kamerstukken II* 1989/90, 21561, no. 3, p. 3-4.

320 For international occurrences see *Kamerstukken II* 1989/90, 21561, no. 3, p. 5. Also see what was mentioned above in Para. 4.5.1 on the WHO Declaration on the Promotion of Patients' Rights in Europe: D'Ancona 1995, p. 2-4 and WHO, Regional Office for Europe 1995b, p. 32.

321 *Kamerstukken II* 1989/90 21561, no. 3, p. 6.

322 *Kamerstukken II* 1989/90 21561, no. 3, p. 6-7.

323 Rang 1973, for instance p. 56.

324 Rang 1973, p. 51.

professional must be codified in private law. He pleaded for mandatory rules of law instead of regulatory law.³²⁵ Van der Mijn, on the other hand, did not consider statutory regulation of patients' rights necessary. Although he believed this might be different in specific situations or with respect to certain groups of patients, such as psychiatric patients.³²⁶ Roscam Abbing, too, did not seem to be in favour of an exhaustive codification with respect to the relationship between patients and health professionals in the Dutch legal order.³²⁷ She acknowledged, however, that developments in medicine might require more protection for patients.³²⁸ Later, she referred to the WGBO as an instrument that could counteract the traditional inequality in the relationship between the physician and the patient.³²⁹ Leenen was in favour of more general rules regarding medical practice, which would be further elaborated in practice. He takes the obligation to keep a medical record as an example. This obligation can be codified but has to be specified by the profession.³³⁰ This bears a resemblance to how this obligation is designed in Article 7:454 Paragraph 1 BW. Based on this provision, a health professional has to record information on the patient's health and the actions they took with respect to the performance of the contract for medical services. Other information must only be included when this is necessary with respect to conscientious health care provision. Article 7:454 Paragraph 1 does not provide any additional instructions on what kind of information must be included in the medical record. This is elaborated in the KNMG Guidelines for dealing with medical data.³³¹

Comparable to what was presented in section 6 about the European perspective, the thinking about patients' rights in the Netherlands changed in the 1970s.³³² From 1980 to 1982, the *Centrale Raad voor de Volksgezondheid* [Council for Public Health]³³³ established a committee which was guided by Leenen.³³⁴ The commission published five subreports on patients' rights.³³⁵ In the 1980s regulation of patients' rights was considered desirable.³³⁶ In 1990 the proposed amendment to the Civil Code with respect to the inclusion of the contract for medical services was presented.³³⁷

325 Van Wijmen 1983, p. 119.

326 Van der Mijn 1983, p. 86-87.

327 Roscam Abbing 1983, p. 98.

328 Roscam Abbing 1983, p. 101-102.

329 Roscam Abbing 1994, p. 190.

330 Leenen, *Medisch Contact* 1977, p. 490-491.

331 KNMG Guidelines for dealing with medical data, Para. 6.2, p. 111-114.

332 *Kamerstukken II* 1982/83, 16771, no. 14, p. 25.

333 Nowadays *Raad voor de Volksgezondheid en Samenleving* [Council for Health and Society] (RvS).

334 *Kamerstukken II* 1982/83, 16771, no. 14, p. 25.

335 Centrale Raad voor de Volksgezondheid 1980; Centrale Raad voor de Volksgezondheid 1981; Centrale Raad voor de Volksgezondheid 1982a; Centrale Raad voor de Volksgezondheid 1982b and Centrale Raad voor de Volksgezondheid 1982c.

336 *Handelingen II* 1981/82, no. 29 and *Kamerstukken II* 1982/83, 16771, no. 14, p. 25.

337 *Kamerstukken II* 1989/90, 21561, no. 2.

In legal literature, not everyone was in favour of this patients' rights Act. Some, for instance, did not think that a separate regulation of a contract for medical services was necessary because the more general regulations and principles, such as reasonableness and fairness, on contract law would suffice.³³⁸ Moreover, the rights to privacy and to bodily integrity³³⁹ were already laid down in the Dutch Constitution.³⁴⁰ Others wondered why the legislator had opted for a regulation of patients' rights in contract law while in other fields legislation to protect the weaker party was established in public law.³⁴¹ Moreover, some did not think the WGBO clarified the legal relationship between the physician and the patient. With respect to the performance of a contract for medical services in a hospital, it is unclear who the patient contracted with. This can be either the health professional, in case they are providing health care in the said hospital based on an admission agreement, or the hospital itself when the health professional is employed by said hospital.³⁴² When a failure in the performance of the contract for medical services occurs, the patient would first have to find out who they contracted with. Only then can they claim damages from this party. To protect the patient, it would have been better to apply the general rules on judicial Acts as laid down in Article 3:33 in conjunction with Article 3:35 BW to this situation, as was the situation prior to the WGBO.³⁴³ Other issues that remained ambiguous according to some in academia are the *locum tenens*,³⁴⁴ the relation between the WGBO and other regulations such as the physician–patient model arrangement³⁴⁵ and the binding force of the contract for medical services against patients who did not conclude the contract for themselves.³⁴⁶ Furthermore, the provision in the WGBO which declares that the WGBO applies equally to certain situations without the existence of a contract for medical services³⁴⁷ has drawn criticism.³⁴⁸

7.4 Patients' rights in the WGBO

7.4.1 Scope of the WGBO

The WGBO defines its scope in Article 7:446 BW. The WGBO is applicable to contracts for medical treatment, as stated in Article 7:446 Paragraph 1 BW. Under the WGBO, patients and health professionals have a contractual relationship. A contract for provision of medical services is established when a natural person or a legal entity – the health care professional

338 Kortmann, *WPNR* 1990, p. 743 and 746.

339 Art. 10 and 11 GW.

340 Kortmann, *WPNR* 1990, p. 746.

341 Hondius & Nadorp-van der Borg, *TvGR* 1988, p. 4.

342 Strens-Meulemeester, *NTBR* 1995, p. 86; *Kamerstukken II* 1989/90, 21561, no. 3, p. 27 and *Kamerstukken II* 1991/92, no. 11, p. 40-41 as referred to by Strens-Meulemeester, *NTBR* 1995, p. 86.

343 Strens-Meulemeester, *NTBR* 1995, p. 86.

344 Hondius & Nadorp-van der Borg, *TvGR* 1988, p. 23 and Hermans, *Sociaal Recht* 1991, p. 6.

345 Hermans, *Sociaal Recht* 1991, p. 6.

346 Hermans, *Sociaal Recht* 1991, p. 6.

347 Currently Art. 7:464 BW.

348 For instance Sluyters, *WPNR* 1990, p. 763-765.

– commits themselves to another – the patient – to provide medical services. Article 7:446 Paragraph 2 and Paragraph 3 define provision of medical services. According to these paragraphs, provision of medical services refers to “*a. all activities – including examination and giving advice – which directly concern a person and which are intended to cure that person of a disease, to prevent that person from contracting a disease or to assess the condition of that person’s health, or which constitute obstetrical assistance;*”³⁴⁹ and “*b. activities other than those referred to under a, which directly concern a person and which are carried out by a physician or dentist in a professional capacity.*”³⁵⁰ This means that, when a patient visits their GP and the GP offers advice, the WGBO is applicable. However, when a patient consults a physician who provides medical services in a hospital, it depends whether this physician has a contract of employment with the hospital or provides medical services in that hospital based on an admission agreement.³⁵¹ In this first situation, a contract for medical services will be generated between the physician and the patient; in the second situation such a contract will be formed between the hospital and the patient.³⁵²

No consensus exists on the exact start of the contract for medical services. When a patient registers at a GP’s surgery, their relationship is referred to as a relationship of availability.³⁵³ From the registration onwards, the GP is available to provide health care to this patient i.e. appointments can be made and the patient can visit during the GP’s consultation hours. It is sometimes argued that this relationship of availability only entails the opportunity to enter into a contract for provision of medical services when necessary and is not a contract for medical services in itself.³⁵⁴ In this view, a distinction is made between the relationship of availability and the relationship of treatment, i.e. the moment when actual medical services are provided. Therefore, in this view, the actual treatment or consultation entails the start of a contract for provision of medical services.³⁵⁵ From this point of view, the relationship of availability is characterised as a so-called framework agreement, only to be transformed into

349 Art. 7:446 Para. 2(a) BW, translated by Hondius and Van Hooft in: Hondius & Van Hooft, *NILR* 1996, p. 9.

350 Art. 7:446 Para. 2(b) BW, translated by Hondius and Van Hooft in: Hondius & Van Hooft, *NILR* 1996, p. 9.

351 See section 7.3 above where the remarks on this regulation as discussed by Strens-Meulemeester in: Strens-Meulemeester, *NTBR* 1995, p. 86 are presented.

352 *Kamerstukken II* 1989/90, 21561, no. 3, p. 9 and 27. For examples and an elaboration, see Wijne 2017a, p. 9-11.

353 Brands 1997, p. 20.

354 Houben 2005, p. 139-140.

355 Exceptions are emergency health care where the relationship might be based on benevolent intervention. Brands 1997, p. 20.

a contract for provision of medical services when the patient is in need of such services.³⁵⁶ Others, however, state that the relationship of availability itself entails the intention to undergo a medical treatment in the future and therefore can be characterised as the start of the contract for provision of medical services, even though the exact time the medical services take place cannot be determined at this point. Therefore, in this view, registering at the GP's surgery can be understood as the conclusion of a contract for provision of medical services.³⁵⁷ Advocates of this view make a connection with the explanatory memorandum to the WGBO, stating that the legislators' intention has been to understand the relationship of availability as the start of the contract for provision of medical services. They hereby refer to the legislators' explanation of the prohibition for the health professional to terminate the contract.³⁵⁸ While elaborating on this prohibition, the legislator uses the example of a GP who is by exception allowed to terminate their contract for medical services with a patient who moves to another part of the country, making the GP unable to provide them with the necessary health care in time.³⁵⁹ This approach seems convincing. The contract for medical services is concluded as soon as a patient has registered at the GP's practice and the contract is continued every time the GP provides medical services to this patient.

In some situations, it is not clear whether a contract for medical services will be established or not. Examples include certain types of eHealth care provision, which will be further elaborated in the following chapters. It can be stated at this point, however, that the patients' rights laid down in the WGBO must be applied in such situations because they are '*generally accepted*'³⁶⁰ In case law it is also shown that the WGBO has a broad range of applicability.³⁶¹

The KNMG *Richtlijn niet-aangaan of beëindiging van de geneeskundige behandelingsovereenkomst* [Guideline on not entering into or terminating a contract for medical services] can be used as a point of reference for answering the question of whether a contract for provision of medical services is established.³⁶² This guideline elaborates on termination of the contract of provision of medical services by the health professional. While explaining the conditions under which

356 Brands 1997, p. 19, referring to Van Wijmen, *NJB* 1985, p. 543, who discusses the relationship between the patient and their health care provider under the law on provision of services; at that time a specific regulation on the relationship between the physician and the patient as a part of the title on provision of services was still being considered.

357 Asser/Tjong Tjin Tai 7-IV 2018/392.

358 Art. 7:460 BW.

359 *Kamerstukken II* 1989/90, no. 21561, no. 3, p. 42.

360 Leenen/Dute & Legemaate (eds.) 2017, p. 104.

361 HR 12 March 2013, ECLI:NL:HR:2013:BY4859, *NJ* 2013/424, m.nt. Legemaate and discussed by Hulst *TGMA*, 2013, issue 2, p. 55-56.

362 KNMG/Doppegieter & Van Meersbergen 2005.

a physician may terminate the contract,³⁶³ the start of the contract and thus the application of Article 7:446 BW is discussed in the guideline too.³⁶⁴ The guideline on not entering into or terminating a contract for medical services states that, in case of uncertainty, the WGBO must be considered applicable.³⁶⁵ Article 7:464 BW extends the scope of the WGBO (and some of the provisions relating to the provision of services in general) to various situations that do not lead to the formation of a contract for medical services.

7.4.2 Rights related to information and consent

Second, the WGBO discusses informed consent. This right entails that a patient can only undergo a medical treatment after they have given their explicit consent. This consent should be given based on information the physician has provided him.³⁶⁶ According to Article 7:448 Paragraph 1 BW the health professional has to provide the patient with information on the examination, the proposed treatment, the developments regarding the examination, the treatment itself and the patients' health. In the most recent amendment to the WGBO, the method of shared decision-making was introduced, because this would reflect current trends in society.³⁶⁷ Although shared decision-making is not explicitly mentioned in Article 7:448 BW, according to the explanatory memorandum to this amendment, it must be the starting point.³⁶⁸ Shared decision-making would result in better decisions³⁶⁹ and counteract the information inequality.³⁷⁰ Article 7:448 Paragraph 2 lists the topics the health professional should provide information about in any case. The explanatory memorandum to this amendment stresses the importance of an ongoing consultation between the physician and the patient to ensure that the patient still approves of the treatment.³⁷¹ Paragraph 4 contains an exception for those cases where informing the patient might be disadvantageous for the patient. This is referred to as the therapeutic exception and cannot be acted on without consulting another physician. However, the information can be shared with a third person when the patients' best interest requires it. The withheld information must be provided to the patient as soon as the disadvantage is no longer expected.³⁷² At the patients' request, the physician must provide the information in writing.³⁷³ This also applies to the permission given by the patient.³⁷⁴

363 These are all exceptions, for Art. 7:460 BW prohibits the health professional from terminating the contract of medical services, unless they have specific reasons to do so. Examples of such specific reasons are provided in the KNMG Guideline on not entering into or terminating a contract for medical services. See KNMG/Doppegieter & Van Meersbergen 2005.

364 KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

365 KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

366 Art. 7:448 in conjunction with Art. 7:450 BW.

367 *Kamerstukken II* 2017/18, 34994, no. 3, p. 3.

368 *Kamerstukken II* 2017/18, 34994, no. 3, p. 3-6.

369 *Kamerstukken II* 2017/18, 34994, no.3, p. 3.

370 *Kamerstukken II* 2017/18, 34994, no. 3, p. 6.

371 *Kamerstukken II* 2017/18, 34994, no. 3, p. 4-5.

372 Art. 7:448 Para. 4 BW.

373 Art. 7:448 Para. 3 BW.

374 Art. 7:451 BW.

The patient also has a right to not receive any information on their health status if they do not wish to receive this information. This right, however, is not absolute. When complying with a request to not receive any information can result in harm for the patient or a third person, the health professional must not comply with such a request.³⁷⁵ Yet, the latter is an exception.³⁷⁶

Contrasting with the physicians' duty to provide the patient with information, is the patients' duty to provide the health professional with information. Furthermore, the patient has an obligation to cooperate in the performance of the contract for provision of medical services.³⁷⁷

7.4.3 Conscientious health care provision

Article 7:453 BW imposes the obligation of good professional conduct on the health professional. This means that the physician, in the performance of the contract for provision of medical services, must act as a good health care provider. Because the duty to act as a conscientious health care provider is an open norm pre-eminently, the legislator stressed that the exact interpretation of this open norm in practice should be filled in by the profession.³⁷⁸ The KNMG takes on this role by providing such interpretations to fill in the professional standards in its guidelines. The guideline on not entering into or terminating a contract for medical services, which is mentioned in section 7.4.1 above, is an example of such a guideline.³⁷⁹

7.4.4 Rights related to personal data and privacy

The WGBO contains several provisions related to patient's personal data and privacy. As already discussed in section 5.3, the physician is obligated to maintain a patient record, which the patient has the right to consult or to delete.³⁸⁰ According to Article 7:455 Paragraph 2 BW the patient cannot exercise their right to delete their medical file when retaining the information in the file is of importance to a third party, or when deleting the medical record will cause a conflict with the law.³⁸¹ The health professional should always grant the patient's request to consult their medical file unless granting this request would violate the privacy of another person.³⁸² Another important right of the patient is the right to medical confidentiality.³⁸³ As already explained in section 7.2.2, this right is ambiguous. On the one hand, this right intends to protect the individual's interest of protecting privacy while on the other hand, the right to medical confidentiality aims to protect the right to health care for

375 Art. 7:449 BW.

376 *Kamerstukken II* 1989/90, 21561, 3, p. 31 and Wijne, in: GS Bijzondere overeenkomsten, Art. 7:449 BW, note 4 (online, updated to 17 June 2020).

377 Art. 7:452 BW.

378 *Kamerstukken II* 1989/90, 21561, no. 3, p. 33-34, explicitly mentioning the KNMG, among others.

379 KNMG/Doppegieter & Van Meersbergen 2005.

380 Art. 7:454 and Art. 7:455 BW.

381 Art. 7:455 Para. 2 BW.

382 Art. 7:456 BW.

383 Art. 7:459 BW.

everyone. The rationale behind this right is the opportunity for everyone to freely consult a health professional without fearing a breach of their privacy.³⁸⁴ The health professional can only breach this obligation when one of the four following conditions apply: the patient gave their consent, a statutory regulation obliges this,³⁸⁵ there is a conflict of duties or other, compelling reasons of interest.³⁸⁶

Another key concept with respect to privacy is the right to spatial privacy, in the context of health care provision laid down in Article 7:459 BW. Based on this right, the contract for provision of medical services shall be performed without the presence of others, unless the patient has given their explicit consent to the presence of a third party.³⁸⁷ The right to spatial privacy also applies to interns. This means that the patient's explicit consent is also required for the presence of an intern during treatment.³⁸⁸

7.4.5 Special nature of the WGBO

The WGBO, being a special statute in the BW, more specifically a *lex specialis* of general contract law, derives from the general law of contracts at an important point: the freedom of contract. The latter is an important principle of (Dutch) contract law.³⁸⁹ While the patient enjoys the freedom to contact any health professional of their preference, a physician should not only always contract with the patient who is seeking their help; they also cannot terminate the contract unless they have serious reasons to do so.³⁹⁰ The explanatory memorandum mentions romantic feelings between the physician and the patient, the situation in which the patient moves away, resulting in the health professional's inability to provide health care within an appropriate time and the situation in which the patient does not cooperate.³⁹¹ Another peculiarity is the fact that the WGBO contains obligations for health professionals but, by contrast, few obligations for the patient.³⁹² Obligations for the patient are the duty to provide information and the duty to cooperate in the performance of the contract for medical services.³⁹³ Finally, the WGBO is a mandatory regulation, which means that it is not allowed to derogate from the WGBO to the detriment of the patient.³⁹⁴

384 HR 21 April 1913, *NJ* 1913, p. 958 and Leenen/Dute & Legemaate (eds.) 2017, p. 151.

385 Art. 7:457 BW.

386 Leenen/Dute & Legemaate (eds.) 2017, p. 158-162.

387 Art. 7:459 BW.

388 *Kamerstukken II* 1989/90, 21561, no. 3, p. 41.

389 Asser/Sieburgh 6-III 2018/50, 55 and 58 This principle is not directly included in the Dutch Civil Law but is however implicitly referred to when stated that a judicial Act that violates the public order or public morality is invalid (Art. 3:40 Para. 1 BW) and that a result of an agreement that is unacceptable according to standards of reasonableness and fairness will not be applicable in such circumstances (Art. 6:248 Para. 2 BW).

390 Art. 7:460 BW.

391 *Kamerstukken II* 1989/90, no. 3, p. 33 and 42. For examples see Buijsen 2016, p. 47-48; Hulst 2016, p. 231-232 and Wijne 2017a, p. 18.

392 Hondius & Nadorp-van der Borg, *TvGR* 1988, p. 5.

393 Art. 7:452 BW.

394 Art. 7:468 BW and Hondius & Van Hoof, *NLJ* 1996.

7.4.6 Malpractice liability

Additionally, the WGBO provides several rules related to liability.³⁹⁵ Whenever the treatment takes place in a hospital, the patient can hold both the physician and the hospital liable for damage suffered in case of a failure in the performance of the medical treatment contract.³⁹⁶ This can help to overcome the difficulties that can be encountered when the patient does not know whether the physician is employed by the hospital or performs health services in that hospital on the basis of an admission contract.³⁹⁷ Section 7.4.1 explained that this is important for the question of who the patient has contracted with. In other words, who to address in case of damages. The doctrine of central liability aims to circumvent this problem.³⁹⁸ Central liability is an example of strengthening the patient's legal status.³⁹⁹ For more explicit rules related to liability, the regulations on liability in the BW should be consulted. The BW contains rules on contractual liability as well as noncontractual liability.⁴⁰⁰

8. CONCLUDING REMARKS ON PATIENTS' RIGHTS

This chapter discussed patients' rights, or, as can be stated as a result of this chapter, the application of human rights in health care. First, the right to health and its importance was examined. Article 12 ICESCR is the leading treaty provision containing the right to health. In this provision, the right to health is formulated as the right to the highest attainable standard of health. The obligations following from this right are explained by the CESCR in its General Comment no. 14.⁴⁰¹ The rights in the ICESCR, including Article 12, should be progressively realised by states. Progressive realisation involves realisation based on what can be expected from a country regarding its social and economic situation. However, countries are expected to use the maximum of their available resources to realise the rights in the ICESCR.⁴⁰² The right to health does not equal a right to be healthy.⁴⁰³ However, it is an inclusive right, meaning that several other social and economic factors can contribute to realising the right to the highest attainable standard of health, such as clean drinking water and the availability of food and nutrition.⁴⁰⁴ Since this study will use the AAAQ framework

395 For a thorough explanation of medical liability in the Netherlands, please consult Giesen & Engelhard 2011 and Wijne 2017b.

396 Art. 7:462 BW.

397 *Kamerstukken II* 1989/90, 21561, no. 3, p. 23.

398 *Kamerstukken II* 1989/90, 21561, no. 3, p. 23.

399 Hulst 2016, p. 230.

400 Art. 6:75 and onwards BW for contractual liability and Art. 6:162 onwards BW for non-contractual liability.

401 CESCR General Comment no. 14 (2000) on Health.

402 Art. 2 ICESCR and Art. 2 (1) ICESCR: UN Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment no. 3 (1990) on the Nature of States Parties' Obligations, Para. 9 and 10.

403 CESCR General Comment no. 14 (2000) on Health, Para. 8 and 9.

404 CESCR General Comment no. 14 (2000) on Health, Para. 4.

as developed in General Comment no. 14 as a framework for assessment, the importance of the work of UN treaty bodies, such as general comments, was discussed. This work is generally seen as authoritative.

The right to health, besides being laid down in several other international treaties and regulations,⁴⁰⁵ is also laid down in the Dutch Constitution.⁴⁰⁶

Section 3 elaborated on the role of human rights in health law and enunciated the theories about health law in doctrine. Although no consensus exists on the exact underlying human rights principles, consensus about the fact that health law in general and patients' rights in particular are based on human rights does exist.⁴⁰⁷

International law as such does not contain specific treaties related to patients' rights. Internationally, patients derive protection from human rights treaties, such as the ICCPR, the ICESCR and the ECHR. Besides these treaties, international guidelines can help in determining the rights of the patient. In this context, the WMA Declaration on the Rights of the Patient of 1981 is of importance.⁴⁰⁸ These guidelines contain ten principles, including freedom of choice⁴⁰⁹ and the right to self-determination.⁴¹⁰

Because of the changes in both society and health care, in the end of the twentieth century the need to provide patients with specific rights grew. Societal developments relate to the change of traditional views in society. Unlike before, when the physician enjoyed absolute authority, patients became increasingly articulate. At the same time, fast and ongoing developments in health care occurred and the fear of 'dehumanization' of health care grew.⁴¹¹ These changes were the incentive for regulating patients' rights, on national as well as on international level. In Europe, these developments started with the WHO Regional Office for Europe Declaration on the Promotion of Patients' Rights in Europe, which was meant as a guideline for European countries to regulate patients' rights in their national legal order.⁴¹²

405 Art. 25 Para. 1 UDHR, Art. 14 UDBHR, Art. 13 ESC, Art. 13 RESC and Art. 35 CFREU.

406 Art. 22 Para. 1 Gw.

407 Dutch health law scholars can be divided into three schools: the school that considers self-determination and equal access to health care as the founding principles of health law (Leenen 1988, p. 20), the school that rejects the idea of principles typical to health law (Sluijters 1985, p. 149) and the school that recognises the realisation of the right to health care as the principle underlying health law. (Buijsen, *Ars Aequi* 2004, p. 428 and Buijsen 2016, p. 45).

408 World Medical Association (WMA) Declaration on the Rights of the Patient. Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981, and amended by the 47th WMA General Assembly, Bali, Indonesia, September 1995, and editorially revised at the 171st Council Session, Santiago, Chile, October 2005.

409 Principle 2 WMA Declaration on the Rights of the Patient.

410 Principle 3 WMA Declaration on the Rights of the Patient.

411 WHO, Regional Office for Europe 1995c, p. 15 and D'Ancona 1995, p. 2-3.

412 D'Ancona 1995, p. 3; Asvall 1995, p. 7 and WHO, Regional Office for Europe 1995c, p. 14-15.

The declaration elaborates on information and consent,⁴¹³ confidentiality and privacy,⁴¹⁴ and rights related to care and treatment.⁴¹⁵

In Europe, on the other hand, several treaties, directives and regulations containing patients' rights have been drafted, such as the Patient Mobility Directive concerning patients' rights in cross-border health care. This directive aims to regulate, among other things, the reimbursement of costs made for cross-border health care⁴¹⁶ and the applicable law in a situation of cross-border health care.⁴¹⁷ Furthermore, in Europe patients can derive protection from the GDPR. This regulation aims to strengthen individuals' rights, for example by adding a right to be forgotten.⁴¹⁸

The Dutch national law contains a body of patients' rights in the WGBO. The WGBO is part of the BW and defines the relationship between the physician and the patient as a contract.⁴¹⁹ The WGBO contains mandatory law, which makes it impossible to derogate from the regulation to the detriment of the patient.⁴²⁰ This comprehensive body of patients' rights is supplemented by professional standards of good practice, such as the various good practice guidelines issued by the Royal Dutch Medical Association (KNMG).

In summary, both in Europe and in the Netherlands, patients' rights treaties, regulations, directives and statutes exist. The WHO genomic resource centre conducted a study on patients' rights in various European countries and found that at least consensus exists about the following patients' rights: the right to privacy, the right to confidentiality, the right to consent, the right to information and the right to equal access to health care of good quality.⁴²¹ The main focus of the present study will be on these patients' rights, supplemented by international as well as Dutch national good practice guidelines.

413 Section 2 and 3 Declaration on the Promotion of Patients' Rights in Europe.

414 Section 4 Declaration on the Promotion of Patients' Rights in Europe.

415 Section 5 Declaration on the Promotion of Patients' Rights in Europe.

416 Art. 7-9 Patient Mobility Directive.

417 Art. 4 Para. 1(a) Patient Mobility Directive.

418 Art. 17 GDPR.

419 Art. 7:446 BW.

420 Art. 7:468 BW.

421 WHO Genomic resource centre, 'Patients' rights', who.int. Source: who.int/genomics/public/patientrights/en/.

Part II

Patients' Rights in eHealth Care Provision

4





E-consultation and patients' rights

1. INTRODUCTION

E-consultation, as a relatively new way to provide health care, leads to the question of how to protect patients' rights when it is applied. This chapter will discuss e-consultation and its implications for patients' rights. Attention will be paid to how patients' rights are or should be applied during e-consultation. If the existing patient's rights require a new interpretation, the chapter will address this new interpretation as well. E-consultation, as explained in chapter 2, is a means by which a patient can contact a health professional by posing a question using ICT.¹ E-consultation can be offered through various applications on a computer or a mobile device such as (video) chat, or an indirect conversation through email.² E-consultation offers health professionals the possibility to make an online diagnosis (e-diagnosis). Once a diagnosis has been made, an online therapy can be started or the physician can prescribe medication (e-therapy).³ Patients can have e-consultations with their own health care providers but e-consultation with a physician they have never met is also possible under certain conditions; these conditions are to be discussed in this chapter. When necessary, this chapter will make a distinction between e-consultation within an existing physician–patient relationship and e-consultation outside the scope of an existing physician–patient relationship.

As presented in chapter 1, the right to health and patients' rights are interwoven and interrelated. Therefore, the extent to which e-consultation can contribute to the realisation of the right to health, a fundamental human right, will be discussed first (section 2). Protection by means of patients' rights, as explained in chapter 1, can help in realising the right to health. Next to this, other factors can contribute to this realisation as well. Because, as stated in chapter 1, the realisation of the right to health antecedes the actual health care provision, the right to health will be discussed before the patients' rights framework in the WGBO, which must be taken into account once the right to health is exercised and health care is provided.

E-consultation in relation to the right to health will be analysed according to the AAAQ framework.⁴ Next, the application of the patients' rights during e-consultation will be discussed. The major part of this patients' rights framework can be found in the WGBO. Therefore, before this framework is applied to e-consultation, the applicability of the WGBO to e-consultation, both within and outside the scope of an existing contract for provision of medical services, will be discussed (section 3). The following sections will elaborate on e-consultation and a selection of patients' rights: the right to privacy (section 4), the right to

1 Van Meersbergen 2012, p. 99-100 and Schuurmans (ed.) 2016, p. 80.

2 Schuurmans (ed.) 2016, p. 80-82.

3 Online prescription of medication is subject to legislation and good practice guidelines. The present chapter will elaborate on this issue.

4 AAAQ stands for availability, accessibility, acceptability and quality. This framework was designed by the CESCR (2000) in CESCR General Comment no. 14 (2000) on Health.

confidentiality of medical information (section 5) and the right to informed consent (section 6) respectively.

2. E-CONSULTATION AND THE RIGHT TO HEALTH

2.1 Availability

Availability of health care facilities, goods and services is, according to the AAAQ framework, the first element that is necessary to realise the right to health.⁵ At first sight, e-consultation seems to be able to contribute to the availability of health care. E-consultation facilitates communication with a health professional at any place and any time, and therefore has the potential to make health care available to people in rural areas.⁶ However, this does not seem to be a major issue in the Netherlands, where most people reside not too far from a health facility. Yet, e-consultation still has the ability to make a positive contribution to the availability of health care. Asynchronous e-consultation especially has the potential to increase the availability of health care because patients and health professionals do not need to be available at exactly the same time.⁷

E-mental health is a field where e-consultation can increase the availability of health care in the Netherlands. Anonymous e-consultation was made possible by an amendment to the *Zorgverzekeringswet* [Health Insurance Act] (Zvw) which facilitates the reimbursement of anonymous e-mental health, including anonymous e-consultations.⁸ Health care providers who offer such e-consultations are paid from public funds.⁹ According to the legislator, e-consultation is likely to reach people who would previously avoid seeking health care.¹⁰ From that point of view, anonymous e-consultation can contribute to increasing the availability of health care by involving this group of patients as well.

E-consultation can increase the availability of health care across borders because it allows patients and health professionals to contact each other online, regardless of their actual place of residence.¹¹ However, not too much should be expected from this greater availability

5 CESCR General Comment no. 14 (2000) on Health, Para. 12(a).

6 Spradley, *Tulane Journal of Technology and Intellectual Property* 2011, p. 312.

7 Timmer 2011, p. 41.

8 *Srb.* 2016, 143, Art. 70a Zvw; elaborated in chapter 6, Para. 2 of the Ministerial Regulation of the Minister of Health, Welfare and Sport of 1 September 2005, no. Z/VV-2611957, containing rules relating to carrying out the Health Insurance Act (Health Insurance Regulation), *Stcrt.* 2005, 171.

9 *Kamerstukken II* 2012/13, 33675, no. 3, p. 7.

10 *Kamerstukken II* 2012/13 33675, no. 3, p. 3.

11 COM(2010)603 final, p. 8 and 9, SWD(2012)414 final, p. 3 and Van der Meer & Nouwt 2011, p. 295.

because other factors, such as language barriers, play a role too.¹² Cross-border e-consultation can be beneficial for people who reside in a country other than their country of origin. An example of a successful e-consultation that increased availability across state borders took place in the United States. Korean patients who live in Georgia were put in contact with a psychiatrist in California who spoke Korean.¹³

The availability of ICT itself, however, can be a drawback for the extent to which e-consultation boosts the availability of health care. As regards the contribution of e-consultation to the availability of health care on the international level, it must be noted that not every country has equal IT facilities nor are IT facilities equally divided within countries. This is referred to as the digital divide.¹⁴ This digital divide might counteract the presupposed increase of availability of health care due to e-consultation.

Even though most people in the Netherlands are connected to the Internet, it is unsure whether they possess the skills necessary to take part in an e-consultation. In 2019, 97% of the population in the Netherlands had access to the Internet according to the *Centraal Bureau voor de Statistiek* [Statistics Netherlands] (CBS).¹⁵ Not everyone, however, possesses equal ICT skills and therefore not everyone will be able to benefit from an increased availability of health care due to e-consultation. Moreover, besides ICT-related skills other skills, such as reading comprehension and writing are important as well.¹⁶ Not every patient is able to explain their health situation in words¹⁷ or to make an estimate about the seriousness of their complaint, as examples in practice sometimes show.¹⁸

A final obstacle for e-consultation to reach its potential to contribute to the availability of health care lies within its actual use. The eHealth-monitor, a yearly study conducted by the *Nederlands Instituut voor onderzoek van de gezondheidszorg* [Netherlands Institute for Health Services Research] (NIVEL) and the *Nationaal ICT Instituut in de Zorg* [Centre of expertise for standardisation and eHealth] (Nictiz), shows that e-consultation is not widespread under

12 Cunningham et al. 2014 mention a language barrier within multilingual countries. Cunningham et al. 2014, p. 26 and Meijman & Den Ouden, *Medisch Contact* 2014, p. 1585.

13 Ye et al., *TELEMEDICINE and e-HEALTH* 2012, p. 797-802.

14 Cunningham et al. 2014, p. 26 mention a digital divide between certain groups of people as a potential challenge for eHealth. Timmer 2011, p. 78-79 mentions the digital divide within society.

15 'Internet; toegang, gebruik en faciliteiten', cbs.nl. Source: opendata.cbs.nl/statline/#/CBS/nl/dataset/83429NED/table?fromstarweb, last modified 8 October 2019.

16 See, for example, Meijman & Den Ouden, *Medisch contact* 2014, p. 1585.

17 KNMG/Van Meersbergen Guidelines for online Physician-Patient Contact, Utrecht: KNMG 2007, supplement 2, p. 15. This guideline was replaced by the KNMG Guidelines for dealing with medical data as of 2020. The supplement containing the pros and cons of online communication, however, has not been added to the KNMG Guidelines for dealing with medical data.

18 A GP once told me that he received an email from one of his patients, stating that her husband did not really feel well and also had pain in the chest. Fortunately, the GP read this email shortly after it was sent and he could provide the necessary health care in time.

patients yet. In 2016, for instance, 3% of patients had consulted their GP online and 3% of patients had consulted their medical specialist online,¹⁹ while in 2019, 8% of patients consulted their GP online and 6% of patients consulted a medical specialist online.²⁰ Even though a slight increase of e-consultations can be observed, e-consultation still has a long way to live up to its potential to increase the availability of health care.

Yet, e-consultation does have the capability to contribute to increasing the availability of health care. As mentioned in chapter 2, eHealth care is usually part of a blended care treatment. This means that it is offered in combination with face-to-face health care provision.²¹ Usually, e-consultation will be presented as an additional way to receive health care, thus increasing the availability of different ways to obtain health care.

2.2 Accessibility

2.2.1 Non-discrimination

The next condition in order to realise the right to health is accessibility. As discussed in chapter 3, accessibility consists of four more specific conditions: non-discrimination, physical accessibility, affordability and information accessibility.²²

Because the patient and the physician often do not see each other during an e-consultation, this type of eHealth care provision has the potential to contribute to combating discrimination. This means that it can help to fulfil the first condition of accessibility: non-discrimination. Sensitive topics which patients would rather not discuss face-to-face can be discussed in a relatively anonymous way, probably diminishing feelings of discrimination. An example can be found in the amendment to the Zvw as presented in section 2.1.

On the other hand, e-consultation can reinforce discrimination because people who do not know how to use ICT or how to perform an e-consultation and people who are not interested in online consultations in particular or ICT in general risk being discriminated against when e-consultations are added to their health care process.²³ Those who do not know how to use ICT are referred to as computer illiterate.²⁴ People who are not interested in using ICT and

19 Krijgsman et al. 2016a, p. 68 and Krijgsman et al. 2016b, table 4-13 and table 4-20, p. 54 and 57.

20 Wouters et al., 2019b, part of Wouters et al. 2019a, p. 8-9 and Wouters et al. 2019c, table 2.27 and 2.28, p. 28.

21 Van Raalte 2015, p. 53.

22 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

23 See, for example, Buijsen, *Medisch Contact* 2012, p. 1609 on the risk of exclusion for the computer illiterate.

24 According to Dikke Van Dale 2015, a 'digibeet' is 'someone who is completely ignorant in the field of computers, information technology.' According to Dikke Van Dale 2015, 'digibeet' can be translated as 'computer illiterate.'

therefore refrain from it will also be excluded.²⁵ According to Zajicek, the elderly are an example of a group that risks exclusion.²⁶ It is more difficult to convince them of the necessity of the Internet because they are not used to it.²⁷ The findings by Selwyn et al. indicated that a group of elderly people does not use ICT because they do not find it interesting or do not think it is necessary.²⁸ Coleman et al. describe in their study possible ways to get elderly people who are not interested in ICT to use ICT in spite of their disinterest.²⁹

That said, the risk of excluding computer illiterate and the digitally self-excluded is minimal if e-consultation is offered as a part of a blended care treatment.

2.2.2 Physical accessibility

The second condition for accessible health care is physical accessibility. Physical accessibility will increase because e-consultations offer people the possibility to contact a health professional at any place, at any time. E-consultations can be particularly beneficial for those with difficulties in travelling to the GP's surgery.³⁰ An example is provided by *Patiëntenfederatie Nederland* in a short video. The video shows a grandmother who is using video chat to communicate with her granddaughter. Afterwards, she visits her GP for a check-up consultation. The elderly lady experiences a lot of trouble travelling to the GP's surgery; her travel time even exceeds the time of the consultation with the GP. In the next scene, the video shows a much happier looking grandmother using video chat to consult her GP. The video illustrates the Dutch Patients' Congress' point of view on e-consultation: every patient should be able to contact their GP by using ICT.³¹ The video, albeit slightly idealistic, does indeed make a good case for an increased physical accessibility.

Because a physical journey is no longer necessary to consult a health professional, health care across borders becomes physically accessible as well.³² However, other problems are imaginable in this situation, such as the language barrier³³ that was mentioned in section 2.1, or the differences in quality of health care between countries.

Concluding, e-consultation can contribute to the physical availability of health care, especially for people with reduced mobility. Nevertheless, expectations related to cross-border availability need to be tempered because of the reasons mentioned.

25 For instance Zajicek 2007, p. 35 and Coleman et al. 2010, p. 175.

26 Zajicek 2007, p. 35.

27 Zajicek 2007, p. 37.

28 Selwyn et al., *Ageing & Society* 2003, p. 575.

29 Coleman et al. 2010, p. 175-178.

30 See, for instance, Schalken et al. 2010, p. 42.

31 'Is oma digitaler dan de dokter?', Patiëntenfederatie Nederland, Youtube.com. Source: [youtube.com/watch?v=GjXd7Gt6a9Y](https://www.youtube.com/watch?v=GjXd7Gt6a9Y).

32 COM(2010) 603 final, p. 8 and 9 and SWD(2012) 414 final, p. 3.

33 Cunningham et al. 2014, p. 26 mention a language barrier within multilingual countries.

2.2.3 Affordability

The third condition of accessibility is affordability.³⁴ This condition can relate to the question whether the health service in question is reimbursable. In the Netherlands, e-consultations have become an integral part of health services, although they remain underutilised.³⁵

According to Nictiz, many GPs in the Netherlands claim fewer expenses for e-consultation than they can actually claim.³⁶ What they are allowed to claim, can be found in the tariff decision.³⁷ E-consultations in general practice are included in the regular health services and can be claimed by physicians, following from the *Prestatie- en tariefbesikking huisartsenzorg en multidisciplinaire zorg 2020* [Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020] by the *Nederlandse Zorgautoriteit* [Dutch Healthcare Authority] (NZa).³⁸ The NZa is – among other things – responsible for describing treatments and setting tariffs for the Dutch Health Care Market.³⁹ E-consultation is claimable when certain conditions formulated by the profession are met.⁴⁰ What these conditions are and how they apply to e-consultation will be discussed in section 3 in more detail. As of 2019, the Performance and Tariff Decision does not make a distinction between online consultation and face-to-face consultation any more; tariffs are based on the duration of the consultation.⁴¹ Moreover, from 2017 on, as already mentioned, anonymous e-mental health, including e-consultations, will be reimbursed by means of a subsidy from public funds.⁴² With the inclusion of e-consultations in regular health services and with opportunities for reimbursement for both health professionals and patients, e-consultations will not harm the affordability of health care. Because e-consultation can take place at any place and any time,

34 CESC General Comment no. 14 (2000), Para. 12(b).

35 Krijgsman et al. 2016b, table 4-13 and table 4-20, p. 54 and 57; Krijgsman et al. 2016a, p. 68; Wouters et al., 2019b, p. 8-9, part of Wouters et al. 2019a and Wouters et al., 2019c, table 2.27 and 2.28, p. 28. As elaborated in section 2.1 above.

36 Nictiz, 'Decalatiemogelijkheden e-consult', nictiz.nl Nieuws 5 February 2018. Source: nictiz.nl/nieuws/declaratiemogelijkheden-e-consult/#:~:text=Huisartsen%20mogen%20voor%20een%20e,de%20Nederlandse%20Zorgautoriteit%20(nza).

37 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04.

38 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, section 1.2, Para. 3 and 4, p. 8.

39 Art. 16 and Art. 16a *Wet marktordening gezondheidszorg* [Health Care Market Regulation Act] (Wmg), *Stb.* 2006, 415.

40 NZa Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REGCU-20622-04, section 1.2, Para. 4, p. 8. The Performance and Tariff Decision refers to the KNMG Guidelines for online Physician–Patient Contact (KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007) for these conditions. This guideline, however, is replaced by the KNMG Guidelines for dealing with medical data as of 2020.

41 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, section 1.2, Para. 3, p. 8.

42 Art. 70a Para. 1 in conjunction with Art. 6.2.1 et seq. *Regeling Zorgverzekering* 1 September 2015, no. Z/VV-2611957.

patients can save travelling costs as well as time.⁴³ Due to this, such consultations will be more affordable for patients. This is an asset of e-consultation as regards affordability.

However, the costs of acquiring software, implementation and training might lessen the advantage slightly.⁴⁴ Even though the new generations grew up with ICT and are therefore faster in making themselves familiar with a certain type of new application (primary schools already pay attention to programming),⁴⁵ it takes a while before these new generations are old enough to work as health professionals. Moreover, learning to work with new software always takes time and therefore costs money, even for those who already possesses ICT-related skills. According to a study conducted by the NHG, start-up costs were perceived as a reason not to offer eHealth care provision.⁴⁶

2.2.4 Information accessibility

The last condition of accessibility is the accessibility of information.⁴⁷ At first sight, e-consultation does not seem to contribute to disseminating health information. E-consultation is a tool to provide health care and takes place between physicians and their patients, in private. Only public e-consultations, such as the Twitter consultation hour (briefly mentioned in chapter 2 and discussed more elaborately in section 3.4.3 have the potential to contribute to access to public health information. The public nature of these consultation hours implies that others can also benefit from answers given during these consultations. A question that is posed on Twitter is published on both the sender's and the receiver's wall. This means that the questions, along with the answers, can be seen by the sender's and the receiver's followers. If the Twitter accounts are public, everyone can see the questions and answers.⁴⁸ Especially in the latter situation, Twitter consultation can contribute to the accessibility of health information. If a person has a general question about their health and someone else posed this question before them on Twitter, this person can find their answer without having to contact a health professional themselves. Therefore, Twitter consultations containing general questions and answers can contribute to the accessibility of information about health. Other electronic consultations, however, cannot because of their private nature.

2.3 Acceptability

The next condition to realise the right to health, is acceptability.⁴⁹ Acceptability is divisible into two subconditions: first, in order to be acceptable, health services should be provided

43 Timmer 2011, p. 77-78.

44 Schalken et al. 2010, p. 79-80 and 124.

45 See FutureNL, *Futurenl.org*, futurenl.org/.

46 Van Duivenboden 2015, p. 7.

47 CESCR General Comment no. 14 (2000), Para. 12(b).

48 See 'New user FAQ', help.twitter.com. Source: help.twitter.com/en/new-user-faq.

49 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

with respect for medical ethics.⁵⁰ Patients' rights Acts such as the WGBO and guidelines by the profession, for instance those drafted by the KNMG, are a point of departure to meet this condition. Other statutes and regulations that must be complied with are the GDPR, the UAVG and the *Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg* [Act on additional regulation on processing personal data in health care].⁵¹ What the WGBO, the GDPR and the KNMG guidelines – and other good practice guidelines – exactly entail for e-consultations will be discussed in section 4.

The other subcondition for acceptable health services is cultural acceptability.⁵² E-consultations can be a means to offer patients health care in a way that they consider appropriate, for instance when they are able to request an e-consultation with a physician of their own linguistic, cultural or religious background. A study conducted by Ye et al. illustrates this. For this study, patients with a Korean background living in Georgia, United States were put into contact with a psychiatrist in California, United States who shared their background and spoke their language. Patients reported that they found this type of health care provision acceptable.⁵³

For e-consultation to contribute to provide health care in an acceptable way, e-consultation itself must be considered acceptable by patients first. For instance, inappropriate security measures to protect patients' privacy might result in a lack of trust and can therefore lead to a hesitance, or a complete unwillingness to use e-consultation.⁵⁴ This is confirmed in a study conducted among patients. One of the outcomes of this study was that patients were more likely to use eHealth applications if they did not fear that their privacy would be violated.⁵⁵ To some people, however, e-consultation might not be an acceptable tool at all. For instance, the digitally excluded would prefer to hold their consultations with their GP offline, during a regular, face-to-face consultation.⁵⁶

Another interesting aspect of acceptability is acceptance by health professionals. For a relatively new tool such as e-consultation, to successfully contribute to enhancing the right to health, acceptance by all its users is of major importance. Notwithstanding a willingness by patients to use this type of eHealth care, without health care providers' willingness to utilise this tool, e-consultation cannot contribute to realising the right to health. In the Netherlands, for instance, GPs were reluctant at first to provide e-consultations. They feared

50 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

51 *Stb.* 2008, 164.

52 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

53 Ye et al., *TELEMEDICINE and E-HEALTH* 2012, p. 797-802. This example was also described in Kokabisaghi, Bakx and Zenelaj, *ELR* 2016, p. 159.

54 Schalken et al. 2010, p. 30-31.

55 Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980-984.

56 See, for example, Coleman et al. 2010, as quoted by Kokabisaghi, Bakx and Zenelaj, *ELR* 2016.

that such a tool would lead to an extra workload, for which they would not be able to charge. Furthermore, they were not always convinced of e-consultations' potential to be a means of delivering health care of good quality. In the meantime, health care providers' acceptance of e-consultation (and other eHealth tools) seems to have increased. A study conducted in 2008 demonstrated that the acceptance of e-consultations by GPs was still rather low in 2008.⁵⁷ The eHealth-monitor 2016 shows that eHealth is gradually more accepted by health professionals, especially in mental health care, but some improvements such as better compensation for eHealth services as well as solving interoperability and implementation issues remain necessary.⁵⁸ As for GPs and medical specialists, 58% and 36% had a positive attitude towards online contact with patients in 2016.⁵⁹ In 2019, 70% of nurses and 60% of physicians had a positive attitude towards eHealth in general.⁶⁰ Hence, acceptance of e-consultation seems to have grown among health professionals.

According to the eHealth-monitor 2016, in 2016 29% of patients reported that they were not interested in asking their GP a question by email or on a website⁶¹ and 27% of patients who visited a medical specialist reported that they had no interest in asking this medical specialist a question by means of a website or by means of email.⁶² 45% of patients reported not to be interested in video consultation with their GP and 39% of patients who visited a medical specialist reported that they were not interested in video consultation with this specialist.⁶³ The eHealth-monitor 2019 showed that 31% of patients were uninterested in asking their GP a question on a website or by means of email.⁶⁴ For patients who visited a hospital, this was 28%.⁶⁵ The results from the respective eHealth-monitors of 2016 and 2019, as presented in section 2.1, showed that the actual use of e-consultation is not yet widespread.⁶⁶ A 2017 Nictiz and NIVEL study on e-consultation showed that not all patients considered e-consultation a secure means of health care provision.⁶⁷ These findings indicate that e-consultation is not yet regarded as an acceptable tool by all patients. Consequently, this aspect of acceptability might be a possible problem for e-consultations' potential to contribute to enhancing the right to health for everyone.

57 Nijland & Van Gemert-Pijnen, *Medisch Contact* 2008, p. 202-203.

58 Krijgsman et al. 2016a, p. 45-46.

59 Krijgsman et al. 2016a, p. 51 and Krijgsman et al. 2016b, table 3-24, p. 28.

60 Wouters et al. 2019d, p. 7 and 9, part of Wouters et al. 2019a.

61 Krijgsman et al. 2016b, table 4-13, p. 54.

62 Krijgsman et al. 2016b, table 4-20, p. 57 and Krijgsman et al. 2016a, p. 71.

63 Krijgsman et al. 2016b, table 4-13 and table 4-20, p. 54 and p. 57 and Krijgsman et al. 2016a, p. 69.

64 Wouters et al. 2019c, table 2.28, p. 28.

65 Wouters et al. 2019c, table 2.33, p. 31.

66 Krijgsman et al. 2016b, table 4-13 and table 4-20, p. 54 and 57; Krijgsman et al. 2016a, p. 68; Wouters et al. 2019b, p. 8-9 and Wouters et al. 2019c, table 2.27 and 2.28, p. 28.

67 Brabers et al. 2017, p. 2 and 4, addendum to Wouters et al. 2017.

2.4 Quality

The last condition to be fulfilled in order to realise the right to health, is quality.⁶⁸ Whether e-consultation leads to health care of good quality is best examined empirically. This exceeds the current study. However, some general remarks on e-consultation and quality can be made at this point. It is imaginable, for instance, that not all topics are suitable for online discussion. The profession assists in determining whether a certain topic can be discussed online by means of good practice guidelines and checklists. The NHG provided a list of topics appropriate for discussion online as well as a list with topics that should not be discussed online.⁶⁹ Although this list might not be exhaustive, it is a good point of reference to help the GP decide whether online consultation is appropriate in a certain case. Noticeable in this respect is the fact that 'emotional problems' are mentioned as inappropriate for e-consultation on this list.⁷⁰ In a later document, however, the NHG, the LHV and Nictiz cite a study that indicates that questions about this topic are among the most prevalent.⁷¹ Moreover, since the Zvw is amended to include coverage for e-mental health,⁷² the NHG's statement that e-consultation is not suitable for 'emotional problems'⁷³ seems to need nuancing.

A quality-related problem of e-consultation is the way in which a health professional and a patient communicate. During a face-to-face consultation, physicians can use verbal, non-verbal and paralinguistic communication to examine and diagnose a patient. However, at least two of these types of communication will fall away when e-consultation is used instead of a face-to-face consultation. Unless video chat is used to carry out the online consultation, non-verbal and paralinguistic communication will not be possible.⁷⁴ This is a disadvantage of e-consultation.

Another possible impairment to the quality of health care is caused by the distance between the health professional and their patient. Because of this distance, physical examination is impossible.⁷⁵ Together with the lack of non-verbal and paralinguistic communication, the chance for a misdiagnosis might increase.

During chat e-consultations without video, the patients' language skills play a role as well. Not every patient has the necessary language skills.⁷⁶ During a face-to-face consultation, the

68 CESCR General Comment no. 14 (2000) on Health, Para. 12(d).

69 NHG-Checklist e-consult 2014, Para. 1, p. 1.

70 NHG-Checklist e-consult 2014, Para. 1, p. 1.

71 Huygens 2018, p. 97-98.

72 *Srb.* 2016, 143, Art. 70a Zvw; elaborated in chapter 6, Para. 2 of the Health Insurance Regulation.

73 NHG-Checklist e-consult 2014, Para. 1, p. 1.

74 Schalken et al. 2010, p. 21.

75 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, p. 15; Van Meersbergen 2012, p. 100 and Meijman & Den Ouden, *Medisch contact* 2014, p. 1585.

76 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, p. 15.

physician has the opportunity to check whether the patient has understood their information. During an e-consultation, however, this might be more difficult, and misunderstandings are more likely to occur. This will be further elaborated in section 6 on informed consent.

Furthermore, when e-consultation is delivered asynchronously, the patient's condition might change during the time they are waiting for the physician's reaction. Therefore, certain health problems are better discussed during a face-to-face consultation. Furthermore, the health professional would be well-advised to mention the time on their website in which a patient can expect a reaction, in order to prevent misunderstandings from occurring. This time should, according to the NHG, not exceed 48 hours during the week and 72 hours on weekends.⁷⁷

An additional issue related to the quality of e-consultation is identification and authentication of both the patient and the health professional. Clear security rules are necessary, and measures should be taken in order to ensure that both parties are who they say they are, and that medical information does not fall into the wrong hands.⁷⁸

As a final drawback of e-consultation for the quality of health care, prudence is especially called for in the situation where physician and patient have never met each other.⁷⁹ The Internet can be a means for non-professionals to spread wrong or potentially harmful information.⁸⁰ Such situations are more likely to occur during e-consultations outside the scope of the existing physician–patient relationship, when the patient starts an online consultation with someone they have never met. This can also happen when a health care provider is hacked, leading to unauthorised parties posing as a physician.⁸¹ This, too, will lead to personal health data falling into the wrong hands. This situation threatens the quality of health care and the patient's health. Therefore, security measures are important for delivering health care of good quality as well.

However, e-consultation might also be beneficial for the quality of the health care that is offered. For example, since e-consultation can be considered an easy way to break down barriers in health care⁸² it might be easier to contact the health professional in time, preventing deterioration. Moreover, e-consultation can contribute to efficient health care provision.⁸³

To sum up, e-consultation seems to be able to increase the availability of health care, although not every individual in every county might derive benefit from it because of the

77 NHG-Checklist e-consult 2014, Para. 3, p. 2.

78 This will be elaborated in section 3.

79 KNMG Guidelines for dealing with medical data 2020, p. 27-28.

80 See, for instance Capello & Luini 2014, p. 138.

81 Schalken et al. 2010, p. 127-128.

82 See, for instance Schalken et al. 2010, p. 25 and Schuurmans (ed.) 2016, p. 80.

83 De Jong, Stuart & Faber 2018, p. 12.

digital divide. E-consultation can also make a positive contribution to the accessibility of health care, if the computer illiterate and the digitally self-excluded are considered. When it comes to acceptability and quality, there are both limitations and reservations to the benefits e-consultation can have as a contribution to the realisation of the right to health. Therefore, it is important to develop applications for e-consultation that are acceptable to as many people as possible, and at the same time not to forget that eHealth is a means to supplement health care instead of replacing it. Thus, for those that do not find e-consultation acceptable, face-to-face consultation should always remain possible.⁸⁴ As for quality, empirical research on e-consultation and its effects on quality of health care is recommended. However, it can be stated that e-consultations of good quality must meet the requirements with respect to data protection and security, and patients' rights must be guaranteed. Sections 4 to 6 will specify what these rights entail for e-consultation.

3. THE APPLICABILITY OF THE WGBO TO E-CONSULTATION

3.1 Introduction to the WGBO and e-consultation

In the Netherlands, most of the legislation pertaining to patients' rights is laid down in the WGBO. Before discussing patients' rights in this Act in relation to e-consultation, the applicability of the WGBO on e-consultation should be examined.

Reflecting on e-consultation, several situations can be imagined. For instance, e-consultation can take place between a patient and their GP, who they have already consulted for years.⁸⁵ As shown by the eHealth-monitor, an increasing number of GPs and other health professionals in the Netherlands offer their patients e-consultations.

E-consultation, however, can typically take place between a patient and a physician who have never met before, although – as presented in the first chapter – this type of e-consultation is subject to criticism as shown by the discussion after Constamed was launched.⁸⁶ CareToGo is another example of a clinic which planned to offer e-consultations on Skype. The physicians of CareToGo did not necessarily have an existing relationship for medical treatment with the

84 E-consultation is a means that is not acceptable in every situation anyway, as will be explained in the following sections.

85 In this chapter, the GP will be taken as an example but what is stated with respect to patients' rights concerns any health professional.

86 For instance NHG 14 February 2014, 'NHG voorstander van e-consult met eigen huisarts', nhg.nl 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts and 'Constamed: Snel antwoord van je huisarts', consumentenbond.nl 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.

patients who consulted them.⁸⁷ In these examples, a relationship for medical treatment does not exist yet at the start of the e-consultation. Both of these types of e-consultation will be presented in this section, beginning with the situation where a patient consults a physician where there is already a physician–patient relationship.

3.2 E-consultation within an existing physician–patient relationship

According to the WGBO, a contract for medical services is established when a patient turns to a health professional for help, examination or advice.⁸⁸ According to Article 7:446 BW a contract for provision of medical services is established when a person turns to a health professional with a request for medical services and the health professional provides those services. Article 7:446 Paragraph 2 defines medical services, or, “acts in the field of medicine”,⁸⁹ as

“a. activities – examination and counselling included – directly relating to a person and intended to cure him of a disease, to protect him from the occurrence of a disease, to judge his state of health or to give such person obstetrical care;”⁹⁰

b. other acts than those referred to in subparagraph (a), directly relating to a person and performed by a doctor or dentist in that capacity.”⁹¹

Judging from this definition of acts in the field of medicine, it becomes clear that e-consultation does constitute such an act. When a patient poses their GP a question by means of (video) chat or email, this entails that they have turned to a health professional with a request for medical services. E-consultation falls within the scope of the definition of acts in the field of medicine as given in Article 7:446 Paragraph 2 BW for it directly relates to a person and involves counselling this person. Whether e-consultation can lead to a contract for medical services between a physician and a patient who have never met before will be elaborated on in section 3.3.

That being said, whether e-consultation between a patient and their GP constitutes a contract for provision of medical services or is simply a continuation of a prior existing contract for

87 CareToGo used to be a walk-in clinic that facilitated face-to-face consultations between physicians and patients who had not met each other before. On top of that, CareToGo planned to offer e-consultations by means of Skype. However, CareToGo closed its face-to-face clinic and its website because of uncertainty about tariffs. See Jacobs, ‘Eerste inloopklinik van Nederland moet sluiten: onduidelijkheid over tarieven’, *smarthealth.nl* 20 May 2014. Source: smarthealth.nl/2014/05/20/caretogo-eerste-inloopklinik-nederland-moet-sluiten/.

88 Art. 7:446 Para. 1 and 2 BW.

89 Translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

90 Art. 7:446 para 2(a) BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

91 Art. 7:446 para 2(b) BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

medical services can be approached in two different ways. In doctrine there is no consensus about the exact start of the contract for provision of medical services between the GP and their patient.⁹² According to one view, the contract for medical services only comes into existence the moment the patient consults their GP; the fact that they register at the GP's practice does not constitute a contract for medical services in this line of thought.⁹³ This means that a contract for provision of medical services is established each time this patient consults their GP.⁹⁴ In this view, e-consultation between a patient and their GP would lead to a new, separate contract for provision of medical services instead of a continuation of a prior existing contract. In this case the question of whether e-consultation actually can lead to a contract for medical services becomes relevant.⁹⁵

Others, however, recognise the moment the patient registers at the GP's practice as the start of the contract for provision of medical services and consider every time this patient consults their GP as a continuation of this contract.⁹⁶ Advocates of this view refer to the explanatory memorandum to the WGBO, which mentions the possibility of an open-ended contract for provision of medical services.⁹⁷ Another argument for this position is derived from the explanatory memorandum as well. When elaborating on the health professional's prohibition to terminate the contract for provision of medical services, the legislator seems to assume that the patient and the GP are parties to an ongoing contract for provision of medical services since they mention that the GP is allowed to terminate the contract with a patient who moves to another part of the country, resulting in the GP not being able to help them in time as an example of an exception to this rule.⁹⁸ Other reasons that the legislator had the intention to understand the "relationship of availability"⁹⁹ as a contract for provision of medical services can be retrieved from legal history as well. The patient's right to give their explicit consent for acts in the field of medicine¹⁰⁰ can be taken as an example, too. In the explanatory memorandum it is explained that the fact that the patient gave their consent to enter into a contract for provision of medical services does not mean that this permission extends to all acts that are performed within this contract; several acts carried out to perform the contract for provision of medical services might require the patient's separate consent.¹⁰¹ Here, too,

92 The establishment of the contract for provision of medical services is governed by the general rules of legal acts and contracts as laid down in Art. 3:33 BW in conjunction with Art. 3:37 BW and Art. 6:217 BW. See Wijne 2017a, p. 16.

93 Houben 2005, p. 139-140.

94 Van Wijmen, *NJB* 1985, p. 542-543 and Houben 2005, p. 140.

95 This will be elaborated on in section 3.3.

96 Asser/Tjong Tjin Tai 7-IV 2018/392. Van Meersbergen 2012, p. 106 seems to support this view, by stating that an e-consultation between a patient and their GP is a continuation of an existing contract for provision of medical services.

97 *Kamerstukken II* 1989/90, 21561, no. 3, p. 7 as mentioned by Asser/Tjong Tjin Tai 7-IV 2018/392.

98 *Kamerstukken II* 1989/90, 21561, no. 3, p. 42 as mentioned by Asser/Tjong Tjin Tai 7-IV 2018/392.

99 Translated from 'beschikbaarheidsrelatie', Brands 1997, p. 20.

100 Art. 7:450 BW.

101 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

the legislator seems to embrace the view that a contract for medical services can exist over a period in time and not every treatment requires a new contract. The legislator explicitly refers to “all acts within the scope of the contract for provisions of medical services”,¹⁰² thus suggesting that these acts are a continuation of the contract that was previously concluded. In conclusion, also due to the arguments that can be retrieved from legal history, this view is the most convincing. This means that, when a patient holds an e-consultation with their GP, this e-consultation takes place within their existing contract for provision of medical services.

3.3 E-consultation outside the scope of an existing physician–patient relationship

Section 3.2 showed that e-consultation can be considered an “act in the field of medicine” as mentioned in Article 7:446 Paragraph 2 BW. An important point of discussion, however, is whether such consultations are allowed and if so, to what extent.

As presented in chapter 1, the initial launch of Constamed – a platform that enabled e-consultations between health professionals and patients they had never met – sparked a discussion about, among other things, the desirability of physician–patient contact outside the scope of an existing physician–patient relationship.¹⁰³

According to the WGBO, as elaborated on in section 3.2, e-consultation can lead to a contract for provision of medical services based on Article 7:446 BW. The WGBO itself does not provide clarity about whether such types of e-consultation are allowed. Since the WGBO consists of so-called open standards, interpretation by the profession is often necessary.¹⁰⁴ The KNMG Guidelines for dealing with medical data are such guidelines. Up until 2020, the KNGM Guidelines for online physician–patient contact existed as a separate guideline with respect to e-consultation.¹⁰⁵ This guideline is now incorporated in the KNMG Guidelines for dealing with medical data. Yet, reference to the KNMG Guidelines for online physician–patient contact will be made when the information mentioned cannot be found in the KNMG Guidelines for dealing with medical data.

A topic presented in these guidelines is the KNMG’s statement on online contact between health professionals and patients who meet for the first time during e-consultation. According to these guidelines, e-consultation between patients and physicians who do not know each

102 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

103 NHG 14 February 2014, ‘NHG voorstander van e-consult met eigen huisarts’, nhg.nl 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts and ‘Constamed: Snel antwoord van je huisarts’, consumentenbond.nl 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.

104 Leenen/Dute & Legemaate (eds.) 2017, p. 71 and the literature cited there, and p. 100.

105 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007.

other is only possible when the following criteria are met: risks are minimised, the patient benefits from the consultation and quality of care can be maintained.¹⁰⁶ In practice, this will result in online consultations about general questions only. The KNMG emphasises that the health professional is responsible for the decision on whether to provide an e-consultation to a particular patient or not.¹⁰⁷ To conclude, the KNMG is not explicitly against e-consultation outside the scope of an existing contract for provision of medical services, although they advise physicians to be cautious when holding such e-consultations.

The NHG, on the other hand, expressly rejects e-consultation outside the scope of an existing contract for provision of medical services.¹⁰⁸ This checklist builds on the KNMG Guidelines for online physician–patient contact¹⁰⁹ and lists additional instructions for GPs who wish to incorporate e-consultation into their daily practice. For instance, the checklist mentions a number of topics which are appropriate to discuss online, as well as some topics for which the NHG considers online consultation to be inappropriate.¹¹⁰ In reaction to the discussion surrounding the website and app Constamed, the NHG stressed that they are in favour of e-consultation between GPs and their own patients. The NHG strongly doubts that standards of good practice can be met during e-consultations between patients and GPs who have not met each other.¹¹¹ According to the NHG, a GP can only provide an e-consultation to a patient who is subscribed to their surgery and where there has been at least one face-to-face consultation. The GP must have access to this patient's medical record.¹¹²

Although the NHG's viewpoint is understandable regarding the fact that e-consultations between patients and health professionals who have never met before are problematic because the health professional does not have any information about the patient,¹¹³ a prohibition would not be in place. I support the KNMG's opinion that e-consultations between patients and physicians who do not know each other should not be forbidden as long as the risks are minimal and the patient can benefit from the health services provided to them.¹¹⁴ Especially if e-consultation can help a patient who would otherwise avoid health care, e-consultation between health professionals and patients who do not know each other should be possible. Anonymous e-mental health, as discussed in section 2.1 is an example.¹¹⁵ The KNMG's

106 KNMG Guidelines for dealing with medical data 2020, p. 27.

107 KNMG Guidelines for dealing with medical data 2020, p. 27-28 about the KNMG Guidelines for online Physician–Patient Contact (incorporated in the KNMG Guidelines for dealing with medical data by 2020), see: Van Meersbergen & Doppegieter, *Medisch Contact* 2005, p. 901.

108 NHG-Checklist e-consult 2014, Para. 2, p. 2.

109 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007.

110 NHG-Checklist e-consult 2014, Para. 1, p. 1.

111 NHG 14 February 2014, 'NHG voorstander van e-consult met eigen huisarts', nhg.nl 14 February 2014. Source: nhg.org/actueel/nieuws/nhg-voorstander-van-e-consult-met-eigen-huisarts.

112 NHG-Checklist e-consult 2014, Para. 2, p. 2.

113 NHG-Checklist e-consult 2014, Para. 2, p. 2.

114 KNMG Guidelines for dealing with medical data 2020, p. 27.

115 Art. 70a Zvw.

viewpoint is also reflected in practice. The NZa Performance and Tariff Decision 2020 refers to compliance with the KNMG Guidelines for online physician–patient contact for eligibility of coverage. The NZa repeats the conditions for e-consultation outside the scope of an existing physician–patient relationship as a condition for claiming a consultation.¹¹⁶ Due to the corona crisis, the NZa temporarily relaxed its policy with respect to online contact, showing that sometimes greater interests call for exceptions.¹¹⁷

Since the relationship between patients and physicians who have not met each other is not characterised by a prior existing contract for provision of medical services, the question of whether e-consultation leads to such a contract should be posed in order to be able to determine whether the WGBO is applicable to this situation. As presented in section 3.2, e-consultation is provision of medical services and can, in that sense, be included in the performance of a medical services contract.¹¹⁸ Although the wording of Article 7:446 Paragraph 2 BW does not leave any doubt as to whether e-consultation is an act in the field of medicine, it is interesting to discuss whether e-consultation itself can lead to a contract for provision of medical services. Considering their guidelines for dealing with medical data, the KNMG thinks so. They underline that e-consultation can lead to a contract for provision of medical services and emphasise that the WGBO applies to these consultations.¹¹⁹ Examples of situations in which online contact does not lead to a contract for provision of medical services according to the KNMG include online provision of general information, or questionnaires by means of which the patient can assess their health situation.¹²⁰

In legislative history no arguments can be found to exclude the establishment of a contract for medical services by means of e-consultation. In fact, it can be derived from the explanatory memorandum that the legislator meant to include health care over distance in the WGBO by elaborating on the fact that the criterion “activities directly relation to a person” does not imply a requirement for physical contact.¹²¹ This seems to make way for health care over distance. Even though e-consultation did not exist at the time, legal history does not give a reason to exclude it from the ways of constituting a contract for provision of medical services. Moreover, the broad understanding of the WGBO that is shown in case law¹²² is another

116 NZa Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REGCU-20622-04, section 1.2, Para. 4, p. 8. The NZa refers to the KNMG Guidelines for online Physician–Patient Contact 2007 (KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007), which by 2020 has been included in the KNMG Guidelines for dealing with medical data 2020).

117 ‘NZa brengt extra verruiming aan voor zorg op afstand’, *nza.nl* Nieuwsbericht 17 March 2020. Source: nza.nl/actueel/nieuws/2020/03/17/nza-brengt-extra-verruiming-aan-voor-zorg-op-afstand.

118 Art. 7:446 BW.

119 KNMG Guidelines for dealing with medical data 2020, p. 27–28.

120 KNMG Guidelines for dealing with medical data 2020, p. 27. Also in that sense: Van Meersbergen 2012, p. 107.

121 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

122 HR 12 March 2013, ECLI:NL:HR:2013:BY4859, *NJ* 2013/424, m.nt. Legemaate and discussed by Hulst, *TGMA* 2013, issue 2, p. 55–56.

indication that there should be no reason why the WGBO should not apply to e-consultation outside the scope of an existing physician–patient relationship. The former Minister for Health, Welfare and Sport even stated that the patient's right laid down in the WGBO also applies outside the scope of a contract for provision of medical services.¹²³ Finally, the KNMG *Standpunt Niet-aangaan of beëindiging van de geneeskundige behandelingsovereenkomst* [Viewpoint on not entering into or terminating the contract for provision of medical services] stresses that when in doubt, the existence of a contract for provision of medical services must be assumed.¹²⁴ Consequently, even in case of uncertainty about the existence of a contract for provision of medical services, such a contract will be assumed quickly. Therefore, the WGBO applies to e-consultation outside the scope of an existing contract for provision of medical services as well.

Since e-consultation can constitute a contract for provision of medical services, the question at what moment in time such a contract starts has to be answered. The contract for provision of medical services, as a contract in the *Burgerlijk Wetboek* [Civil Code], is subject to the general rules of establishment of contracts. This means that an offer and acceptance of that offer are required in order for the contract to be realised.¹²⁵ In literature it is stressed that this depends on the type of e-consultation and who initiates the consultation. When a health professional is offering e-consultations on a specific topic, the moment the patient consults this professional is considered to be the patient's acceptance of this professional's offer and a contract for provision of medical services is created. When the e-consultation is initiated by the patient, however, i.e. in case the physician only states that e-consultations are possible, the moment the patient contacts them for an online consultation can be seen as the offer. Only when the health professional decides to accept this offer – in other words, when they decide to provide an e-consultation – a contract for provision of medical services is established.¹²⁶ Nevertheless, some refinement of the first statement is in place. When a health professional invites patients to pose questions about a certain topic and a patient accepts this offer by posing a question, this does not necessarily have to lead to a contract for provision of medical services. When the physician, for instance, decides they cannot offer the appropriate help online and therefore urges the patient to contact them or another physician in person, this is not an “act in the field of medicine” as meant in Article 7:446 Paragraph 2 BW. Therefore, existence of a contract for provision of medical services must not be assumed in this situation. Only when the physician provides the patient with advice, will such a contract be established.

123 *Kamerstukken II* 2013/14, 33509, no. 7, p. 18 and Jacobs, ‘Wet- en regelgeving niet klaar voor online huisartsen’, *smarthealth.nl* 13 March 2014. Source: smarthealth.nl/2014/03/13/wet-en-regelgeving-niet-klaar-voor-online-huisartsen/.

124 KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

125 Art. 6:217 BW. See Wijne 2017a, p. 16.

126 Van Meersbergen 2012, p. 106.

3.4 Exceptions

3.4.1 Introduction

As the previous sections show, the WGBO applies to e-consultation. E-consultation can take place within an existing physician–patient relationship but can also constitute a new one, albeit only allowed under certain conditions.¹²⁷ This section will elaborate on two situations that differ from the situations presented in sections 3.2 and 3.3. The first, prescription of medication, is not permitted during e-consultations outside the scope of an existing physician–patient relationship. The second, Twitter consultation, does not lead to a contract for provision of medical services and the applicability of the WGBO.

3.4.2 Prescription of medication

Prescription of medication during e-consultations between patients and physicians who have never met before, is not permitted under the *Geneesmiddelenwet* [Dutch Act on Pharmaceuticals] (Gnw).¹²⁸ According to Article 67 Gnw, prescription of medication is only appropriate when the patient and the health professional know each other and have had at least one face-to-face meeting. Furthermore, the physician should know the patient's medication history.

Before this provision was added to the Gnw,¹²⁹ distribution of medication over distance by health professionals and pharmacists to patients they did not know, occurred. An example can be found in a case from 2005. In this case, a patient committed suicide by overdosing medication that was given to her through *dokteronline.com*, by a physician who did not know her or her medical history. This physician was unconditionally suspended by the regional disciplinary tribunal for the health care sector in Amsterdam.¹³⁰ The same physician was issued a warning in another case, which also involved online prescription of medication without sufficient information about the patient.¹³¹ In the discussion that followed, the *Raad voor de Volksgezondheid & Zorg* [Council of Public Health and Health Care] (RVZ) stressed that the advantages of the use of the Internet for health care still outweigh the disadvantages, adding that a person who wants to commit suicide will do so anyway, regardless of a prohibition of online prescription of medication.¹³² This should not be the reason to omit a prohibition; people's health must be protected, no matter what they can do to themselves to damage their

127 KNMG Guidelines for dealing with medical data 2020, p. 27.

128 *Stb.* 2006, 650.

129 Added by amendment; *Kamerstukken II* 2005/06 29359, no. 81.

130 Regionaal Tuchtcollege voor de Gezondheidszorg Amsterdam 26 November 2006, 05/140, *JGR* 2007/34, m.nt. Schutjens.

131 Regionaal Tuchtcollege voor de Gezondheidszorg Amsterdam 26 November 2006, 05/321, *JGR* 2007/35, m.nt. Schutjens.

132 RVZ 2005.

health. Others were also not in favour of a prohibition, stressing that the existing KNMG guidelines provide sufficient protection.¹³³

In spite of these opinions, Article 67, including the prohibition to prescribe medication online without an existing physician–patient relationship was added to the Gnw.¹³⁴ The *Inspectie voor de Gezondheidszorg* [Health Care Inspectorate] (IGZ) is entrusted with the enforcement of the Gnw on Dutch territory and can take action whenever Article 67 Gnw is violated on this territory.¹³⁵ Moreover, in case of a violation of Article 67 Gnw, the Minister of Health, Welfare and Sport is authorised to impose a fine on the offender.¹³⁶ As a response to questions about dokteronline.com, the Minister of Health, Welfare and Sport said that the Gnw is only justiciable on Dutch territory. Therefore, websites such as dokteronline.com cannot be reprimanded under the Gnw. When medication is prescribed outside the Netherlands, the Gnw can nevertheless be violated in the Netherlands, for instance by pharmacists who hand out the medication to patients.¹³⁷

This is what happened in the case of Multatuli. This pharmacy delivered medication that was prescribed against Article 67 Gnw into patients' hands. This medication was prescribed by a foreign physician through dokteronline.com. Similar to the physician in the case that was taken as an example above, this physician prescribed medication to patients where they were unaware of their medication history. The situation was uncovered when a patient, who requested a repeat prescription through dokteronline.com, received a large amount of medication with a higher strength than their usual medication. This led to hospitalisation.¹³⁸ Even though the actual breach of the law took place outside the Netherlands, the summary proceedings judge agreed with the Minister for Health, Welfare and Sport that by distributing these pharmaceuticals, Multatuli was not providing responsible health care in the sense of Article 2 *Kwaliteitswet Zorginstellingen* [Care Institutions (Quality) Act] (Kwz).¹³⁹ Not only were the pharmaceuticals distributed by the pharmacist in violation of Article 67 Gnw because they did not possess the medication history of the patient that the medication was delivered to, the pharmacist also failed to examine whether the physician behind dokteronline.com was authorised to prescribe medication at all. According to the summary proceedings

133 Van Meersbergen & Doppegieter, *Medisch Contact* 2005, p. 902. The Guidelines the authors are elaborating on are the Guidelines for online Physician–Patient Contact 2005 (KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2005).

134 *Kamerstukken II* 2005/06, 29359, no. 81.

135 Art. 100 Para. 1 Gnw.

136 Art. 101 Para. 1 Gnw.

137 *Aanhangsel Handelingen II* 2008/09, 2128, p. 4470.

138 Regionaal Tuchtcollege voor de Gezondheidszorg Den Haag 31 August 2010, ECLI:NL:TGZRSGR:2010:YG0556, juridical ground 2 and Rb. Den Haag (vzr.) 20 mei 2010, ECLI:NL:RBSGR:2010:BM5482, *JGR* 2010/28, m.nt. De Best (*Multatuli*).

139 *Stb.* 1996, 185, as of 1 January 2016 replaced by the *Wet Kwaliteit, Klachten en Geschillen Zorg* [Healthcare Quality, Complaints and Disputes Act] (Wkkgz), *Stb.* 2015, 525. This Act replaces the *Wet klachtrecht cliënten zorgsector* [Right to Complain (Care Sector) Act] (Wkcz), *Stb.* 1995, 308, as well.

judge, pharmacists are responsible for the quality of health care as well.¹⁴⁰ To emphasise this, the summary proceedings judge referred to the *Richtlijn Online farmaceutische zorgen dienstverlening* [Guideline Online Pharmaceutical Care and Service Provision],¹⁴¹ drafted by the *Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie* [Royal Dutch Pharmacists Association] (KNMP), which mentions pharmacists' responsibility with respect to Article 67 Gnw.¹⁴²

Furthermore, the pharmacist was given a reprimand by the Regional Disciplinary Court for Health Care.¹⁴³ According to the disciplinary court, the pharmacist violated several of the standards of medication and medication counselling laid down in the KNMP Guideline Online Pharmaceutical Care and Service Provision. Furthermore, by distributing medication prescribed against Article 67 Gnw, the pharmacist created a hazard to patients. According to the disciplinary court for health care, this course of action results in a violation of Article 47 BIG Act: the pharmacist fell short in the health care they were supposed to provide.¹⁴⁴

Notable in this respect is the KNMG *Richtlijn Elektronisch Voorschrijven* [Guideline for Electronic Prescribing] that entered into force in 2014. The guideline deals with – among other things – the requirements that must be met by the electronic prescription system.¹⁴⁵

To sum up, medication that is ordered online across borders remains a difficult situation. Based on Article 67 Gnw, prescription of medication to patients a physician does not know is prohibited. Both the KNMG and the KNMP repeated this in their respective guidelines on dealing with medical data and online pharmaceutical care and service provision.¹⁴⁶ Moreover, the prohibition was confirmed in jurisprudence in the *Multatuli* case.¹⁴⁷ When neither the pharmacist, nor the prescribers reside in the Netherlands, however, the Gnw is not justiciable.¹⁴⁸ International agreements on this matter seem to be in place. Moreover, (e-) prevention can help in counselling patients about the risks of ordering medication online

140 Rb. Den Haag (vzr.) 20 mei 2010, ECLI:NL:RBSGR:2010:BM5482, *JGR* 2010/28, m.nt. De Best (*Multatuli*).

141 KNMP Guideline Online Pharmaceutical Care and Service Provision 2008.

142 KNMP Guideline Online Pharmaceutical Care and Service Provision 2008, recommendation 14, p. 7 and 8.

143 Regionaal Tuchtcollege voor de Gezondheidszorg Den Haag 31 August 2010, ECLI:NL:TGZRSGR:2010:YG0556.

144 Regionaal Tuchtcollege voor de Gezondheidszorg Den Haag 31 August 2010, ECLI:NL:TGZRSGR:2010:YG0556, ground 5.4 and 5.5.

145 KNMG Guidelines for Electronic Prescribing 2013.

146 KNMG Guidelines for dealing with medical data 2020, p. 30-31 and KNMP Guideline Online Pharmaceutical Care and Service Provision 2008, recommendation 14, p. 7-8.

147 Rb. Den Haag (vzr.) 20 mei 2010, ECLI:NL:RBSGR:2010:BM5482, *JGR* 2010/28, m.nt. De Best (*Multatuli*) and Regionaal Tuchtcollege voor de Gezondheidszorg Den Haag 31 August 2010, ECLI:NL:TGZRSGR:2010:YG0556.

148 *Aanhangsel Handelingen II* 2008/09, 2128, p. 4470.

without the involvement of a health professional registered in their own country and advising patients against ordering medication online.

Although prescription of medication outside the scope of an existing physician–patient relationship is not allowed as the law stands, the exception that has been made due to the corona crisis is worthy of mention. The IGJ temporarily allows physicians to prescribe medication during video consultations that are not preceded by a face-to-face consultation if they have access to the patient's medication history and notify this patient's own physician afterwards. This exception is justified because it helps to limit face-to-face contact, which is necessary to combat the virus.¹⁴⁹

3.4.3 The Twitter consultation hour

This section will elaborate on e-consultation by means of Twitter, a type of e-consultation that can lead to problems with respect to the applicability of the WGBO, as opposed to the types of e-consultation that were discussed in sections 3.2 and 3.3. Similarly, the KNMG Viewpoint on not entering into or terminating a contract for medical services states that provision of general information will not lead to a contract for provision of medical services.¹⁵⁰

A while ago, several health service providers in the Netherlands offered public consultation hours on Twitter. People were able to pose a question to a health professional with a certain specialism during a predetermined period of time, usually an hour. Within this hour, the health professional would reply to the patient's question, publishing the answer on the health service provider's website as well as the patient's personal Twitter page, for both the patient's as well as the health professional's followers to see.¹⁵¹ An advantage of this kind of e-consultation is that everyone can read the responses, making the health professional's answer useful to more than one person at a time.¹⁵² However, this advantage is simultaneously a disadvantage as regards the content of the questions that can be asked and answers that can be obtained during a Twitter consultation hour. That is, due to the public nature of this kind of e-consultation, questions as well as answers must remain general and superficial.¹⁵³ The KNMG briefly addressed the Twitter consultation hour in its *Handreiking Artsen en social media* [Guide for Physicians and Social Media],¹⁵⁴ stating that physicians must not offer advice via Twitter when they do not possess enough information about the patient.

149 'Coronavirus: recepten mogelijk na online video-contact tussen arts en patiënt' igj.nl, *nieuwsbericht* 26 March 2020. Source: [igj.nl/actueel/nieuws/2020/03/26/coronavirus-recepten-mogelijk-na-online-video-contact-tussen-arts-en-patient](https://www.igj.nl/actueel/nieuws/2020/03/26/coronavirus-recepten-mogelijk-na-online-video-contact-tussen-arts-en-patient).

150 KNMG/Doppegieter & Van Meersbergen 2005, p. 3.

151 Kwak et al. 2010, p. 592.

152 KNMG Guide for Physicians and Social Media 2020, p. 11.

153 KNMG Guide for Physicians and Social Media 2020, p. 11.

154 KNMG Guide for Physicians and Social Media 2020.

Furthermore, the use of disclaimers is recommended.¹⁵⁵

This leads to the question of what this entails for the applicability of the WGBO to such consultations and whether a difference exists between a Twitter consultation with a patient's own GP and a Twitter consultation with a physician they have never met before. The WGBO indicates that the provision of medical services should be aimed at a specific patient, by referring to "acts in the field of medicine, directly concerning the person"¹⁵⁶ and defining "acts in the field of medicine" as "all activities – examination and counselling included – directly relating to a person."¹⁵⁷ On the one hand, the health professional who offers Twitter consultations provides advice based on a specific question that was posed to them. Even though the answers given by the health professional during the Twitter consultation are aimed at a particular patient, they must remain general¹⁵⁸ and can therefore hardly be considered to be directed at this particular patient only. It is highly likely that others will refer to these answers when they have a similar question about their health. This is inherent in a public medium such as Twitter, which makes it difficult to look upon these answers as aimed only at the questioner; they can be considered to be aimed at the general public as well. Therefore, it is doubtful whether the Twitter consultation would meet the criteria for acts in the field of medicine under the WGBO.¹⁵⁹

Furthermore, the public nature of the Twitter consultation as well as the many restrictions to the content of the consultation conflict with many obligations in the WGBO, such as the patient's duty to provide the physician with information as laid down in Article 7:452 BW. This obligation can hardly be met in 140 characters. Finally, the public nature of the Twitter consultation precludes compliance with several privacy-related rights in the WGBO, such as medical confidentiality¹⁶⁰ and spatial privacy;¹⁶¹ Twitter is everything but confidential and due to its public nature, guaranteeing spatial privacy is impracticable. In literature too, the applicability of the WGBO seems not to be assumed, although it is mentioned that physicians who do provide bad or too detailed advice during a Twitter consultation, can be held responsible under disciplinary law, in spite of possible disclaimers on their website.¹⁶² Disciplinary law, however, aims to protect good professional conduct and therefore has another purpose than civil actions that the patient would undertake if their rights are violated.¹⁶³ Yet, disciplinary law can protect the patient because of its purpose to protect quality of health care. Finally, the

155 KNMG Guide for Physicians and Social Media 2020, p. 12.

156 Art.7:446 Para. 1 BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

157 Art.7:446 Para. 2 BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

158 KNMG Guide for Physicians and Social Media 2020, p. 11.

159 Art. 7:446 Para. 2 BW.

160 Art. 7:457 BW.

161 Art. 4:459 BW.

162 Ekker, Nouwt and Legemaate in *Haarlems Dagblad*, 5 April 2013. Disciplinary measures are invoked based on Art. 47 in conjunction with Art. 48 BIG Act.

163 Kastelein 2009, p. 40 and 45.

patient can impose a civil claim based on tort when they suffer damage.¹⁶⁴ Patients, however should also take their own responsibility with respect to Twitter consultation.¹⁶⁵ They should understand – to some extent – that a health professional cannot always help them on Twitter and that sometimes a visit to the physician's practice or a private e-consultation is required.

In conclusion, due to its public nature and design, the Twitter consultation does not seem to be intended to fall within the scope of the WGBO. If Twitter consultation would fall under the WGBO, a prohibition would be in place since many of the patient's rights laid down in the WGBO cannot be guaranteed during this type of e-consultation. Physicians can be held responsible under disciplinary law for consultations they provide on Twitter.¹⁶⁶

4. E-CONSULTATION: THE RIGHT TO PRIVACY AND MEDICAL CONFIDENTIALITY

4.1 Introduction and e-consultation's privacy implications

Privacy is a right that, because of the nature of health care, traditionally risks being violated during the health care process. For instance, medical treatment almost always entails an invasion of a person's physical integrity and their spatial privacy. Furthermore, medical data will be processed, which also leads to a potential invasion of informational privacy.¹⁶⁷ As discussed in chapter 3, privacy, as a fundamental right, is not only protected in various provisions in the WGBO, but by the Dutch Constitution¹⁶⁸ and international treaty law¹⁶⁹ as well. Protection of personal data is also protected by the GDPR, which entered into force in 2018.

Informational privacy has always been one of the main concerns regarding eHealth applications in any form.¹⁷⁰ Let's assume a patient wants to pose a health-related question to their GP. They decide to send the GP an email or maybe even initiate a (video) chat, which is offered by this GP on the practice website. Now, the patient will have to provide personal information, such as their name and date of birth. The question itself, assuming it contains

164 Art. 6:162 BW.

165 Art. 6:101 BW.

166 Art. 48 in conjunction with Art. 48 BIG Act, see Ekker, Nouwt and Legemaate in *Haarlems Dagblad*, 5 April 2013.

167 Leenen/Dute & Legemaate (eds.) 2017, p. 168-169.

168 Art. 10 Gw.

169 For instance Art. 12 UDHR, Art. 17 ICCPR and Art. 8 EVRM

170 Van Rijen & Ottes, *Medisch Contact* 2002, issue 17; Baumer and Earp & Poindexter, *Computers & Security* 2004; Keizer 2011, p. 377; Kranenborg 2011, p. 292-299; Nouwt, *Medisch Contact* 2010, p. 932 and Ploem 2012, p. 121-124. These are some examples where privacy is mentioned as a possible (legal) issue for eHealth.

information on the patient's health situation, can be qualified as personal health information. The GP must collect this information and save it into the medical record as well. As shown in chapter 3, keeping a medical record is processing of personal data within the meaning of the GDPR.¹⁷¹ Whenever they answer the patient, this answer will entail new personal health information that has to travel over the Internet, too. The GP has the obligation to protect all this health information. This example illustrates the pivotal role informational privacy plays during e-consultation and just how much information is transmitted and shared through ICT during such a consultation.

Informational privacy in health care as a right can be found in the right to medical confidentiality. Medical confidentiality typically applies to the relationship between the physician and the patient.¹⁷² Informational privacy can exceed this relationship, for instance when information is stored and administered by third parties.¹⁷³ Even though medical confidentiality does not only serve to protect the individual privacy but rather the right to access to health care for society as a whole,¹⁷⁴ medical confidentiality and informational privacy will be discussed together because of the overlap.

Medical confidentiality is typically something that is often mentioned in relation to eHealth care provision. E-consultation, as a type of eHealth care provision, leads to questions about protecting this right. Besides the complications that arise because of the use of ICT, which can lead to personal data breaches, more parties are involved during an e-consultation. Examples include employees of the ICT department who need to access the health professional's ICT systems in case of technical malfunctions or maintenance. Moreover, questions arise about the responsibility for protecting the confidentiality of the data included in the medical record. Back when health professionals kept their patient's files on paper in their practices, it was clear that they were the owner of the medical file. With the increasing possibilities of digital storage and the easier ways for patients to access their medical file and save it on their own devices (or print it out, for that matter), it has been suggested that patients acquire ownership of their medical data instead of the health professional.¹⁷⁵ Such a view will lead to a shift in responsibilities and it raises the question of who is charged with protecting the medical confidentiality: the physician or the patient? We can wonder whether making the patient the owner of their medical file is desirable at all. This section will elaborate on these questions. Besides discussing potential difficulties for medical confidentiality during e-consultation, relevant legislation as well as good practice guidelines will be presented.

171 Art. 4 Para. 1 and 2 GDPR.

172 This can be seen by its placement in the WGBO in Art. 7:457 BW.

173 Nouwt 1997, p. 4.

174 HR 21 April 1913, *NJ* 1913, p. 958; Buijsen et al. 2012, p. 25 and Leenen/Dute & Legemaate (eds.) 2017, p. 151.

175 European Union 2012, p. 9-10.

Digital information, such as medical records or transcripts of email or chat conversations, risk being easily exposed to unauthorised parties when security measures are inadequate or completely absent. Exposure of data is referred to as a personal data breach under the GDPR.¹⁷⁶ Personal data breaches can be caused by various actors, such as health professionals, others employed within their practice, technical malfunctions and even the patient themselves.¹⁷⁷

Another problem with online (chat) consultation is that patients can pose as someone else.¹⁷⁸ Health professionals might then disclose information about a patient to the wrong person, when they share information from the medical record or repeat what was discussed during previous online and offline consultations.

This means that e-consultation requires a secured Internet connection, a conscientious health professional who treats this information with respect, and an ICT system in the physician's practice that is protected against external attacks by hackers (as far as possible, because IT is developing fast and hackers tend to find new ways to attack IT systems).¹⁷⁹ That being said, it is clear that any use of e-consultation will result in the necessity to implement measures to protect patients' personal medical data. This section will present how to deal with medical confidentiality within (section 4.2) and outside the health care facility (section 4.3). Next, attention will be paid to medical confidentiality outside the scope of an existing contract for the provision of medical services (section 4.4). Finally, remarks on privacy protection on the patient's side will be made (section 4.5), followed by a reflection on the ownership of the medical record (section 4.6).

4.2 E-consultation and medical confidentiality within the health care institution

Applied to e-consultation, medical confidentiality should be guaranteed for everyone to be able to contact a health professional over the Internet, without the fear that their information will end up in the wrong hands. Based on Article 7:457 BW health professionals should not provide information about the patient to third parties. This includes written information as laid down in the medical record, information that is spoken and the consultation itself.¹⁸⁰ Therefore, the obligation of medical confidentiality stretches out to the e-consultation itself.

176 Art. 4 Para. 12 GDPR.

177 Schalken et al. 2010, p. 31.

178 Schalken et al. 2010, p. 39.

179 In June 2017, it was revealed that several hospitals in the Netherlands had been subject to so-called ransomware attacks. During these attacks, hackers take away files and will only give them back after a ransom payment. Fortunately, most hospitals declared that no patient data were taken away by the hackers. However, this shows that protecting systems against hackers is challenging and difficult. See: Schellevis & Meindersma, 'Zeker vijftien ziekenhuizen geïnfecteerd met ransomware', *nos.nl* 25 June 2017. Source: nos.nl/artikel/2179941-zeker-vijftien-ziekenhuizen-geinfecteerd-met-ransomware.html.

180 Leenen/Dute & Legemaate (eds.) 2017, p. 153.

The text of the consultation, whether this is a chat or an email conversation, should remain confidential. The same is true for video consultations; the contents of these conversations are protected by the obligation of medical confidentiality, even before they are recorded in a medical file. This means that holding e-consultations with inappropriate applications which are not safeguarded can result in a violation of the obligation of medical confidentiality and a personal data breach under the GDPR.¹⁸¹

Exceptions are health professionals involved in the patient's treatment and those who represent the patient in case of a lack of legal capacity.¹⁸² This does not mean that health professionals can freely discuss a patient's entire medical history with all professionals involved in this patient's treatment. Only the information that others involved in the patient's treatment need to carry out their job can be shared with them.¹⁸³ This means that, during e-consultation, a physician cannot let colleagues who are not involved in the patient's treatment read along. Furthermore, when the health professional uses email to carry out e-consultations, they should make sure they are the only person with access to this email account. Therefore, it is recommended that health professionals who offer e-consultations via email use individual email accounts instead of general accounts belonging to the practice. However, some health professionals are using the general email address for e-consultations. Various physicians let their assistants filter the questions posed by patients – and answer those that are less complicated. This is comparable to telephone triage when a patient calls the physician's practice to make an appointment for a face-to-face consultation.¹⁸⁴ The question arises how problematic this really is. It already used to be common practice for assistants to filter questions patients pose over the phone. This is also a way to distinguish between urgent and less urgent questions. Since the duty of protecting medical confidentiality as laid down in the WGBO stretches out to assistants and secretaries,¹⁸⁵ it will not conflict with medical confidentiality when they scan the questions that are sent to the practice's or health care provider's email account first. The KNMG Guidelines for online physician–patient contact used to add to this that the health professional must include a disclaimer to the consultations they have via email, stating that the email contains confidential information. However, as the guideline also noted, such a disclaimer does not prevent the health professional from being disciplinary prosecuted for violation of their professional confidentiality.¹⁸⁶ This recommendation still seems sensible, although such a disclaimer does not prevent a violation of medical confidentiality as such. As remarked above in section 4.1, an email containing a patient's personal information that ends

181 Art. 4 Para. 12 GDPR.

182 Art. 7:457 Para. 2 and 3 BW.

183 Art. 7:457 Para. 2 BW. Leenen/Dute & Legemaate (eds.) 2017, p. 152 provides examples.

184 On the patient portal of the Leiden University Medical Center for instance, it is explicitly mentioned that questions are answered by the assistant or the nurse and that complicated medical questions are forwarded to the medical doctor.

185 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

186 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, Para. 7.2, p. 11.

up in the wrong hands – either online or in print – constitutes a personal data breach under the GDPR as well as a violation of the obligation of medical confidentiality under Article 7:457 BW. When communicating with (or about) patient by email, it is recommended to use a trustworthy email application.¹⁸⁷

Consequently, clear rules on who has access to the email account that is used for electronic consultations are needed. Assistants are bound by a duty of professional confidentiality, derived from the physician's duty of professional confidentiality, but the question is how to deal with other health professionals working in the practice of the health care provider. As mentioned, colleagues sharing the practice are not allowed to read along with or view the e-consultation if they are not involved in this patient's treatment. The WGBO states that a physician only can discuss their patient with another physician when this other physician is involved in the treatment of the patient. Even then, only the information that is relevant for this particular part of the treatment should be shared with this other health professional.¹⁸⁸ This means that information cannot be shared with other health professionals – not even the health professionals within a physician's practice – who are not involved in a particular patient's treatment or who are not serving as their locum tenens. Applied to e-consultation, it can be concluded that it is not allowed for other health professionals in the practice to read e-consultations between patients and their colleagues. Should they read it, their obligation of medical confidentiality based on Article 88 BIG Act applies. When a health professional chooses to offer e-consultations via email, they should use their own email account. This should be a secured email application, designed for professional use instead of a private email account. This is for the very reason that private email accounts are generally less safeguarded than applications especially designed for e-consultation, or at least for professional use in health care.

4.3 E-consultation and medical confidentiality, and third parties

An issue that deserves particular attention in this respect is the role of third parties, such as IT workers. All means used to carry out e-consultations – including email – are using a network and are dependent on the functioning of various systems, such as computers. Because of the nature of such devices, people other than co-workers and receptionists might be able to view the (sensitive information exchanged during) e-consultation. IT workers might assist the health care provider in designing secured web applications that can be used for e-consultation. In particular, when these IT professionals are responsible for regularly monitoring the system and for maintenance and assistance during technical malfunctions, they are likely to view medical information and additional steps need to be taken to protect patients' health data.

187 Also in this respect: KNMG Guidelines for dealing with medical data 2020, p. 23-24. The guidelines refer to trustworthy systems at p. 24.

188 Art. 7:457 Para. 2 BW.

Depending on the situation, IT workers are either employed within the health care institution or hired externally. It is imaginable that larger health care institutions have their own IT departments, while smaller health care institutions more often hire IT workers from an external company.¹⁸⁹ People who are not subject to the obligation of medical confidentiality based on Article 7:457 BW or Article 88 BIG Act but nevertheless have access to patient information because they work for the physician or the health care facility, are subject to the so-called derivative obligation of medical confidentiality. Without such a derivative obligation, the health professional's obligation would be undermined.¹⁹⁰

Based on legislative history, the derivative duty of medical confidentiality applies to others whose assistance is necessary in conducting the medical treatment, including assistants.¹⁹¹ This leaves the question of whether IT workers can be qualified as necessary in conducting the medical treatment. Assistants and receptionists are directly working within the health professional's practice and assist in the functioning of the health care process: they answer patient's questions over the phone, filter between urgent and less urgent questions and assist in carrying out the treatment by helping the physician. Assistants can function as gatekeepers to the physician during e-consultation as well. Some health care facilities have the questions read by assistants, who filter them and forward complicated medical questions to the physician.¹⁹² This way, they can help in counteracting the increasing pressure of work caused by the fact that e-consultation is breaking barriers to contact a health professional. IT workers, on the other hand, do not have direct contact with patients nor are they supposed to deal with medical questions. Even though their work is of importance for health care provision by means of e-consultation, e-consultation is not possible without a safe and secured system. Moreover, they can help in implementing the rules and guidelines related to data security and data protection. Yet, they are not a part of the actual health care process.

It has been stated that it is usually clear who has a derivative obligation of medical confidentiality and who does not have such an obligation. However, those who are subject to such an obligation should be notified of this because the further away they are from the actual health care process, the more difficult this is for them to know.^{193,194} Even though it is

189 Schalken et al. 2010, p. 121.

190 Leenen/Dute & Legemaate (eds.) 2017, p. 152-153.

191 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

192 An example is the email consultation held by the Leiden University Medical Center (LUMC), to be accessed after logging on to its patient portal. Questions sent by email are read by the assistant first. Less complicated questions are answered by the assistant or a nurse. Other questions are forwarded to the physician.

193 Duijst 2012, p. 22.

194 The KNMG made a similar recommendation in its Guidelines for online Physician–Patient Contact 2007 (KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007), Para. 8.3, p. 11-12 and even added an illustrative clause to include in the contract of employment: KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, appendix 5, p. 17-18.

unclear what IT professionals can or cannot see, it is advisable to establish a derivative duty of medical confidentiality for them, for the same reasons that others have a derivative obligation of medical confidentiality in the first place: to ensure the physician's obligation of medical confidentiality.¹⁹⁵ The KNMG also recommended this in its Guidelines for online physician–patient contact. Concluding, both IT workers within the health care facility and IT workers who are not employed within the health care facility but are hired occasionally instead must be notified of their derivative obligation of medical confidentiality.¹⁹⁶ For the last group, it is suggested in the literature that additional agreements on confidentiality of patients' data can be made in their contracts.¹⁹⁷

4.4 E-consultation outside the scope of an existing relationship for medical treatment and the right to medical confidentiality

As presented in section 3, e-consultation between a patient and a physician who have never met each other, albeit under particular circumstances, is allowed.¹⁹⁸ Since the WGBO applies to this situation, too,¹⁹⁹ health professionals have an obligation of medical confidentiality during e-consultations with patients they have never met. Moreover, health professionals have an obligation of medical confidentiality based on Article 88 BIG Act as well.

Regarding the obligation to maintain medical confidentiality, e-consultation does not differ from regular, face-to-face consultation. Health professionals should guarantee confidentiality of both the e-consultation itself and the transcript or recordings of this. Moreover, physicians as well as others working within their practice, who have a derivative obligation of professional confidentiality, should not discuss information that they come across during the patient's treatment with others who are not involved in carrying out this treatment. What has been stated in section 4.3 also applies to them.

However, e-consultation outside the scope of an existing relationship for medical services provision leads to another difficulty. The KNMG Guidelines for dealing with medical data state that a physician, who is holding an e-consultation with a patient as a first encounter, should inform this patient's own physician. If the patient, however, objects to this, the physician must urge the patient to do so themselves.²⁰⁰ It is imaginable that the latter situation occurs. One of the reasons a patient contacts a health professional who does not know them can be that they hesitate to discuss this matter with their own GP. Therefore, it seems unlikely that this patient, who consults another GP online, will inform their own GP about this.

195 Leenen/Dute & Legemaate (eds.) 2017, p. 153.

196 KNMG Guidelines for dealing with medical data 2020, p. 132.

197 Schalken et al. 2010, p. 121.

198 KNMG Guidelines for dealing with medical data 2020, p. 27.

199 As elaborated on in section 3 above.

200 KNMG Guidelines for dealing with medical data 2020, p. 29.

Consequently, it is likely that the patient's own GP will not be notified of the e-consultation. If the health professional who conducts the e-consultation does inform the patient's own GP against the patient's wishes, they are violating their obligation of medical confidentiality. The obligation of medical confidentiality can be breached under four circumstances. One of these circumstances is the situation where the patient gives their consent to provide certain information to third parties. Then, breaching the obligation of medical confidentiality by informing the patient's own GP about the e-consultation is allowed.²⁰¹ The other grounds to breach the obligation of medical confidentiality do not apply in this case.²⁰²

Given the limitations that apply to e-consultation with patients a physician has never met,²⁰³ it is not likely that an in-depth diagnosis or treatment will be given during these consultations. Moreover, as presented in section 3, prescription of medication is not allowed at all during this type of electronic consultation.²⁰⁴ Because of this, the damage might not be too substantial when the patient decides, in spite of the health professional's express advice, to not inform their own GP. Therefore, in case of e-consultation between a physician and a patient who have never met, the physician cannot breach their obligation of medical confidentiality by notifying the patient's own GP of the e-consultation against the patient's wishes. The health professional might wonder whether conscientious health care provision²⁰⁵ requires informing the patient's own physician. The patient's own GP might need this information to provide health care of good quality to their patient. It depends on the situation and on the topic of the e-consultation whether conscientious health care provision will allow the physician to breach their obligation of medical confidentiality and inform the patient's own GP. In case of a casual health or lifestyle advice this is less likely than in a case where the health professional gives in-depth medical advice. The latter will hardly be the case though since e-consultations outside the scope of an existing contract for medical services are only allowed when they are fairly superficial.²⁰⁶

201 The patient's consent to provide information about their situation to third parties does not always mean that the health professional can do so without being in violation of their obligation of medical confidentiality. The health professional instead of the patient should decide whether information can be given to third parties; even when the patient gave their consent the decision remains for the health professional to make. See for instance Buijsen et al. 2012, p. 48 and Wijne 2017b, p. 257.

202 As presented in chapter 3 above.

203 KNMG Guidelines for dealing with medical data 2020, p. 27-31.

204 Art. 67 Gnw, confirmed in Rb. Den Haag (vzr.) 20 mei 2010, ECLI:NL:RBSGR:2010:BM5482, *JGR* 2010/28, m.nt. De Best (*Multatuli*) and Regionaal Tuchtcollege voor de Gezondheidszorg Den Haag 31 August 2010, ECLI:NL:TGZRSGR:2010:YG0556 and repeated in KNMP Guideline Online Pharmaceutical Care and Service Provision 2008, recommendation 14, p. 7 and 8 and KNMG Guidelines for dealing with medical data 2020, p. 27-31.

205 Art. 7:453 BW.

206 As established above in section 3. According to the KNMG Guidelines for dealing with medical data 2020, e-consultation outside the scope of an existing relationship for medical treatment should only take place if the risks are low and the e-consultation is beneficial for the patient (p. 27). In practice, this means that those kinds of e-consultations cannot be too substantial.

The KNMG recommends that health professionals who are conducting electronic consultations verify their patients' identities.²⁰⁷ The old KNMG Guidelines for online physician–patient contact used to make an exception for anonymous e-mental health when this allowed patients who otherwise avoided help to contact a health professional at an early stage.²⁰⁸ Certain types of e-mental health were mentioned as an example. As elaborated on in chapter 2 and section 2 of this chapter, anonymous e-mental health in the Netherlands is recognised in legislation.²⁰⁹ This indicates that anonymous e-consultation for mental health is still permitted. Nevertheless, the obligation of the health professional to advise the patient to contact their own GP about the e-consultation still stands.²¹⁰

In conclusion, health professionals should take their obligation of medical confidentiality into account while providing online consultations. This is particularly important during e-consultations that take place outside the scope of an existing relationship for medical treatment: this leads to a contract for medical service provision and thus the applicability of Article 7:457 BW. Otherwise, the physician is subject to an obligation of medical confidentiality based on Article 88 BIG Act. Contracts with third parties who might be able to oversee e-consultations must include a derivative obligation of medical confidentiality, based on the physician's obligation.²¹¹

The following section will elaborate on patients' rights with respect to informational privacy during eHealth care provision. The section will do so by highlighting something that is very much related to informational privacy: the medical record. Whenever appropriate, a difference will be made between e-consultation within an existing physician–patient relationship and e-consultation within a new physician–patient relationship, i.e. when the patient and the physician have their first encounter during the e-consultation.

4.5 Safety measures and the patient

After presenting all the rules and regulations with respect to informational privacy in relation to e-consultation that must be met by health professionals and health care facilities, an important remark needs to be made. Despite all the safety measures health care institutions and physicians can take to protect their systems against invasions from third parties, one aspect of privacy protection is remarkable, namely the security-related risks on the patient's side.

207 KNMG Guidelines for dealing with medical data 2020, p. 29.

208 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, Para. 5.a. (IV), p. 8 in conjunction with reference no. 6 at the bottom of the page.

209 Art. 70a Para. 1 Zvw.

210 KNMG Guidelines for dealing with medical data 2020, p. 29.

211 As also recommended by the KNMG: KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, appendix 5, p. 17-18, including an illustrative clause that can be included in a contract.

As discussed in this section, various statutes consisting of national as well as supranational regulation, combined with practical safety norms and good practice guidelines contain rules and advice for health professionals on how to deal with medical data. However, the patient might still use devices that are not protected.²¹² A patient cannot be expected to implement the same level of safety measures as the health professional, nor can a patient be obliged to protect their personal devices. An option is to refuse to provide an e-consultation to a patient who is using a device that is inappropriately secured. This happens in other fields. The Erasmus University, for instance, does not give employees access to their work email and agenda account on their smartphone if they do not adjust the safety settings of their mobile device by installing a screensaver and locking it by a pin code. However, turning down a request for e-consultation can infringe a person's right to health because they are not given access to health.²¹³ On the other hand, turning down the request does not have to do with an unwillingness to provide health care, but with a willingness to protect another fundamental right of the patient instead: their right to informational privacy. This means that these two fundamental rights must be balanced against each other.

However, since e-consultation does not replace face-to-face health care provision, it should be possible to refuse e-consultations to patients who use devices with inappropriate security settings. It is advisable to provide these patients with information on how to adjust the settings of their device to make e-consultation possible. Moreover, the information must contain the health professional's contact information and information on how the physician can be reached otherwise. When an individual consults a health professional via an email account shared with their family members, it is unsure who will read the health professional's reply. Another example can be found in the NHG-Checklist e-consult, which states that health professionals must explain to their patients that they should not use an email application which is not safeguarded.²¹⁴ This sounds a sensible recommendation. Of course, physicians should always advise their patients to use secured applications and not to send confidential information and personal health information over an unsecured email application. However, it seems optimistic to expect that patients will never use their own email applications any more to email their GP.

As Nouwt explains, a difference exists between data protection and privacy. Data protection refers to rules related to the protection of informational privacy that authorities, health professionals et cetera should protect for citizens, or, in this instance, patients. Privacy on the other hand refers to what people experience themselves, making this a subjective concept. Not everyone will be equally concerned by a violation of their informational privacy and

212 See also Richards in Gunning & Richards, *BMJ* 2014, p. 3.

213 As presented in section 3.2 above, access to health care is an element of the right to health: CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

214 NHG-Checklist e-consult 2014, Para. 4, p. 3.

not everyone will experience the same action as a violation of their privacy.²¹⁵ Therefore, health professionals are bound by various statutes, regulations and good practice guidelines to protect their patients' informational privacy, while patients themselves are in principle allowed to post their medical records or a transcript of an e-consultation on social media. This is especially relevant in light of the patient's right to access their personal medical information following from Article 7:456 BW. Sometimes, authorities or companies request medical information. According to the KNMG Guidelines for dealing with medical data, health professionals must stress that patients do not share their entire medical record with third parties.²¹⁶

While the physician, based on their duties as a conscientious health care provider, is obliged to urge the patient to be cautious with their medical data, they can by no means forbid the patient to share their medical record. At the very most, health professionals can and must advise patients against doing so, for instance by explaining the potential risks of the exposure of personal health data or by advising the patient to avoid using shared devices or shared email accounts for e-consultations. However, these days, where public customer service on social media seems to be the standard, it can be difficult to make this case.

In summary, health care institutions and health care providers are obliged to observe various regulations on the protection of patients' personal data. However, they have little control over the protection of patients' own devices or over the way patients manage their personal health data and whether, to whom and where they expose them. Therefore, all that health professionals can and must do is advise patients against using devices that are not safeguarded and recommend them to take precautions to protect their privacy.²¹⁷ It is recommended that patients who use devices that do not have the right settings to protect their privacy are denied access to e-consultation until the settings of their devices are adjusted. These patients' right to health will not be infringed since e-consultation does not serve as a replacement of face-to-face consultations but is supplementary to regular health care instead. This means that patients still have access to other ways of health care provision. Finally, health professionals should stress the risk related to sharing personal medical information and advise patients against sharing their personal medical data.

4.6 E-consultation, medical confidentiality and ownership of the medical record

A study conducted by *Patiëntenfederatie Nederland* [Dutch Patient Association] in collaboration with the television show *Kassa* showed that in spite of the (more or less) absolute right of

215 Nouwt, *RGD Nieuwsblad* 2014, issue 6, p. 10-11.

216 KNMG Guidelines for dealing with medical data 2020, p. 17.

217 Schalken et al. 2010, p. 139.

access to one's own medical record, this access was not always provided.²¹⁸ As explained in chapter 3, patients have a right of access to their medical files, based on Article 7:456 BW. This is a more or less an absolute right. The situation shown by *Patiëntenfederatie Nederland* and *Kassa* in combination with the increasing possibilities for someone to access their own medical file raised questions of ownership of the medical record. Developments related to eHealth facilitate the exercise of the right to access one's medical file. Because medical records nowadays can be opened and stored on almost any device, at any place and because of societal developments that lead to more articulate patients who want a say in their medical treatment, questions arise over whether the ownership of the medical file should be transferred from the health professional to the patient.²¹⁹

Traditionally, the ownership of the medical record was very clear. A physician used to keep a written file which was stored in a filing cabinet in the practice. Obviously, the medical record was owned by the health professional; the fact that the medical file was kept physically in the office meant that they had ownership of the physical record and were responsible for protecting the confidentiality of the data included in it. Nowadays, medical records are stored electronically and can be opened from various devices. Patients at times even have the opportunity to access their files digitally, which is far easier than accessing a paper medical file stored in the physician's practice. Maybe they can obtain (a copy of) their medical record without even having to ask their physician first. In the Netherlands, patient portals are frequently used to provide patients with access to their medical data.²²⁰ An example of such a portal is the patient portal of the Leiden University Medical Center (LUMC), which gives patients who log on access to their medical information, including lab test results and information about medication.²²¹

At first sight, transferring the ownership of the medical record from the health professional to the patient sounds reasonable. The information included in the medical record is about the patient thus it seems reasonable that they should be the one to determine what happens with this information and what they will do with it. As sensible as this might sound, it can be quite problematic. First, health professionals include all kinds of information in the medical file, such as personal annotations. When the patient is in control of the medical record, this can be hampered. Ownership is, according to Dutch law, "*the most comprehensive right a person can*

218 Van Harten & Lekkerkerk 2016, p. 13-14. The results of the report were also discussed in *Kassa*, on 17 September 2016. The part of the episode about this study can be accessed on bnnvara.nl/kassa/artikelen/veel-problemen-met-medisch-dossiers. 'Veel problemen met medische dossiers', 17 September 2016.

219 European Union 2012, p. 9-10.

220 De Haan et al. 2017, p. 8.

221 See LUMC, *Handleiding LUMC Patiëntportaal* ('mijnLUMC', lumc.nl. Source: lumc.nl/org/mijnlumc/. The patient portal of the Erasmus Medical Center has a similar functionality: patients can access medical information about themselves in their online patient record. See 'Mijn Erasmus MC' erasmusmc.nl. Source: erasmusmc.nl/nl-nl/patientenzorg/mijn-erasmus-mc.

have in a thing".²²² This means that the patient instead of the physician will determine what will happen with the medical file. Among other things, they might have the opportunity to alter the medical record. This impedes the health professional's duty of conscientious health care provision,²²³ because they might not be able to control the medical file any more once the ownership is transferred to the patient. Moreover, when the patient stores their own medical file, it will be difficult for the physician to use the file as a point of reference during (online) consultations. Second, ownership and storage of the medical record by the patient means that the patient will be responsible for sharing their medical information with their health professionals. The question is, exactly how big a difference this is. In current Dutch legislation, patients can give health professionals permission to share their medical file in the LSP.²²⁴ Under legislation, which has yet to take effect, however, this permission can be more specified. Patients will not only have a right to give permission or to refuse to share their medical record, they will also have a right to specify exactly which health professional is allowed to access which part of the record.²²⁵ Such a regulation seems to imply a certain kind of ownership by the patient because determining exactly who gets to see which parts enables them to administer their own medical record. Of course, the patient already had the right to determine who can access their medical file by giving their consent, but the new regulation offers the patient even more concrete possibilities to provide or deny access to their medical record. This upcoming legislation might mean that in the Netherlands, we are moving closer to an ownership of the medical record by the patient. Yet, in this situation the responsibility still lies with the health professional, as opposed to a situation where the patient is the owner of the medical record: ownership also means responsibility. This is an important difference with the situation as the law stands.

An important question, however, is whether it is even possible to own something that is digital. It all used to be very clear when physicians used to store medical records physically within their practice. As already mentioned before, nowadays most health professionals store their patients' medical files digitally. When taking a closer look at ownership in Dutch law, we see that the BW defines ownership as the most encompassing right a person can have in a thing.²²⁶ Thus, things can be owned. This leads to the question of whether things can be digital. According to Article 3:2 BW, things are objects which are material and controllable by people. A digital file is definitely controllable by people. However, something that is digital is not material. In the *travaux préparatoires* to the WGBO, ownership of the medical record

222 Art. 5:1 Para. 1 BW. Translated by Warendorf et al., Warendorf Legislation/1 CC Bk 5.

223 Art. 7:453 BW.

224 Art. 15a Para. 1 Wabvpz.

225 This provision was supposed to enter into force in July 2020. However, this was not feasible according to the Minister for Medical Care. *Kamerstukken II* 2019/20, 27529, no. 192 and *Kamerstukken I* 2019/20 27529, K. The minister refers to the advice of the *Adviescollege toetsing regeldruk* [Dutch Advisory Board on Regulatory Burden] (ATR), Appendix to *Kamerstukken II* 27529, no. 192-903663 and KPMG 2019.

226 Art. 5:1 BW, translated by Warendorf et al., Warendorf Legislation/1 CC Bk 5.

by the health professional was assumed.²²⁷ However, later in the law-making process it was added that even though the physician owns the medical record, they cannot own the data in it. According to the *travaux préparatoires* the health professional has a so-called control over the data.²²⁸ For instance by deciding about including and changing data, albeit under strict conditions formulated by the WGBO, such as the obligation to include relevant information in the medical record.²²⁹ The patient, on the other hand, also has certain rights of control over the medical file, for instance by asking the physician to alter or delete certain information.²³⁰ Thus, although the physician owns the medical record, they do not own the data included in the record. This was confirmed in case law.²³¹ Both the physician and the patient have certain rights of control over these data, such as altering and accessing them, stemming from multiple statutes and regulations²³² but neither the health professional nor the patient is the owner of these data. Thus, in the old situation, when medical records were kept by the physician on paper, the physician only had the ownership of the paper record but not of what was written on it. Likewise, a health professional can own or control the server or the computer, but not the information placed on that server.²³³

That being said, it will not be easy to own a medical record according to Dutch law. As noted in the *travaux préparatoires* to the WGBO and confirmed in case law, instead of ownership of a medical file, it is about decision-making power, and management and control of the data.²³⁴ Therefore, the question is not who owns the medical record but who mostly manages and control the data in it.

As soon as a person is responsible for controlling and managing their own medical file, they are responsible for its safety and security as well. As presented in section 4, all kinds of regulations and obligations to ensure safety and security of digital systems are imposed on health professionals and health care institutions. Imposing these rules on patients, however, is seemingly impossible or at the very least difficult, as discussed in section 4.6. Making patients the controllers of their medical records will make them responsible for protecting them. Imposing safety and security measures on patients will be difficult since the statutes, regulations and guidelines presented above either aim at individual health professionals or health care institutions. For the most part, the statutes, regulations and guidelines are

227 *Kamerstukken II* 1990/91, 21561, no. 6, p. 46.

228 *Kamerstukken II* 1990/91, 21561, no. 15, p. 22.

229 Art. 7:454 BW.

230 Art. 7:454 Para. 2 and Art. 7:455 BW.

231 HR 25 May 2012, ECLI:NL:HR:2012:BV8508, *NJ* 2012/566, advisory opinion De Vries Lentsch-Kostense, Para. 14 and Legemaate in his comment on the decision, Para. 8.

232 Art. 7:454 Para. 2 and 7:456 BW and Art. 15 and 16 GDPR.

233 Also in that sense: KNMG Guidelines for dealing with medical data 2020, p. 120.

234 *Kamerstukken II* 1990/91, 21561, no. 6, p. 46 and HR 25 May 2012, ECLI:NL:HR:2012:BV8508, *NJ* 2012/566, advisory opinion De Vries Lentsch-Kostense, Para. 14 and Legemaate in his comment on the decision, Para. 8.

complicated, even for professional organisations, although these organisations and health professionals are their target group. Enforcement when a patient violates them will be a problem as well; a person cannot be summoned in court for violating their own privacy, nor can a fine be imposed upon them for this reason. Moreover, such violations might be difficult to discover since they take place in the patient's private sphere. Besides, not every individual will be equally careful with their own personal data,²³⁵ where health professionals and health care institutions are obliged to protect everyone's privacy in an equal fashion based on various statutes and regulations, such as the WGBO, the BIG Act and the GDPR.

Consequently, the combination of the differences between people in their attitude towards personal privacy and the impossibility of enforcing the statutes, regulations, standards and guidelines related to privacy and medical confidentiality, which do not aim at individuals, leads to the conclusion that making patients the controllers of their medical records instead of health professionals and professional organisations is highly undesirable.

Confidentiality of medical data is a human right and cannot be protected by individuals themselves; it should be protected by others, even though and perhaps because individuals themselves sometimes undervalue their privacy. Health professionals and health care institutions should be primary responsible for controlling and protecting the medical data. Only then, the purpose of medical confidentiality, i.e. guaranteeing a right to freely access a health professional without having to fear the exposure of personal information, can be fulfilled.

5. E-CONSULTATION AND SPATIAL PRIVACY

Spatial privacy, as explained in chapter 3, entails the kind of privacy you have within a relationship of treatment. Unless the patient has given their explicit consent, third parties are not allowed to be present during a consultation or treatment, nor are they allowed to hear what is discussed between the health professional and their patient.²³⁶

E-consultation, at first sight, seems to be a means by which the patient's spatial privacy can be protected very well. During an online consultation, a patient can pose their questions from within their own private sphere, where they can make sure they cannot be disturbed. This is especially because e-consultation enables them to choose a time when they wish to contact their physician, although it is imaginable that some health professionals only hold e-consultations during certain preset hours, or they prefer to hold e-consultations by

235 Dupuis, p. 9 and 12 and Nouwt, *RGD Nieuwsblad* 2014, issue 6, p. 10-11.

236 Art. 7:459 BW.

appointment. Moreover, we can assume that a patient who is having an e-consultation from home ensures that they have privacy during the online consultation.

However, some disadvantages exist on both sides. First, a patient cannot verify whether the health professional they have an online consultation with, is really alone. Especially when the physician and the patient communicate by means of chat or email, it is impossible for the patient to notice if someone else, such as a trainee, is reading along. In case of email, it can be unclear to the patient who can read the email and the reply. Nevertheless, an important recommendation to the physician is that they should ensure that no one else can read their emails. For instance by using a regularly changed password²³⁷ or locking the computer when walking away from it.

Second, the physician does not have the opportunity to check whether the patient is accompanied by someone else who might want to read or listen along during the e-consultation. The WGBO allows others to overhear the consultation when the patient has given their explicit consent.²³⁸ When the consultation takes place over distance, the health professional cannot examine whether the patient really has given consent for third parties to attend the consultation. Even when the consultation is carried out by means of a video chat, it is not possible to verify whether the patient has given their consent. That being said, when the e-consultation takes place by chat or email, the health professional cannot even see whether or not the patient is alone.

Based on the *travaux préparatoires* to the WGBO, spatial privacy entails that third parties should not be present during the consultation and should not be able to overhear the consultation without the patient's explicit consent.²³⁹ Even though Article 7:459 BW mentions 'observing', this does not only refer to visual observation of treatment but to observation by hearing as well.²⁴⁰ 'Observing' in Article 7:459 BW must be interpreted to also include observation over time and over distance. Originally, Article 7:459 BW covers protection against others being present during the consultation. Although this will take place over distance, 'observing' an online consultation – even when it is written only – is possible. In accordance with the intention of the right to spatial privacy, namely protecting the fundamental right to privacy and providing treatment without hindrance,²⁴¹ the obligation to respect spatial privacy can be assumed to extend to observing written consultations. The right to privacy, including spatial privacy, should be equally protected whether the consultation is carried out face-to-face or online.

237 Schalken et al. 2010, p. 133.

238 Art. 7:459 BW.

239 *Kamerstukken II* 1989/90, 21651, no. 3, p. 17.

240 *Kamerstukken II* 1989/90, 21651, no. 3, p. 17.

241 *Kamerstukken II* 1989/90, 21561, no. 3, p. 41.

Protecting spatial privacy can be more difficult over distance. Attention should be paid to ensure that compliance of this legal obligation does not fail for the sake of convenience. Even though the patient might never find out that someone is following the e-consultation, they still have a fundamental right to privacy that should be protected. The patient should always give their consent for others overseeing the consultation, although this does not always happen in practice. Even during face-to-face consultations, trainees or assistants are sometimes present,²⁴² although the explanatory memorandum to the WGBO states that explicit consent is always required. When a patient simply does not object to the presence of these third parties, this cannot be considered the same as giving their consent.²⁴³ Interns working in Dutch health care facilities report that it does happen in practice that the patient objects to their presence.

Perhaps a more difficult question is how spatial privacy can be protected on the patient's side. When patients consult a health professional from home, protecting spatial privacy will be more complicated because of family members who live with the patient.²⁴⁴ Perhaps the patient does not want them to oversee the consultation, but they do not tell them so. If that is the case, the presence of these people will stand in the way of good health care provision. During a face-to-face consultation, the physician can ask these people to wait outside while they provide the consultation. When the consultation takes place over distance, however, chances are that a health professional does not even know that somebody is invading the patient's spatial privacy. If they suspect that this is the case, it might be harder to intervene compared to the situation of a face-to-face consultation. As a starting point, the health professional can pose certain questions at the beginning of the consultation, or even before the start of the consultation, to verify that the patient is really alone. However, there is still a chance that the patient does not tell the physician the truth about this.

The WGBO regulates the relationship between a patient and their physician and this relationship is seen as a contractual relationship. The statute does not stretch to the relationship between a patient and their family members, except for those provisions that elaborate on representation for minors or representation when a patient lacks legal capacity. Therefore, it will be difficult to implement a provision on the protection of spatial privacy during e-consultations, against family members. That being said, when a physician suspects that the patient is not alone, for instance because they give ambiguous answers or remain superficial, they should take action to be able to provide the care of a conscientious health care provider and invite the patient for a face-to-face consultation. During such a consultation, the health professional can deny the attendance of third parties based on Article 7:459 BW and thus provide the care of a conscientious health professional. When a physician suspects

242 Sluijters & Biesart 2005, p. 118.

243 *Kamerstukken II* 1989/90, 21651, no. 3, p. 41.

244 Ploem, *TvGR* 2008, p. 319.

that a patient cannot speak freely during a consultation over distance, they should stop the e-consultation and invite the patient to their practice for a face-to-face consultation because spatial privacy cannot be protected otherwise.

In summary, Article 7:459 BW fully applies to e-consultation. This means that health professionals must take precautions and ensure that the obligation of spatial privacy can be met in the surgery. While it might be more difficult for the health professional to observe a potential violation of spatial privacy on the patient's side, it is advisable that they invite the patient over to their practice as soon as they suspect such a violation.

6. E-CONSULTATION AND THE RIGHT TO INFORMED CONSENT

6.1 Introduction to e-consultation and the right to informed consent

As discussed in chapter 3, health professionals can only carry out treatment when a patient has given their explicit consent, based on the information the health professional provided. This is known as the right to informed consent.²⁴⁵ Since this right is laid down in the WGBO, it should be observed during e-consultation because it was established in section 4 of this chapter that the WGBO applies to online consultation, no matter whether this takes place within or outside the scope of an existing contract for medical services.

Informed consent can be obtained by means of a shared decision-making process between the patient and the health professional. eHealth in general and e-consultation in particular present implications for the right to informed consent. eHealth is often associated with enhancing the shared decision-making process²⁴⁶ because ICT in health care and the possibilities to gather information that it provides is said to lead to more articulate patients,²⁴⁷ who actively want to participate in the decision-making process.²⁴⁸ In the recent amendment to the WGBO, attention is paid to shared decision-making.²⁴⁹ Article 7:448 BW, on the patient's right to information, must be understood to facilitate shared decision-making.²⁵⁰

This section will discuss whether and how the right to informed consent will change because of e-consultation and how the patient's right to undergo no treatment without prior consent can best be protected. However, when using e-consultation to provide health care another,

245 Art. 7:448 in conjunction with Art. 7:450 BW.

246 Pelotti & Pari 2014, p. 79 mention multiple studies which show that eHealth applications can make a positive contribution to strengthen the shared decision-making process.

247 Platform Internetzorg en Patiëntportalen 2012, p. 3 and 5.

248 Baardman, *Tsg* 2015, p. 43.

249 *Kamerstukken II* 2017/18, 34994, no. 3, p. 3-6. *Stb.* 2019, 224.

250 *Kamerstukken II* 2017/18, 34994, no. 3, p. 3-6.

(new) aspect of informed consent is relevant. As well as giving consent for the treatment, the patient should also give their consent for aspects related to electronic consultation, such as processing medical data (which occurs during e-consultation, as shown in section 5) and the acknowledgement that third parties might view this information.²⁵¹

Because information precedes consent, this will be discussed first. The following subsection (6.2) will discuss both the ways in which e-consultation can make a positive contribution to providing information to the patient²⁵² and the ways in which e-consultation changes or complicates the right to information. Moreover, several recommendations will be made on what (additional) information to provide before giving advice or treatment via e-consultation.

6.2 E-consultation and the right to information

eHealth in general and e-consultation in particular are likely to change the way patients retrieve and handle information. E-consultation is a tool to provide patients with information in a quick and efficient way. Because of eHealth in general, patients acquire and possess more information about health and health care, resulting in articulate patients with an active role in their own health care process.²⁵³ This is in conformity with what patients seem to prefer: making decisions together with their physician. This is referred to as shared decision-making.

According to Article 7:448 BW, the health professional should inform the patient about the possible examination, the proposed treatment and the possible outcomes of this treatment, and the patient's health. The recent amendment to the WGBO endorses shared decision-making by proposing to alter Article 7:448 BW; not only should the physician inform the patient about the treatment and their prospects, they should also discuss this with the patient, instead of only informing them and asking them to give their consent or not.

E-consultation is a means that can be used to inform patients about their situation and can be used to meet their wishes to receive information from their physician at any time from any place.²⁵⁴ For instance, e-consultation can be used by patients to contact their physician with questions about information in their medical file, which they might have seen on a patient portal. Patients can use e-consultation to pose additional questions to their health professional after they have paid them a visit as well. Moreover, e-consultation can also be utilised by patients to discuss information about their health or their treatment that they found online, for instance on the website *thuisarts.nl*.²⁵⁵ In some instances, health professionals use

251 Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380, who cites Goldstein, *J Law Med Ethics* 2010, p. 31.

252 Insofar this is not done yet in section 2.2.4 above.

253 Platform Internetzorg en Patiëntportalen 2012, p. 3 and 5 and Baardman, *Tig* 2015, p. 43.

254 Platform Internetzorg en Patiëntportalen 2012, p. 3.

255 'Thuisarts,' *thuisarts.nl*. Source: thuisarts.nl/. This website contains information by GPs and is regularly updated under the responsibility of the NHG.

e-consultation to provide patients with test results. They think that patients will understand and remember more of this information because they receive it in writing. Moreover, they can pose their health professionals questions based on this information.²⁵⁶

It is stated that provision of information via ICT is beneficial, because it can be adapted to individual patients.²⁵⁷ During e-consultation, information can be provided in a way that the patient will understand. Obviously, health professionals will do the same during a regular, face-to-face consultation but an electronic consultation will give the patient more time to read and re-read the information and then pose their questions. Moreover, when the patient can save the e-consultation in their inbox or in their PHR,²⁵⁸ they can re-read and reflect on the information at any time.

Another question is what information should be provided during an online consultation. In literature, a distinction is made between information and consent for the treatment, and information and consent related to the nature of online health care provision.²⁵⁹ The first equates to information and consent that should be given during offline consultations.²⁶⁰ The WGBO lists several topics about which a health professional at least should inform their patient in article 7:448 BW. These include the nature of the examination or treatment, the expected outcomes and the potential risks thereof, possible alternatives and the patient's health with regard to this particular treatment or examination.

The second includes recommendations on additional information to provide before the e-consultation can be carried out. This information relates to the nature of this type of health care provision such as the risks of electronic consultation and the fact that personal medical data might be viewed by third parties.²⁶¹ For e-consultation, this entails the physician explaining what they can and cannot do during an e-consultation. This is confirmed in the KNMG Guidelines for dealing with medical data and the NHG-Checklist e-consultation.²⁶² In other words, information should be provided about when a patient should consult a health professional face-to-face instead,²⁶³ such as in case of problems that require physical examination.

256 O. Vogels, in: Jacobs, 'eHealth op de werkvloer: chatten met je arts over uitslag MRI-scan', smarthealth.nl 5 October 2015. Source: smarthealth.nl/2015/10/05/ehealth-op-de-werkvloer-chatten-met-je-arts-over-uitslag-mri-scan/.

257 Coulter & Collins 2011, as cited by Pelotti & Pari 2014, p. 82.

258 Personal Health Record, as explained in chapter 2. Also see the literature cited there.

259 Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380, who cites Goldstein, *J Law Med Ethics* 2010, p. 31.

260 Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380.

261 Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380, citing Goldstein, *J Law Med Ethics* 2010, p. 31.

262 KNMG Guidelines for dealing with medical data 2020, p. 28 and NHG-Checklist e-consult 2014, Para. 2, p. 1.

263 Ploem *TvGR* 2008, p. 317.

Health professionals should decide whether e-consultation is appropriate in this particular situation; as the guidelines point out, the physician is responsible for good medical conduct.²⁶⁴ This means that a physician, after explaining the risks of e-consultation in general and in this particular case, should decide whether to continue the e-consultation or not. Thus, even if the patient, after the health professional has explained that e-consultation is unsuitable in this particular situation, insists on having an online consultation, the health professional should urge them to make an appointment for a face-to-face consultation instead of continuing to advise this patient online.

Information on the nature of e-consultation also includes practical information. First, the physician should provide information about the time within which the patient can expect a response.²⁶⁵ When a health professional offers their e-consultations through email, they should clearly indicate when the patient can expect a reply. They can do this on their website or in an automatic reply. When they deliver their e-consultations through (video) chat, the response time will be shorter. However, when multiple patients request an online consultation at the same time, a feature such as an online waiting room is recommended. In this online waiting room, patients can be informed about the number of patients before them and the estimated waiting time. According to the NHG, patients should receive a confirmation of their message when the e-consultation takes place via email.²⁶⁶

In (international) practice, various good practice guidelines are published. An example of such good practice guidelines are the 'practice guidelines for video-based online mental health services' of the American Telemedicine Association (ATA). These guidelines elaborate on – among other things – informed consent. Since e-consultation can also be conducted by means of video chat, these guidelines can serve as an example for e-consultation in the Netherlands insofar as they include recommendations that are not included in the KNMG Guidelines for dealing with medical data 2020 and the NHG-Checklist e-consult. The following recommendation is an example of a recommendation that can be followed in the Netherlands as well. According to the ATA, the health professional should inform the patient on how often the online consultation will take place and when the consultation will take place in case of subsequent e-consultations.²⁶⁷

Another important topic that the patient must receive information about is what they can do in case of emergencies.²⁶⁸ I would like to add that the information the physician provides

264 KNMG Guidelines for dealing with medical data 2020, p. 27.

265 KNMG Guidelines for dealing with medical data 2020, p. 28 and NHG-Checklist e-consult 2014, Para. 2, p. 1.

266 NHG 2015, p. 11.

267 Turvey et al./ATA Practice Guidelines for Video-Based Online Mental Health Services 2013, p. 726.

268 Ploem, *TvGR* 2008, p. 317; NHG Checklist e-consult 2014, Para. 2, p. 2 and KNMG Guidelines for dealing with medical data 2020, p. 29.

the patient with should include the address of the practice or, when the practice is situated at a great distance from the patient, the contact information of a health professional near the patient. The latter does not apply in case of anonymous e-mental health because in that case the physician does not have information about where the patient resides. When a patient contacts a health professional via e-consultation, they should always be able to have face-to-face contact when the situation deteriorates. Depending on the situation and the location of the health professional who holds the e-consultation, emergency contact details should always be provided, should the patient be in need of emergency care. Especially when a part of the treatment takes place online instead of face-to-face, for instance when monthly check-ups are replaced by online conversations, the patient should always know how to reach their physician, or, when the travel time between the patient and their physician is too long, the contact details of another health professional they can contact during emergencies.

Another potential risk of e-consultation inherent to the nature of online consultations is related to data protection and medical confidentiality. The patient should receive information about this aspect of e-consultation in order to be able to give their consent.²⁶⁹ In literature it is suggested that the health professional who provides the electronic consultation provides information about the way they process data obtained during the consultation and how they store this information.²⁷⁰ The KNMG Guidelines for dealing with medical data contain a similar recommendation, adding to this that the patient should also be informed about locum tenency and triage of questions by others within the practice.²⁷¹ The NHG-Checklist e-consult also contains such a recommendation: physicians must clarify who can access the online consultation, including receptionists and potential locum tenens.²⁷² The NHG-Checklist e-consult urges the physician to explain which security measures are observed to prevent unauthorised parties viewing the electronic consultation.²⁷³ The ATA guidelines go a step further by advising health professionals to mention that in spite of everyone's best efforts to prevent personal data breaches, these might occur.²⁷⁴ This makes sense because these kinds of problems are inherent to online communication. As described in section 3, e-consultation is subject to privacy-related risks. Health care providers are obliged to take precautions and follow a variety of rules and regulations related to data security, yet privacy cannot always be guaranteed the same way online as it is offline. For instance, protecting privacy is more difficult when a patient uses a shared computer for the electronic consultation or when the patient does not adequately protect their devices. Moreover, health care providers, in

269 Compare Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380, who cites Goldstein, *J Law Med Ethics* 2010 and Goldstein, *J Law Med Ethics* 2010.

270 Ploem *TvGR* 2008, p. 317. As Ploem notes, this is also imposed by art. 33 Wbp. This provision is now replaced by Art. 13 GDPR.

271 KNMG Guidelines for dealing with medical data 2020, p. 28.

272 NHG-Checklist e-consult 2014, Para. 2, p. 1.

273 NHG-Checklist e-consult 2014, Para. 2, p. 1.

274 Turvey et al./ATA Practice Guidelines for Video-Based Online Mental Health Services 2013, p. 726.

spite of all the security measures they take, always risk becoming the victim of hackers. For health professionals in the Netherlands, this recommendation means that they must explain that they are providing e-consultations in accordance with the GDPR. An example of an explanation of which security measures are being taken is a declaration that the applications for e-consultation are designed in compliance with the NEN standards, such as NEN7510 on data protection in health care.²⁷⁵ Other standards to refer to are NEN7512 on online communication in health care, NEN7513 on electronic medical records and logging of data and the ISO 27001 norm on data security.²⁷⁶ Moreover, physicians can provide information on the action they or the health care facility will take when a personal data breach occurs. This information is essential, since studies already have shown that patients who are worried about their privacy are less likely to use eHealth.²⁷⁷

Finally, the physician should provide information about the costs of e-consultation.²⁷⁸ However, most e-consultations provided by GPs are eligible for coverage by health insurance.²⁷⁹ E-consultations with specialists are reimbursable as well, as long as they take place within a contract for provision of medical services. Even e-consultations without the prior existence of a medical treatment contract that lead to such a contract, can be eligible for coverage. Moreover, developments such as the possibility of reimbursement of anonymous e-mental health shows a willingness to reimburse any type of e-consultation,²⁸⁰ as long as the consultation takes place in accordance with existing legislation and good practice guidelines.²⁸¹ Based on all this information, the patient should give their consent for the e-consultation.

6.3 E-consultation and consent

In the WGBO, consent is laid down in Article 7:450 BW. Together with the right to information in Article 7:448 BW this constitutes the right to informed consent. Article 7:450 BW is in itself very clear; treatment as meant in Article 7:446 BW requires the patient's consent. E-consultation does not differ from any other type of consultation in this respect. The difference can be found in the aspect of consent. According to the WGBO, the parents or

275 NHG-Checklist 2014, Para. 4, p. 3.

276 'Informatiebeveiliging', nen.nl. Source: nen.nl/NEN-Shop/Informatiebeveiliging-1.htm.

277 Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980, cited by Kokabisaghi, Bakx & Zenelaj, *ELR* 2016, p. 158.

278 KNMG Guidelines for dealing with medical data 2020, p. 28. A similar obligation can be found in Art. 38 Wmg and Art. 10 Wkkgz.

279 NZa Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, section 1.2, Para. 3 and 4, p. 8.

280 Art. 70a Zvw, elaborated in chapter 6, Para. 2 of the Health Insurance Regulation.

281 NZa Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REGCU-20622-04, section 1.2, Para. 4, p. 8 refers to the KNMG Guidelines for online Physician–Patient Contact 2007 (KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007), which by 2020 has been included in the KNMG Guidelines for dealing with medical data 2020).

guardian should give consent in the place of minors aged twelve or younger.²⁸² Minors between the age of twelve and sixteen should give their consent together with their parents or their guardian.²⁸³ Minors from sixteen to eighteen years are, based on the WGBO, legally capable of giving their consent themselves.²⁸⁴ For patients over twelve years who are not considered to possess legal capacity, it needs to be the parents or guardian, or the legal guardian or the guardian *ad litem* when the patient is under legal restraint or a mentorship is imposed on them.²⁸⁵ Over distance, it can be hard for a physician to assess whether somebody possesses legal capacity or not. This might impose a difficulty on the online treatment because it is difficult to assess whether the information is understood. This requires a practical solution in the future to help the health professional assess whether the person who is requesting an e-consultation has legal capacity.

6.4 E-consultation and e-consent

A topic such as e-consent might as well be discussed in the section on privacy but because of its relationship with informed consent it is presented here. E-consent refers to consent about access to health information. This type of consent is given digitally, at times by means of a so-called e-consent system.²⁸⁶ While e-consent usually refers to consent about access to personal health data, it is worthwhile to investigate whether informed consent for an online treatment can also be obtained this way. For instance, before an electronic consultation is started patients can be presented with questions about the electronic consultation and its characteristics. After receiving this information, they can decide to continue the online consultation or not. Even though this tool will not give a perfect indication of a person's capacity to understand the given information, it can help to determine what they have understood. This tool will most likely not help to determine whether a person has legal capacity though, a problem that was presented in section 5.3.

6.5 E-consultation and the right to information about options

Another right related to the right to information, which has been developed in recent years, is the right to information about options. As well as the information the health professional is supposed to provide the patient with based on Article 7:448 BW and the additional information discussed in section 5.2 that the health professional who holds an e-consultation should provide, patients have a so-called right to information about options.²⁸⁷

282 Art. 7:465 Para. 1 BW.

283 Art. 7:450 Para. 2 BW.

284 Art. 7:447 BW.

285 Art. 7:465 Para. 1, 2 and 3 BW.

286 Coiera & Clarke, *Journal of the American Medical Informatics Association* 2004, p. 129-140.

287 Art. 38 and 40 Wmg.

The right to information about options is laid down in Dutch statutes in the *Wet Marktordening Gezondheidszorg* [Health Care Market Regulation Act] (Wmg)²⁸⁸ in Articles 38 and 40. Article 38 Wmg relates to health care providers. According to this provision they should at least inform patients of the quality and the tariff of the services they provide. It is essential that this information is easy to compare with information provided by other health care providers. According to Article 40 Wmg health insurers should inform patients about the quality and the tariff of the health services they offer patients as well i.e. the quality and tariff of the health care providers they contracted with. The purpose of the right to information about options is facilitating patients to make a choice.²⁸⁹ This way, it is an addition to the right to informed consent in the WGBO. This means that patients also have a right to know which treatment a particular physician does not provide.²⁹⁰ They can base their choice to not enter into a contract for medical services with this physician on this information. In academia, the question is posed as to how far-reaching this right actually is.²⁹¹ In the literature it is stated that health professionals should only mention that other methods exist and that a reference to a health professional who does provide a particular treatment is not necessary.²⁹² In case of e-consultation, this is indeed a solid recommendation. When a patient contacts their own GP and asks for an electronic consultation and the GP does not offer these kinds of consultations, it can be wondered whether this patient should be informed of other opportunities for e-consultation. Logically, the GP requests the patient in this case to visit their surgery. Informing the patient about possibilities of electronic consultations with other GPs will most likely result in an e-consultation outside the scope of an existing physician–patient relationship if the patient decides to request an e-consultation with one of the GPs who does provide such consultations. As elaborated on in section 3, this is not always preferable and is only allowed in some cases.²⁹³ Simply referring the patient to another GP, who probably does not know this patient and their medical history, for an online consultation seems to not result in conscientious health care provision and moreover conflicts with several good practice guidelines by the KNMG and the NHG.²⁹⁴ Therefore, the GP should inform the patient that they do not provide e-consultations and invite the patient for a face-to-face consultation in their practice. Informing the patient about other health professionals who do offer online consultations is not necessary or desirable in this case. When a health professional does not offer e-consultations because they think this conflicts with their duty to act as a conscientious health care provider,²⁹⁵ it cannot be expected that they will refer their

288 *Sib.* 2006, 415.

289 *Kamerstukken II* 2004/05, 30186, no. 3, p. 62.

290 Legemaate, *TvGR* 2011, p. 480.

291 Legemaate, *TvGR* 2011, p. 480.

292 Legemaate, *TvGR* 2011, p. 480.

293 KNMG Guidelines for dealing with medical data 2020, p. 27.

294 KNMG Guidelines for dealing with medical data 2020, p. 27 and NHG-Checklist e-consult 2014, Para. 2, p. 2.

295 Art. 7:453 BW.

patient to another physician who does provide such consultations. Inviting the patient for a consultation in their own practice is sufficient.

Whereas the WGBO contains civil rights, the Wmg is a statute of administrative law.²⁹⁶ Thus, the right to information about options is an example of a patients' right in public law. For e-consultation, this means that health care providers as well as health insurers should allow patients insight into the services that health providers offer via e-consultation, the quality of the online consultations provided, the costs of such a consultation and information on whether these costs are reimbursable. eHealth can assist in providing this information, but this does not necessarily have to be e-consultation. On the contrary, it is unlikely that the information meant in the Wmg is presented during online consultation. Other types of eHealth, such as online provision of information (e-Public Health) are more suitable and more likely to be used for this purpose. However, since these kinds of eHealth exceed the topic of this study, this will not be discussed any further.

For individual patients, the right to information about options can be found in Article 10 of the *Wet kwaliteit, klachten en geschillen zorg* [Healthcare Quality, Complaints and Disputes Act] (Wkkgz).²⁹⁷ Based on this statute, patients can invoke against a health care provider a right to receive information about the services a particular health care provider offers, including the quality of these services.²⁹⁸ Furthermore, patients have a right to be informed of the scientific character and the waiting list for a particular treatment.²⁹⁹ Finally, patients have a right to receive information about incidents occurred during the treatment when this incident is likely to affect the patient.³⁰⁰ For e-consultation, this entails patients being informed about the limitations of e-consultation.³⁰¹ These conditions will impact the possible outcomes of the e-consultation. The right to information about incidents should be understood to, next to the right to information about medical incidents, contain a right to receive information about technical malfunctions and system failures during or shortly after the e-consultation as well. This can namely impact the quality and safety of the e-consultation equal to a medical error.³⁰²

Another example that gives patients the opportunity to exercise some kind of right to information about options in order to make the right choice for a health care provider and treatment is laid down in Article 9 in conjunction with Article 1 of the BIG Act, in

296 Meersma, in: *T&C Gezondheidsrecht* 2020, Art. 38 Wmg.

297 *Stb.* 2015, 525.

298 Art. 10 Para. 1 Wkkgz.

299 Art. 10 Para. 2 Wkkgz.

300 Art. 10 Para. 3 Wkkgz.

301 KNMG Guidelines for dealing with medical data 2020, p. 28.

302 Compare Art. 34 GDPR which obliges the controller to inform the data subject in case of potential damage due to a personal data breach.

conjunction with Article 5 Paragraph 2 Section b of the *Registratiebesluit BIG* [Registration Resolution Individual Health Care Professions]. As soon as disciplinary action is taken against an individual health professional, this will be placed in the BIG register, the register for individual health professionals. Everyone can consult this register.³⁰³ Much is written about the (in)desirability of such a public register, in popular speech known as the blacklist.³⁰⁴ However, since there is little connection with e-consultation, or, rather little difference between e-consultation and face-to-face consultation in this respect, this will not be discussed any further at this point.

In sum, because of eHealth patients will have more information at their disposal. The patient's right to information, however, should be expanded during e-consultation: as well as the information listed in Article 7:448 BW, information inherent to the nature of e-consultation such as the procedure, the costs, privacy issues and contact information in case of emergencies should be provided.³⁰⁵

303 'Disciplinary Measures healthcare professionals' *bigregister.nl*. Source: english.bigregister.nl/documents/publications/2017/03/03/disciplinary-measures-health-care-professionals.

304 See, for instance Buijsen, *NJB* 2009, p. 1508-1511 and Van Meersbergen, *Medisch Contact* 2009, p. 1224.

305 Ploem *TvGR* 2008, p. 317; Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380, citing Goldstein, *J Law Med Ethics* 2010; Turvey et al./ATA Practice Guidelines for Video-Based Online Mental Health Services 2013, p. 726; NHG-Checklist e-consult 2014, Para. 2, p. 1-2 and Para. 4, p. 3 and KNMG Guidelines for dealing with medical data 2020, p. 28-29 (and footnote, p. 29).

5





Tele-expertise and patients' rights

1. INTRODUCTION

As explained in chapter 2, tele-expertise refers to a consultation over distance between two (or more) health professionals, the requesting physician and the tele-expert, related to the treatment of an individual patient, by means of ICT. Tele-expertise always entails communication about the treatment of a particular patient and can take place through a variety of ICT applications and devices. The most important difference with e-consultation is that the communication takes place between two (or more) health professionals instead of a health professional and a patient.¹ Through tele-expertise, physicians can assist each other in making a diagnosis and decide whether (online) therapy, prescription of medication or referral is necessary (e-diagnosis).

An example of tele-expertise in the Netherlands is teledermatology. Teledermatology refers to tele-expertise between GPs and dermatologists. The GP can ask a specialist for advice or whether a referral is necessary.² This type of eHealth care provision seems to contribute to efficient health care delivery and teledermatology in particular has been reported to improve the quality of health care.³ Another example of tele-expertise is teleradiology (intra- or extramural communication between radiologists).⁴

Despite its many advantages, questions about the legal aspects of the use of tele-expertise arise. Examples include the question of whether the patient must give their physician their explicit consent to consult another health professional over distance and the question of how the patient's privacy can be protected when their medical information is sent to another physician by means of ICT. The latter also came up in the example on the use of the popular messenger app WhatsApp by health professionals to consult each other about the care for a

-
- 1 Tele-expertise is in doctrine often referred to as 'teleconsultation' but that word will not be used in this study to prevent confusion with e-consultation. For instance in Van de Heijden & Schepers, *Bijblijven* 2011, issue 8, p. 8. The RVZ 2002, p. 17 does not name this type of eHealth and just refers to 'consultations between colleagues.' This phrase is not distinctive enough for the purpose of this study.
 - 2 Van der Heijden & Witkamp, *NTvDV* 2013, p. 538-544 and the earlier study conducted by Van der Heijden et al., *NtVG* 2012, issue 4, p. 1-7, published before as Van der Heijden et al., *BJD* 2011, p. 1058-1065.
 - 3 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539-540 and the earlier study conducted by Van der Heijden et al., *NtVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063-1064.
 - 4 Dans & Van der Vorst, *TvGR* 2008, p. 188.

patient.⁵ These questions – among others – will be discussed in this chapter. The examples mentioned in this section will be used as case studies throughout the chapter to illustrate the questions related to patients' rights that arise during tele-expertise.

In chapter 2, tele-expertise, alongside e-consultation was categorised as an application of eHealth care provision (a subdivision of professional eHealth), which can consist of e-diagnosis, e-therapy and e-care. Tele-expertise can be classified as e-diagnosis.⁶

Similar to the previous chapter, this chapter will elaborate on tele-expertise and the contribution it can make to realising the right to health as well as the potential limitations and reservations to the benefits tele-expertise can have as a contribution to this right. Similar to what was done in chapter 4, the AAAQ framework will be applied (section 2). Then, the applicability of the WGBO to tele-expertise will be discussed (section 3). The subsequent sections will present a choice of patients' rights; the rights to informational privacy and medical confidentiality (section 4), the right to spatial privacy (section 5) and the right to informed consent (section 6) in relation to tele-expertise.

2. TELE-EXPERTISE AND THE RIGHT TO HEALTH

2.1 Availability

The first condition for health services to contribute to realising the right to health is the availability of these services.⁷ Tele-expertise might make a positive contribution to the availability of health services. Tele-expertise, maybe one of the oldest eHealth applications, was originally designed for this purpose. The example cited in chapter 2, where a physician provides advice about the treatment of wounded people over a distance of about 1800

5 Van Noort 2015, *NRC Next*, p. 7, Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809, 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', knmg.nl/Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm; The Federation of Patients in the Netherlands gave a reaction in: Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809 and Van Noort, *NRC Next*, 8 July 2015, p. 7, The Dutch DPA reacted in current affairs programme *EenVandaag*, broadcast on 23 February 2016, *Eenvandaag*, 'Medische info delen via Whatsapp', [eenvandaag.nl](http://eenvandaag.avrotros.nl/binnenland/item/medische-info-delen-via-whatsapp/). Source: <https://eenvandaag.avrotros.nl/binnenland/item/medische-info-delen-via-whatsapp/>. Also see Van Noort, 'Artsen moeten stoppen met whatsappen over patiënten', *nrc.nl* 23 February 2016. Source: nrc.nl/nieuws/2016/02/23/artsen-moeten-stoppen-met-whatsappen-over-patienten-a1409107 and *Aanhangsel Handelingen II* 2015/16, no. 2203, p. 2.

6 For an explanation of these categories, see chapter 2, Para. 6.2.

7 CESCR General Comment no. 14 (2000) on Health, Para. 12(a).

kilometres in Australia in 1874,⁸ is a typical example of an early form of tele-expertise.⁹ This example shows that tele-expertise can function as a way to increase the availability of health care in rural or remote areas because it enables health professionals to advise each other over a large distance, or even assist colleagues who reside at the other side of the world.¹⁰ In areas with a lack or a shortage of a certain type of specialist, tele-expertise can enable GPs to treat patients while a specialist advises them. The examples of teledermatology and the use of WhatsApp mentioned in chapter 1 and in section 1 previously also illustrate this. In the case of teledermatology, patients can receive personal advice from a dermatologist without actually visiting them.¹¹ In the other example, where health professionals consult each other by means of a private messaging application (WhatsApp), advice can also be obtained from another professional without the need for the patient to actually travel to this professional's practice. This means, in both instances, that the care from these health professionals becomes available to patients, without the need for them to travel to these professionals' practices by themselves. Of course, tele-expertise cannot replace visits to specialists entirely. At times, this will remain necessary. However, in the first instance tele-expertise is an easy way to consult a health professional in another part of the country, or even any part of the world. The case of teledermatology showed another asset of this type of tele-expertise in respect of the availability of health services: studies showed a significant decrease in referrals to the dermatologist for GPs who used teledermatology compared to GPs who did not use teledermatology.¹² This will decrease the dermatologist's waiting list and therefore increase the availability of dermatology for those patients who do need a referral.¹³ In conclusion, tele-expertise has the potential to make a positive contribution to the availability of health services.

2.2 Accessibility

2.2.1 Non-discrimination

First, in order to be accessible, health services must be free of discrimination.¹⁴ As for accessibility, tele-expertise seems to not really contribute to providing health services without discrimination, unless tele-expertise can be put into service by GPs to provide assistance to groups who do not have easy access to a specialist. However, this does not seem likely to be

8 *South Australian Advertiser* 24 February 1874, cited by Eikelboom 2012, p. 71.

9 Although this particular case can also be called tele-assistance, because a physician assisted non-health professionals in taking care of a patient over distance.

10 Beuscart et al. 2014, p. 415-416 on health professionals assisting each other over distance. They mention an example as well.

11 Elbert et al., *NTvDV* 2013, p. 542.

12 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 and the earlier study conducted by Van der Heijden et al., *NrVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

13 One of the purposes of the use of teledermatology was, among other things, to shorten waiting lists: Du Moulin et al., *NTvDV* 2005, p. 155. Teledermatology is also mentioned in combination with the Dutch GP's function of gatekeepers: Van der Heijden et al., *NrVG* 2012, issue 4, p. 2, published before as Van der Heijden et al., *BJD* 2011, p. 1059.

14 CESC General Comment no. 14 (2000) on Health, Para. 12 (b).

necessary in the Netherlands. Issues such as discrimination of the computer illiterate or the digitally self-excluded as presented in chapter 4 on e-consultation are not under discussion with regard to tele-expertise. The patient does not have to possess certain ICT skills or to show a particular interest in ICT because the health professionals are the users of ICT in this case; tele-expertise does not require a certain action from the patient besides giving their consent for requesting the tele-expertise.¹⁵ Consequently, tele-expertise does not seem to have any direct effects on the accessibility of health services without discrimination. Tele-expertise neither encourages nor discourages discrimination.

2.2.2 Physical accessibility

After non-discrimination, physical accessibility is a condition for health services to be accessible.¹⁶ Physical accessibility of health services can increase due to tele-expertise for the reasons mentioned in section 2.1 on availability of health services above. During tele-expertise, the requesting physician has contact with the tele-expert without the patient having to travel. This can be beneficial for patients who experience difficulties in travelling.¹⁷ They only need to travel when the tele-expert decides they should see the patient in person. Otherwise, the requesting physician can ease the patient's mind or proceed with treatment based on the advice of the tele-expert.

As presented in section 2.1, studies on teleradiology showed a decrease in referrals.¹⁸ This means that patients had access to a dermatologist without physically having to travel to this specialist. This increased physical accessibility applies to any kind of tele-expertise, for instance teleradiology. Teleradiology refers to tele-expertise between radiologists and can take place intramurally as well as extramurally.¹⁹ Extramural teleradiology usually entails the interpretation of a radiologic image by a commercial teleradiology enterprise. To maintain quality of care, the radiologist in the first instance should occasionally reinterpret the image themselves. Complex cases should always be discussed within the health care institution.²⁰ During teleradiology, patients can be diagnosed by a radiologist without having to travel to them in person, increasing the physical accessibility of the services offered by these radiologists.²¹ This shows that the independency of time and place of tele-expertise can make a positive contribution to the physical accessibility of health services.

15 The right to give consent (Art. 7:450 BW) and when and about what the patient must give their consent in the case of tele-expertise will be elaborated on in section 7 below.

16 CESC General Comment no. 14 (2000) on Health, Para. 12(b).

17 See, for example, Beuscart et al. 2014, p. 415.

18 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 and the earlier study conducted by Van der Heijden et al., *NrVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

19 Dans & Van der Vorst, *TvGR* 2008, p. 188.

20 Dans & Van der Vorst, *TvGR* 2008, p. 188-189.

21 Dans & Van der Vorst, *TvGR* 2008, p. 188 discuss the teleradiology services offered by Eurad Consult.

2.2.3 Affordability

The next condition for accessible health services is affordability.²² When considering the effects of tele-expertise on affordability, the above-mentioned Dutch studies on teledermatology can serve as an example again. A cost reduction was found with the use of teledermatology.²³ Moreover, teledermatology has been reimbursable in the Netherlands since 2006,²⁴ which also contributes to the affordability of this tool. According to the NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, teledermatology is only reimbursable when secure equipment is used.²⁵ For types of tele-expertise where the requesting physician sends a quick image to the tele-expert, such as in the example of the use of WhatsApp, the patient will not be charged. A while ago, when it became known that WhatsApp was used in health care to communicate about patients, the lack of implementation costs of this service was mentioned as an advantage and a reason to use this application for tele-expertise. WhatsApp is (almost) free and most people in the Netherlands will already have installed it and know how to use it. For the other applications, purchasing costs as well as implementation costs have to be made, making them less affordable.²⁶ In conclusion, tele-expertise can contribute to accessibility of health services because of affordability; it has led to a reduction in costs²⁷ and it is reimbursable.²⁸

2.2.4 Information accessibility

As a final condition for accessibility, health services should contribute to the accessibility of information.²⁹ Tele-expertise facilitates a rapid exchange of information and therefore facilitates information accessibility. It facilitates health professionals to communicate with each other to give the patient the appropriate treatment within a short time. The examples of teledermatology, teleradiology and the use of WhatsApp to consult a colleague all illustrate this. For teledermatology, the average time within which general practitioners received a reaction from the dermatologist was in 4.6 hours³⁰ one study and 5.5 hours in another study.³¹

22 CESC General Comment no. 14 (2000) on Health, Para. 12(b).

23 Van der Heijden et al., *NtVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

24 Elbert et al., *NTvDV* 2013, p. 542; Van der Heijden et al., *NtVG* 2012, issue 4, p. 2, published before as Van der Heijden et al., *BJD* 2011, p. 1059. Also see NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, Para. 4.11, p. 42-43.

25 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, Para. 4.11, p. 42.

26 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2314. Various alternatives for WhatsApp and their costs are mentioned here.

27 Van der Heijden et al., *NtVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

28 Elbert et al., *NTvDV* 2013, p. 542; Van der Heijden et al., *NtVG* 2012, issue 4, p. 2, published before as Van der Heijden et al., *BJD* 2011, p. 1059 and NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, Para. 4.11, p. 42-43.

29 CESC General Comment no. 14 (2000) on Health, Para. 12(b).

30 *NtVG* 2012, issue 4, p. 5, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

31 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539.

During teleradiology, patients will receive information about their health from a radiologist (via the requesting physician) without visiting them in person;³² this makes their access to information by this radiologist easier. In case of the use of WhatsApp for tele-expertise, information can be received even faster. Quick access to information was mentioned by health professionals as a reason to use this medium to contact colleagues.³³ Moreover, physicians indicated that they used WhatsApp or at times even its group chat function to inform each other about the current situation at work or to share experiences.³⁴ Another advantage of the use of WhatsApp for tele-expertise is its broad range: it has more than 1 billion users worldwide.³⁵

In conclusion, tele-expertise can contribute to the accessibility of health services by increasing access to information.

2.3 Acceptability

Third, to contribute to enhancing the realisation of the right to health, health services should be ethically as well as culturally acceptable.³⁶ To be ethically acceptable, tele-expertise should be carried out under compliance with patients' rights such as those laid down in the WGBO, privacy legislation such as the GDPR, the Wabv pz,³⁷ and privacy standards and norms such as the NEN standards³⁸ and the ISO 27001 norm on data security, and ethical and professional standards such as the guidelines provided by the KNMG. This means that, in case of tele-expertise, the health professional should give thought to the medium they use for tele-expertise. While choosing a means for tele-expertise they should – among other things – consider whether this means is meeting the standards for safety and security as required for the use of ICT in health care. How to perform tele-expertise as the law regarding patients' rights stands will be elaborated on in section 4 and further on. At this point, the second condition for acceptable health services provision will be presented: cultural acceptance.³⁹

At first sight, tele-expertise seems an appropriate means to offer culturally acceptable health care; it offers physicians the opportunity to consult with colleagues who share the patient's culture or religion, as we have seen in chapter 4 regarding e-consultation: this type of eHealth care provision can enable patients to contact a physician who shares their background. Tele-expertise can do the same but since the contact takes place between two health professionals instead, the advantage will be less apparent and less probable.

32 Dans & Van der Vorst, *TvGR* 2008, p. 188.

33 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2313.

34 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2313.

35 'About WhatsApp', whatsapp.com. Source: whatsapp.com/about/?lang=en.

36 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

37 *Stb.* 2017, 279.

38 NEN7510, NEN7512 and NEN7513; see 'Informatiebeveiliging', nen.nl. Source: nen.nl/NEN-Shop/Informatiebeveiliging-1.htm.

39 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

Studies on tele dermatology demonstrate that this type of tele-expertise is considered acceptable by patients.⁴⁰ A potential downfall is the degree to which patients consider tele-expertise itself acceptable. First, there is the group of patients who have a lack of trust or a lack of interest in ICT or otherwise do not believe in its use for health care, such as the digitally self-excluded.⁴¹ To them, tele-expertise might not be an acceptable way of health care provision. Second, there is the group of patients who fear that their privacy will be violated because of the tele-expertise. A study showed that patients find eHealth applications less acceptable when they had the idea that it infringed their right to privacy.⁴² That some ways of conducting tele-expertise are subject to privacy-related risks is not unthinkable. Concerns were addressed in the discussion surrounding health professionals' use of WhatsApp to consult each other about patients; this medium does not have the best reputation regarding privacy protection.⁴³ Many (mobile) applications have been developed since the media reported the use of WhatsApp for tele-expertise.⁴⁴ *Patiëntoverleg*, by *Zorgdomein*, is an example of such an application. This application enables communication between health professionals in different locations by means of short questions. Patient data can be transferred safely according to *Zorgdomein* and communication with multiple professionals at once is possible.⁴⁵ *Siilo* is another application

40 Van der Heijden et al., *NrVG* 2012, issue 4, p. 6-7 and the studies cited there, published before as Van der Heijden et al., *BJD* 2011, p. 1064-1065 and the studies cited there.

41 An example is mentioned in Selwyn et al., *Ageing & Society* 2003, p. 561-582. Their findings indicate that a group of elderly does not use ICT because they do not find it interesting or they do not think it is relevant for them. Moreover, Selwyn et al. found that some of the elderly did not think it is necessary to use ICT. See Selwyn et al., *Ageing & Society* 2003, p. 575. Zajicek also mentions that when certain groups cannot or do not want to use ICT, they risk exclusion. According to Zajicek, the elderly are such a group. For a large part of their lives, they have been without the Internet. Therefore it is harder to convince them of its necessity. See Zajicek 2007, p. 35 and 37.

42 Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980-984. Mentioned in chapter 4, section 2.3 as well.

43 For example 'Constamed: Snel antwoord van je huisarts', *consumentenbond.nl* 26 February 2014. Source: consumentenbond.nl/zorgverzekering/constamed-huisarts.

44 An example of a messenger app especially designed for health care, is the application '*Patientoverleg*' designed by '*Zorgdomein*'. For more information, please consult '*Patiëntoverleg*', *zorgdomein.com*. Source: <https://zorgdomein.com/patientoverleg/> and M. Kregting, 'ZorgDomein lanceert messengerdienst patiëntoverleg landelijk', *ICT&health, icthealth.nl* 6 June 2017. Source: icthealth.nl/nieuws/ZorgDomein-lanceert-messengerdienst-Patientoverleg-landelijk. Another application that is already used by health professionals is '*Siilo*'. *Siilo.com*. Source: siilo.com/. Also mentioned on nos.nl in: 'Nieuwe app wil veilig alternatief zijn voor whatsappende artsen', *nos.nl* 18 April 2016. Source: <https://nos.nl/artikel/2099898-nieuwe-app-wil-veilig-alternatief-zijn-voor-whatsappende-artsen.html>. More alternatives for the use of WhatsApp are mentioned J. Jacobs, 'Wie weet nu echt of WhatsApp mag in de zorg', *Smarterhealth.nl* 14 April 2016. Source: smarterhealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/; Nouwt, *Medisch Contact* 2016, issue 12, p. 20-23, 'Veiliger alternatieven voor WhatsApp', *knmg.nl* Nieuws 23 March 2016. Source: knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/veiliger-alternatieven-voor-whatsapp.htm and 'Strijd om verovering markt medische WhatsApp', *telegraaf.nl* 23 May 2016. Source: telegraaf.nl/tech/409960/strijd-om-verovering-markt-medische-whatsapp.

45 '*Patientoverleg*' designed by '*Zorgdomein*'. For more information, please consult '*Patiëntoverleg*', *zorgdomein.com*. Source: <https://zorgdomein.com/patientoverleg/> and M. Kregting, 'ZorgDomein lanceert messengerdienst patiëntoverleg landelijk', *ICT&health, icthealth.nl* 6 June 2017. Source: icthealth.nl/nieuws/ZorgDomein-lanceert-messengerdienst-Patientoverleg-landelijk.

that is especially designed for health care.⁴⁶ This app does not store patients' data on the user's device but in the app instead. After 30 days, information is deleted. Access to the application can only be obtained by means of a pin code and claims to comply with legislation, and safety and security standards, such as the GDPR, ISO-27001 and NEN7510, NEN7512 and NEN7513.⁴⁷ Moreover, (video) calls are possible via *Siilo* and it is possible to work with the app as a team.⁴⁸ Because of the corona crisis, *Siilo* is free for health care organisations.⁴⁹ *Zorg Messenger* by KPN is also an example of an app that can be used for tele-expertise. *Zorg Messenger* enables communication between health professionals and communication between health professionals and their patients. This app, too, is secured by a pin code and holds ISO-27001 and NEN7510 certifications.⁵⁰ *Siilo* and *Zorgmessenger* are also mentioned as alternatives for WhatsApp in the KNMG Guidelines for dealing with medical data.⁵¹

The eHealth-monitor displays a positive attitude towards tele-expertise among health professionals. Many GPs reported that asking advice from a tele-expert is possible within their practice and many specialists reported that they were willing to implement tele-expertise with GPs in the future.⁵² Judging from these results, acceptability of tele-expertise among health professionals does not seem to be a problem.

In conclusion, tele-expertise that is provided as the law stands and according to good practice guidelines and standards for safety and security of procession patients' data, can be considered ethically acceptable health care provision. As for cultural acceptability, tele-expertise has the potential to contribute to the provision of culturally appropriate health services because of the possibilities for health professionals to contact a colleague with the same background as the patient for example, but there are potential pitfalls as well. The patient might not find the use of ICT acceptable, for instance because they do not care for ICT or because they fear their privacy will be violated.⁵³

46 *Siilo.com*. Source: siilo.com/. Also mentioned on nos.nl in: 'Nieuwe app wil veilig alternatief zijn voor whatsappende artsen', *nos.nl* 18 April 2016. Source: <https://nos.nl/artikel/2099898-nieuwe-app-wil-veilig-alternatief-zijn-voor-whatsappende-artsen.html>.

47 'Beveiliging' *Siilo.com*. Source: siilo.com/nl/beveiliging.

48 'Siilo Messenger', *Siilo.com*. Source: siilo.com/siilo-messenger.

49 'Siilo in crisissituaties', *Siilo.com*. Source: siilo.com/nl/siilo-in-crisissituatie.

50 'KPN Zorg Messenger. Veilig communiceren in de zorg', *ezorg.nl*. Source: ezorg.nl/kpn-zorg-messenger/.

51 KNMG Guidelines for dealing with medical data 2020, p. 25.

52 Wouters et al. 2019e, p. 9, part of Wouters et al. 2019a and Wouters et al. 2019c, table 5.16 and 5.17, p. 75.

53 For instance Coleman et al. 2010 on elderly who are not interested in ICT. One study, also quoted in chapter 4, found that patients were more willing to engage in eHealth care provision when they trusted their privacy would not be harmed; see Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980-984.

2.4 Quality

Finally, to contribute to realising the right to health for everyone, health services that are offered must be of good quality.⁵⁴ Although an empirical study on the effects of tele-expertise on the quality of health care is beyond this study, a few remarks related to quality can be made.

The educational effect that was found in the studies on teledermatology can be seen as a positive aspect regarding the quality of health services.⁵⁵ When professionals in primary health care consult specialists in secondary health care and they experience an educational effect, the quality of primary health care can be improved because of the increased knowledge of the health professionals in primary health care.

Enabling quick responses is one of the assets of tele-expertise. When specialists react to GPs' questions within a reasonable time, tele-expertise will only contribute to enhancing the quality of care. This can be seen in the example of teledermatology in the fast response time.⁵⁶ A positive effect of quick response during tele-expertise can be that diagnosis will be faster, treatment can start on time and deterioration can be prevented. Experience with tele-expertise in dermatology in the Netherlands shows that GPs who use tele-expertise experienced a decrease in referrals to the dermatologist compared to the GPs who did not use this type of eHealth. It has been established that the decrease in referrals was 27.3% after 5 years.⁵⁷ In the example of teleradiology, the response time is short as well; after the request for tele-expertise, a report is usually sent within 24 hours.⁵⁸ This is also the case for tele-expertise by means of WhatsApp; a message through this medium usually leads to a quick response; health professionals even indicated that they use WhatsApp because it enables them to reach their colleagues quickly.⁵⁹

However, such an improvement is only feasible when the right equipment is used. If, for instance, photos with inferior quality are used during tele-expertise, the tele-expert will not be able to give good advice.⁶⁰ When a physician gives advice or a diagnosis based on a photo of inferior quality, the chances of a misdiagnosis increase. This can also be a concern in the example of the use of WhatsApp for tele-expertise. By this means, the photos that are sent to the tele-expert are made by smartphones and not all smartphones have a good quality camera.

54 CESCR General Comment no. 14 (2000) on Health, Para. 12(d).

55 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 and the earlier study conducted by Van der Heijden et al., *NrVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

56 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 and the earlier study conducted by Van der Heijden et al., *NrVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

57 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539.

58 Dans & Van der Vorst, *TvGR* 2008, p. 189.

59 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2313.

60 Du Moulin et al., *NTvDV* 2005, p. 157.

That being said, health professionals might take the time every now and then to ensure the quality of tele-expertise. In the example of teleradiology as described in the literature, a random extra check is carried out for every tenth report to assess the quality.⁶¹

In conclusion, tele-expertise seems to be able to make a positive contribution to realising the right to health for everyone. Availability and accessibility of health services can increase because of tele-expertise. Teledermatology, as a type of tele-expertise, is reimbursable;⁶² this contributes to the affordability of this type of tele-expertise. A point of special interest is patients' acceptability of tele-expertise: it is likely that some patients will not perceive tele-expertise as an acceptable means of health care provision, for instance because they are afraid for a violation of their privacy.⁶³ For those people, tele-expertise cannot contribute to realising the right to health because of the criterion of acceptability. As for quality, when the right equipment is used tele-expertise can be considered health care provision of good quality. In this section, several studies related to teledermatology have been quoted.⁶⁴ Although this particular field makes the case for tele-expertise's ability to contribute to health care of good quality,⁶⁵ empirical research has to provide decisive answers for its contribution to the quality of health care provision in other fields. Conducting empirical research, however, exceeds the scope of this study.

3. TELE-EXPERTISE AND THE APPLICABILITY OF THE WGBO

Tele-expertise leads to a different question regarding the applicability of the WGBO than e-consultation. The question with respect to e-consultation is whether this type of eHealth care provision can lead to a contract for provision of medical services.⁶⁶ Tele-expertise on the other hand does not lead to the question of whether such a contract is established but rather to the question of who the parties of such a contract are. To answer the question of whether a contract for medical services is established between the patient and the tele-expert, the case of teledermatology, as described in section 1, will be taken as an example. Considering what

61 Dans & Van der Vorst, *TvGR* 2008, p. 189.

62 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, Para. 4.11, p. 42-43.

63 Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980-984.

64 Van der Heijden & Witkamp, *NTvDV* 2013, p. 538-544 and the earlier study conducted by Van der Heijden et al., *NfVG* 2012, issue 4, p. 1-7, published before as Van der Heijden et al., *BJD* 2011, p. 1058-1065 and Elbert et al., *NTvDV* 2013, p. 541-544.

65 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 and the earlier study conducted by Van der Heijden et al., *NfVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

66 As elaborated on in chapter 4.

was discussed in the previous chapter, a contract for provision of medical services between the patient and their GP can be assumed.⁶⁷

According to Article 7:446 Paragraph 1 BW a contract for medical services is concluded when a health professional commits themselves to a party to provide health care. Therefore, it is important to assess whether the tele-expert is a health professional according to the WGBO. Based on Article 7:446 Paragraph 1 BW a health professional is a “*natural or legal person practising medicine in the course of his business or profession.*”⁶⁸ When a health professional is employed within a health care facility, such as a hospital, the hospital will be the contracting party. The health professional will be the contracting party when they are self-employed.⁶⁹ The fact that this natural or legal person must provide health services “*in the course of his business or profession*”⁷⁰ implies that a person taking care of their family does not fall within the scope of this clause.⁷¹ A natural person who provides health services as an occupation is usually a health professional as meant in Article 3 BIG Act (e.g. physician, nurse or dentist, among others) but does not necessarily have to be. Determining factors according to the explanatory memorandum to the WGBO are whether or not the professional receives payment, how often they provide medical services and the extent to which they profile themselves as a health professional.⁷² In case law, alternative healer Jomanda, who was not a health professional according to Article 3 BIG Act, was considered a health professional under the scope of Article 7:446 BW.⁷³ Since a dermatologist will most likely be a health professional according to Article 3 BIG Act and they will be either self-employed or employed within a hospital, they are a ‘health professional’ under Article 7:446 Paragraph 1 BW.

Second, this health professional has to agree to provide medical services to the patient. During teledermatology, however, the tele-expert does not see the patient in person but examines one or more photos. It is the GP instead of the patient who asks the dermatologist for advice. Therefore, the GP is the principal in this situation. The WGBO does not require the principal to be the patient: the Act mentions that the provision of medical services must be directly aimed at the principal or “a specific third party”. This means that the patient and the principal do not have to be the same person, as long as it is clear who this patient is.

67 Although in academia no consensus exists as to when such a relationship is formed: either when the patient consults the GP (for instance Van Wijmen, *NJB* 1985, p. 542-543; Houben 2005, p. 140 and Wijne 2017a, p. 16) or prior to this moment, as soon as the patient subscribes themselves to the GP’s practice (for instance Asser/Tjong Tjin Tai 7-IV 2018/391.)

68 Art. 7:446 para 1 BW, translated by Warendorf et al., Warendorf Legislation/1 CC Bk 7.

69 *Kamerstukken II* 1989/90, 21561, no. 3, p. 27.

70 Art. 7:446 para 1 BW, translated by Warendorf et al., Warendorf Legislation/para. 1 CC Bk 7.

71 Sluijters & Biesart 2005, p. 5.

72 *Kamerstukken II* 1989/90, 21561, no. 3, p. 27. Also see Sluijters & Biesart 2005, p. 4-5; Wijne 2017a, p. 8 and Asser/Tjong Tjin Tai 7-IV 2018/396.

73 Hof Amsterdam 16 December 2010, ECLI:NL:GHAMS:2010:BO7698, *NJFS* 2011/55, legal ground 2.3.12; HR 12 March 2013, ECLI:NL:HR:2013:BY4859, *NJ* 2013/424, m.nt. Legemaate and Hulst, *TGMA* 2013, issue 2, p. 55.

The contact with the patient does not necessarily have to be direct.⁷⁴ Consequently, the fact that the patient does not contact the dermatologist by themselves is not an impediment to a contract for provision of medical services.

Finally, the agreement that is made with the health professional must concern provision of medical services in order to conclude a contract for medical services. Article 7:446 Paragraphs 2 and 3 BW define provision of medical services as follows:

“2. The provision of medical treatment shall mean the following:

a. activities – examination and counselling included – directly relating to a person and intended to cure him of a disease, to protect him from the occurrence of a disease, to judge his state of health or to give such person obstetrical care.”⁷⁵

‘b. other acts than those referred to in subparagraph (a), directly relating to a person and performed by a doctor or dentist in that capacity.’⁷⁶

3. The acts referred to in paragraph (1) also include the nursing and care of the patient within the context of those acts, and providing, directly for the benefit of the patient, in any other manner for the material facilities enabling the treatment.”⁷⁷

Medical treatment thus entails every action directly aimed at a specific person with the intention of cure or prevention of disease, assessing health, obstetric assistance or any other actions performed by someone in their capacity as health professional aimed at a specific person. The tele-expert will examine the photos and give the GP advice and/or a diagnosis.⁷⁸ Article 7:446 Paragraph 2 BW includes examination and the provision of advice in its definition of medical services provision as well. Thus, the tele-expert meets the criteria for provision of health services.

Having considered Article 7:446 BW, a contract for provision of medical services between the patient and the tele-expert does not seem improbable at first sight. Be that as it may, a contract for provision of medical services based on Article 7:446 BW remains a contract above all else. This means that, in order to determine who the parties are, it needs to be established what they could expect based on each other's behaviour and statements towards each other.⁷⁹ Applied to teledermatology, this means that it depends on the situation whether tele-expertise leads to a contract for medical services.

⁷⁴ Wijne 2017a, p. 5 and *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

⁷⁵ Art. 7:446 para 2(a) BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

⁷⁶ Art. 7:446 para 2(b) BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

⁷⁷ Art. 7:446 Para. 3 BW, translated by Warendorf et al., Warendorf Legislation/446 CC Bk 7.

⁷⁸ Van der Heijden & Schepers, *Bijblijven* 2011, issue 8, p. 9; Van der Heijden et al., *NTvG* 2012, issue 4, p. 1 and Tensen et al., *Bijblijven* 2017, p. 103,

⁷⁹ Wijne 2017a, p. 8; Asser/Tjong Tjin Tai 7-IV 2018/77, mentioning HR 11 March 1977, ECLI:NL:HR:1977:AC1877, *NJ* 1977/521, m.nt. Scholten (*Kribbenbijter*) and HR 8 September 2000, ECLI:NL:HR:2000:AA7041, *NJ* 2000/734, m.nt. Bloembergen (*Baby Joost*).

The practice of health professionals asking other health professionals for advice in certain situations is not a new phenomenon that is only connected to eHealth care provision. It is common practice that a physician asks a colleague for their expertise related to the treatment of a patient. Complex or invasive treatments, for instance, are carried out within a team. Contracts for medical treatment between the patient and multiple health professionals is likely in such cases. In other cases, those who are involved in the patient's treatment are considered 'auxiliary persons' based on Article 6:76 BW within that treatment; they do not conclude a contract for provision of medical services with the patient.⁸⁰ Tele-expertise can hardly be considered to be a complex treatment or a very invasive one. In academia it has been stated that the character of the discussions between the two health professionals is a reason to not assume a contract between the patient and the tele-expert, because the tele-expert is merely giving advice.⁸¹ Even though tele-expertise might be perceived as invasive because of the potential risk of violation of privacy,⁸² this is not a reason to assume that tele dermatology leads to a contract for provision of medical services between the patient and the tele-expert.

Whether others who are involved in the patient's treatment conclude a contract with the patient based on Article 7:446 BW or whether they are considered an auxiliary person within the patients' treatment based on 6:76 BW, can subsequently be judged by their level of involvement: do they have an independent role or do they support the physician in the performance of their contract for medical services?⁸³ Although the dermatologist is not managed by or working under supervision of the GP, they are not treating the patient by themselves: they merely assist the GP with advice and/or a diagnosis. This is the second reason to assume that the tele-expert is an auxiliary person to the health professional and does not conclude their own contract for provision of medical services with the patient; they merely have a supporting role.

To confirm this view, the tele-expert will be compared with two other situations: a locum tenency and laboratory examination in an external lab. Although these situations are not perfect parallels, they can serve as a signpost for the question of whether a tele-expert should conclude a contract for provision of medical services with the patient or whether they are an auxiliary person to the GP.

In literature, it was discussed whether a contract for provision of medical services is established between a locum tenens and a patient.⁸⁴ This practice can serve as a point of departure for determining whether a contract for provision of medical services is concluded with a tele-

80 Wijne 2017a, p. 14 and Wijne 2017b, p. 168.

81 Dreezen, *Med. & Law* 2004, p. 546.

82 The tele-expert does have an obligation of medical confidentiality based on Art. 88 BIG Act. This will be presented in section 4.

83 Wijne 2017a, p. 14-15 and Wijne 2017b, p. 168.

84 Wijne 2017a, p. 15-16.

expert. Whether a locum tenency leads to a contract for provision of medical services depends on parties' behaviour and statements to each other as well.⁸⁵ When a physician deploys a locum tenens, the circumstances of the case play a role in determining whether a contract for provision of medical services is formed. Based on case law, relevant circumstances are the duration of the locum tenency, where the locum tenency takes place, the information provided to the patient and who must be paid for the health services by the patient (i.e. the physician or their locum tenens).⁸⁶ It might not be easy to compare tele-expertise to locum tenency, but these conditions stemming from case law provide an appropriate assessment framework for tele-expertise. Usually, tele-expertise takes little time. Tele-expertise consists of one or more short questions. Studies show that the average response time lies between 4.6 and 5.5 hours for teledermatology.⁸⁷ Because the time is short, a contract for medical services provision is unlikely. Based on this criterion it seems more logical to consider the teledermatologist as an auxiliary person to the GP. The requesting physician's practice would be the place where the patient receives the advice from the tele-expert. Because the patient does not move during the tele-expertise, a new contract with the tele-expert does not seem probable. For the third criterion, the information provided to the patient, it can be stated that it is unlikely that any information from which the patient can deduce that they concluded a contract with the tele-expert is provided to the patient.⁸⁸ For this reason, too, the establishment of a contract for medical services seems unlikely in this case. Finally, the patient will not pay the dermatologist.

A second comparison that can be made is the one between the tele-expert and the laboratory technician who is hired externally by a health professional. At first sight this situation seems comparable to tele-expertise because both the tele-expert and the laboratory technician analyse the patient's health situation based on information and body material respectively that is sent to them by the patient's physician. The explanatory memorandum to the WGBO suggests that the WGBO applies in the relationship between the patient and the laboratory technician, by taking the laboratory technician as an example to illustrate that direct contact is not a requirement for provision of medical services within the meaning of the WGBO.⁸⁹ In literature, some state that a contract for provision of medical services will be created when the laboratory technician is not employed by the health facility but by a lab elsewhere.⁹⁰ However,

85 Wijne 2017a, p. 15-16.

86 HR 10 January 1997, ECLI:NL:HR:1997:ZC2245, *NJ* 1998/544, m.nt. Brunner (*Praktijkwaarnemer tandarts*). Also see Wijne 2017a, p. 15-16 and Asser/Tjong Tjin Tai 7-IV 2018/77.

87 Tensen et al., *Bijblijven* 2017, p. 111 (5,3h); Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 (5,5h) and Van der Heijden et al., *NiVG* 2012, issue 4, p. 5-6 (4,6h), published before as Van der Heijden et al., *BJD* 2011, p. 1063 (4,6h).

88 Section 6 below will elaborate on which information must be provided to the patient.

89 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

90 Swillens & Van Wijmen, *Ned Tijdschr Klin Chem* 2002, p. 14.

this view does not seem widely accepted.⁹¹ Arguments in academia to support the view that a contract for provision of medical services is not established between the laboratory technician and the patient are the fact that the latter acts on behalf of the physician and not on behalf of the patient; the results are interpreted by the physician. Van der Most substantiates this by examples from practice, stating that labs usually do not keep a medical record as Article 7:454 obliges under a contract for provision of medical services. Van der Most also elaborated on the General Delivery Conditions for laboratory examination of the University Medical Center Utrecht (UMC), which state that no contract for provision of medical services is established between the patient and the laboratory technician.⁹² These arguments can be applied to teledermatology as well. The teledermatologist is involved by the physician instead of the patient. They will reply to the physician, who will communicate the outcome of the teledermatologist's observations to the patient.

According to Article 7:464 BW the WGBO can be applicable to situations where a contract for medical services is lacking if medical services are provided. The explanatory memorandum to the WGBO mentions the example of an emergency. A patient is brought in unconscious, not able to enter into a medical services contract. In order to protect the patient, the legislator considered it desirable to apply the WGBO to this situation.⁹³ This situation, however, can hardly be considered an analogous case to tele-expertise. The patient in the example is able to consult the dermatologist by themselves. In 2000, a Parliamentary Decree on the applicability of the WGBO in the absence of a medical service contract was adopted.⁹⁴ The decree shows that Article 7:464 BW was laid down in the patients' rights Act to protect the patient, who remains the weaker party in relation to the physician. When they encounter a health professional who provides medical services to them in the absence of a contract, protection of the patient as the weaker party is still desirable.⁹⁵ The decree mentions the examples of work-related physical examination, examination necessary for social security and examination of detainees.⁹⁶ These are situations where a (legal) obligation to undergo medical examination exists.⁹⁷ This leads to the question of whether it has been the legislator's intention to include situations such as tele-expertise under this provision. Since these situations are not comparable to tele-expertise, Article 7:464 BW cannot be applied by reasoning analogously.

91 Hooghiemstra, *Ned Tijdschr Klin Chem* 2000, p. 261 and Van der Most, *TvGR* 2018, p. 111 and 113-114.

92 Van der Most, *TvGR* 2018, p. 111 and 113-114 and Article 6 Para. 1 UMC Utrecht Algemene leveringsvoorwaarden laboratoriumonderzoek 2019.

93 *Kamerstukken II* 1989/90, 21561, no. 3, p. 46.

94 *Stb.* 2000, 121.

95 *Stb.* 2000, 121, p. 3.

96 *Stb.* 2000, 121, p. 3 and 4.

97 *Stb.* 2000, 121, p. 4.

All things considered, it will depend on the circumstances of the case, such as duration, place, information provided to the patient and who is paid by the patient,⁹⁸ whether teledermatology will lead to a contract for provision of medical services between the patient and the teledermatologist. Based on the example of the laboratory technician and the fact that it is unlikely that tele-expertise will be considered as complex or invasive, a contract for provision of medical services will not be established between the patient and the teledermatologist in most instances. This is also the case for teleradiology⁹⁹ and the use of a messenger app for tele-expertise.

Assuming otherwise will not only be met with legal difficulties, but will lead to some practical obstacles as well. First, when a contract for provision of medical services is established between the patient and the tele-expert, the tele-expert must comply with the duties laid down in the WGBO. This means they would have to provide the patient with information, and discuss and confer with the patient whether to proceed with tele-expertise.¹⁰⁰ From a practical point of view, it is only logical that the requesting physician fulfils this obligation. After all, they will act as an intermediary between the patient and the tele-expert. The patient will not be put into contact with the tele-expert. Second, it will not always be reasonable to ask a tele-expert to keep a medical record about the tele-expertise. In case of a contract for provision of medical services, the WGBO will oblige them to do so.¹⁰¹ It is more likely that the teledermatologist, who takes some time to review the photos that are sent to them, keeps a record than the physician who is providing tele-expertise by means of WhatsApp. It would not be reasonable to oblige a health professional to start a medical record for every message they send via WhatsApp. This situation shows similarities with asking a colleague who is passing by the office for a quick advice. An obligation to keep a medical record would not be sensible in such a situation. A practice with laboratory technicians who work externally also shows that a medical record is usually not kept by the laboratory technician but by the health professional who enlists the laboratory technician's expertise instead.¹⁰² There is no reason to assume that this should be otherwise for tele-expertise. Finally, clarity to the patient is important. It must be clear for the patient who they have a contract with. By analogy with the rules of central liability, it should not be too complicated for the patient to enforce their rights.¹⁰³ Enforcing their rights will be easier against the requesting physician than against the tele-expert. Moreover, it would be difficult for the patient to assess whether they entered a contract for provision of medical services with the requesting physician, the tele-expert or both of these professionals.

98 HR 10 January 1997, ECLI:NL:HR:1997:ZC2245, *NJ* 1998/544, m.nt. Brunner (*Praktijkwaarnemer tandarts*). Also see Wijne 2017a, p. 15-16 and Asser/Tjong Tjin Tai 7-IV 2018/77.

99 Accordingly: Dans & Van der Vorst, *TvGR* 2008, p. 190, 195 and 197.

100 Shared decision-making; Art. 7:448 BW. Based on this information, the patient will have to give their explicit consent; Art. 7:450 BW (informed consent).

101 Art. 7:454 BW.

102 Van der Most, *TvGR* 2018, p. 114.

103 *Kamerstukken II* 1989/90, 21561, no. 3, p. 43 and Dans & Van der Vorst, *TvGR* 2008, p. 190.

In conclusion, during tele-expertise, the medical services contract between the patient and the health professional they consulted (in the example, the GP) prevails. This will only be different when the requesting physician invites the tele-expert for a live video consultation with themselves and the patient.¹⁰⁴ This situation shows similarities with e-consultation and is more likely to lead to a contract for provision of medical services because the patient and the tele-expert will have direct contact, and the patient is able to ask the tele-expert questions. Because this type of tele-expertise inclines to e-consultation, a contract for provision of medical services can be established. However, according to the eHealth-monitor, these types of tele-expertise do not occur yet in the Netherlands. Therefore, during tele-expertise as discussed in this chapter, a contract for provision of medical services exists between the patient and the requesting physician. Therefore, this health professional has to fulfil the obligations following from this contract while requesting tele-expertise. That being said, this does not mean that the tele-expert has no obligations towards this patient. First of all, the tele-expert, as a health professional, has the duty to act as a conscientious health care provider and has an obligation of medical confidentiality based on the BIG Act.¹⁰⁵ Second, the patients' rights in the WGBO are "generally accepted"¹⁰⁶ in the Netherlands. This means that health professionals are expected to respect them, even when they are not sure of the existence of a contract for medical services.¹⁰⁷ Finally, the tele-expert must comply with the rules following from the GDPR, since they gain access to patients' personal data during tele-expertise.

The following sections will elaborate on the contents of these rights and how to apply them to tele-expertise, starting with the right to medical confidentiality and the right to privacy.

4. TELE-EXPERTISE: THE RIGHT TO MEDICAL CONFIDENTIALITY AND THE RIGHT TO PRIVACY

4.1 Introduction to tele-expertise's privacy implications

When personal information about a patient is sent to another professional through ICT, questions about the protection of personal information will arise. In the case of tele-expertise, privacy implications can occur at three moments. The act of taking a patients' photo or writing down medical information on an ICT device mostly concerns physical integrity. When the information is saved on an ICT device, informational privacy is of importance.

104 According to the eHealth-monitor 2019, this is not possible yet, but 3% of GPs and 2% of specialists would like to implement this in their practice within a year and 29% of GPs and 40% of specialists would like to implement this in their practice in due course. Wouters et al. 2019c, table 5.16 and 5.17, p. 75.

105 Art. 47 and Art. 88 BIG Act.

106 Leenen/Dute & Legemaate (eds.), p. 104.

107 Leenen/Dute & Legemaate (eds.), p. 104.

The point at which the information is transmitted to the tele-expert and the moment the latter receives the photo or the information is a matter of informational privacy as well.

Tele-expertise also leads to questions about protecting medical confidentiality because of the different ways health professionals consult each other as opposed to consulting each other face-to-face. Equal to e-consultation or maybe even more so, tele-expertise involves transferring personal medical data by means of ICT. Moreover, tele-expertise involves at least one health professional who does not have a contract for medical services with the patient. This physician also has an obligation of medical confidentiality, although this does not follow from the WGBO but rather from the BIG Act.

Medical confidentiality during tele-expertise will be compared with two health professionals consulting each other face-to-face about the treatment of a particular patient. The section will present what the differences are between these two kinds of physician–physician consultation. Certain aspects of medical confidentiality may be similar for e-consultation and therefore are already presented in chapter 4. These aspects will be mentioned only briefly and if necessary the present section will refer back to the relevant sections of chapter 4.

In order to provide an indication of the issues that need to be tackled with respect to tele-expertise and informational privacy, the use of WhatsApp for tele-expertise will be discussed in detail below. This example shows questions that come up during tele-expertise. What can be said about WhatsApp applies to other applications and other ways of carrying out tele-expertise as well: personal medical data should be transferred by means that respect rules of privacy, security and data protection.

4.2 Medical confidentiality and informational privacy during tele-expertise – the application

For the protection of informational privacy, it is relevant to address the question of exactly how and by what means the tele-expertise takes place. The application that is used should be safe in order to avoid invasion of privacy. Therefore, it is important that the applications that are used are chosen very carefully.

The use of the messenger application WhatsApp by health professionals to consult each other was much discussed in media and specialist journals.¹⁰⁸ Moreover, various stakeholders both

108 Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809, Van Noort, *NRC Next* 8 July 2015, p. 7, Croonen, *Medisch Contact* 2015, p. 2312-2315, 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/arsenifolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm and Wiggelinkhuizen et al., *Medisch Contact* 2015, p. 2310-2311.

within and outside the field of health care reacted to this phenomenon. Because WhatsApp does not have a very good reputation in relation to privacy protection, that application was generally considered to be an inappropriate means for tele-expertise in the Netherlands.¹⁰⁹ Although only a small number of the specialists reported that they considered the use of WhatsApp to send patient's medical data acceptable, they also stated that this facilitates efficient and fast health care. Moreover, specialists reported that they used their personal devices to store patient's personal medical data.¹¹⁰

Another study, conducted among radiologists, indicates that these specialists want a secured system to exchange information with colleagues within other health care institutions in order to request second opinions. At the time of the study, however, such a system did not exist and information was still transferred using DVDs sent by mail or given to the patient.¹¹¹ Therefore, WhatsApp was seen as a welcome alternative way to consult a colleague.¹¹²

In publications relating to this issue it is explained, for instance, that the health professionals who participated in a study conducted by the KNMG are actually aware of the risks of violating privacy by using WhatsApp for work-related purposes, but they report that they also consider WhatsApp a medium for fast and efficient communication. It is stated, however, that they mostly use WhatsApp for general questions or to initiate meetings because they are aware of the risks related to this application.¹¹³ At the same time, physicians indicate that WhatsApp has a great practicability and can assist in analysing the situation quickly.¹¹⁴ Others acknowledge this, but prefer more secure alternatives.¹¹⁵

In an interview, a specialist stated that even though protecting patient's personal information is important, dissemination of personal information occurs in other fields as well and is not a development unique to medicine. Moreover, patients themselves do not always seem to handle their personal data very carefully.¹¹⁶ Objections against this statement can be put forward. The right to medical confidentiality is meant to both protect informational privacy and the right to access to health care.¹¹⁷ These are both human rights.¹¹⁸ The fact that people themselves, based on their actions, do not seem to value these rights or even handle them

109 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2313.

110 Wiggelinkhuizen et al., *Medisch Contact* 2015, p. 2311.

111 Ranschaert & Wanders, *ECR* 2014.

112 Ranschaert & Wanders, *ECR* 2014.

113 'KNMG Artsenpanel: WhatsApp is waardevol, maar beveiliging een must', *knmg.nl/Nieuws* 25 November 2015. Source: knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/knmg-artsenpanel-whatsapp-is-waardevol-maar-beveiliging-een-must.htm.

114 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2313.

115 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2314-2315.

116 Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2315.

117 Hof Den Bosch, 13 October 1998, *TvGR* 1999/13, p. 125-127.

118 Art. 17 ICCPR, Art. 8 ECHR and Art. 10 Para. 1 Gw and Art. 12 ICESCR, Art. 11 ESC and Art. 22 Para. 1 Gw.

carelessly, does not mean that others can treat these rights with indifference as well. On the contrary, others should continue to respect these human rights. In health care, professionals should advise patients on the risks of exposing their personal medical data and prevent them from doing so without careful consideration.¹¹⁹ Whether patients agree and stop sharing their personal medical information or not, is irrelevant. It is the professional who has the duty to respect patients' privacy, explicitly laid down as the obligation of medical confidentiality in Article 7:457 BW. A health professional can breach confidentiality when the patient gives their explicit consent. However, whether confidentiality will be breached in this situation is subject to the physician's judgement. Patients' consent is not equivalent to an obligation to breach confidentiality.¹²⁰

In an online comment below a publication of an interview with three physicians on the use of chat applications such as WhatsApp, for instance, it is mentioned that WhatsApp's settings can be adjusted to avoid saving incoming photos on the device.¹²¹ However, this option only exists for iOS (Apple's and thus iPhone's mobile operating system) and has so far not been found in systems operation on Android, the mobile operating system on which most other smartphones operate.¹²² This means that only iPhone users can benefit from this option; all other devices will save the images and combine them with other photos the user receives.

In advice to health professionals, which the KNMG published on its website, the association advises against the use of WhatsApp to exchange patients' medical data but does not expressly prohibit this. Instead, the KNMG states that the use of WhatsApp for tele-expertise is, in principle, allowed. However, health professionals should prevent transferring information that can easily be traced back to an individual patient.¹²³ The *Patiëntenfederatie Nederland* [The Federation of Patients in the Netherlands] said the same in its reaction.¹²⁴ This means that transferring a photo of a spot on somebody's skin via WhatsApp does not constitute a

119 An example of a similar recommendation can be found in the KNMG Guidelines for dealing with medical data 2020, in which the KNMG urges health professionals to advise their patients to handle their medical record with care; when third parties request access to the patient's medical record, health professionals should advise them to not hand over their entire medical record, but only the information that is relevant with regard to the third party's request. See p. 17.

120 Appendix to *Kamerstukken II* 2015/16, 34300 XVI, no. 161-772286, p. 5.

121 K. van der Winden-Haalboom, comment on Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2312-2315, *knmg.nl* 26 November 2015. Source: medischcontact.nl/nieuws/laatste-nieuws/artikel/veilig-whatsapp-en-must-voor-dokters.htm.

122 Examples of smartphones operating on Android are Samsung, Huawei, Google, Motorola, LG, Sony, HTC, Nokia and Blackberry.

123 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/arseninfolijn/praktijkdilemma-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm.

124 The Federation of Patients in the Netherlands gave a reaction in: Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrcq.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809 and Van Noort, *NRC Next* 8 July 2015, p. 7.

violation of the obligation of medical confidentiality, as long as the photo does not include a patient's face or any other recognisable features of this particular patient. However, the KNMG notes that information can sometimes be traced back to an individual in another way than by means of personal information or recognisable photos.¹²⁵ The KNMG seems to refer to metadata here. These are data that are included in digital data but cannot be seen at first sight.¹²⁶ Examples include the time and the place when the pictures were taken. Moreover, the KNMG strongly recommends that health professionals delete photos and other personal information from their devices after the tele-expertise.¹²⁷ The KNMG's advice to physician is that, when in doubt, WhatsApp should not be used for tele-expertise. Health care institutions should bear the responsibility to inform and counsel their employees on tele-expertise and data protection.¹²⁸ Even though the KNMG in principle seems to allow physicians to disseminate patient's personal data through WhatsApp, the recommendations and precautions the association prescribes leave very little room to actually use WhatsApp for tele-expertise.

Because of the increasing utilisation of social media by professionals and other developments in the field of personal data and health care, such as the GDPR taking effect in 2018, the KNMG included its opinion on the use of WhatsApp for tele-expertise in its Guidelines for dealing with medical data.¹²⁹ Its advice on WhatsApp remains the same: consulting each other via this medium is not expressly prohibited. However, the KNMG notes that information sent via WhatsApp is difficult to protect and repeats that using this application to send information is allowed insofar as the information cannot be traced back to an individual in any way. Therefore, the guideline warns health professionals that using WhatsApp for tele-expertise might result in a breach of medical confidentiality after all.¹³⁰ It can also lead to a personal data breach and thus be a violation of the GDPR.¹³¹ Although this is not a prohibition, it is a strong recommendation against using this application in practice.

Where the KNMG seems relatively mild on the utilisation of WhatsApp for tele-expertise by not imposing a ban on this application, the Dutch DPA on the other hand, spoke firmly against the use of WhatsApp among physicians. According to the privacy authority, WhatsApp

125 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Federatienieuws 25 November 2015. Source: medischcontact.nl/nieuws/federatienieuws/federatiebericht/Praktijkdilemma-Mag-een-arts-patientgegevens-uitwisselen-via-WhatsApp.htm.

126 Duval, *Journal of Universal Computer Science*, 2001, p. 591.

127 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm.

128 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Federatienieuws 25 November 2015. Source: medischcontact.nl/nieuws/federatienieuws/federatiebericht/Praktijkdilemma-Mag-een-arts-patientgegevens-uitwisselen-via-WhatsApp.htm.

129 KNMG Guidelines for dealing with medical data 2020.

130 KNMG Guidelines for dealing with medical data 2020, p. 24.

131 Art. 4 Para. 12 GDPR and Art. 33 GDPR.

does not meet the standards for security and safety that are required to transfer sensitive personal data, such as medical data.¹³² In response, the KNMG stated that the association is against a ban on the use of WhatsApp by health professionals. Not only does the association stress that it is unlikely that individuals will be identified by means of metadata included in the files sent through WhatsApp, the association also stresses that, in certain situations WhatsApp is the fastest way to make contact. In emergency situations, communication between physicians through WhatsApp might be the only way to help the patient. Therefore, using this application should not be forbidden, although safer applications are preferable.¹³³ The difference in points of view between the KNMG and the Dutch DPA can be explained by their respective tasks. The KNMG stands for health care of good quality¹³⁴ whereas the Dutch DPA is the supervisory authority with the task of ensuring privacy protection by means of supervision and provision of advice on compliance of statutes and regulations with respect to data protection, such as the GDPR.¹³⁵ These different goals and tasks lead to a difference in points of view in this case. Where the KNMG acknowledges that WhatsApp can be useful when no other means are available and time is limited, the Dutch DPA always prohibits it.

In a session of parliament, questions were posed about this issue as well. The Minister of Health, Welfare and Sport replied that, in accordance with what the Dutch DPA stated, exchange of personal health data between health professionals should be done as the privacy law stands. The Minister acknowledges that, even though an application such as WhatsApp has the ability to quickly make a connection between two or more physicians, this app does not meet the standard for safety and security and thus alternatives are preferable.¹³⁶

What all stakeholders in this discussion seem to agree on is the fact that no data that can be traced back to individual patients should be disseminated by means of WhatsApp. Both the KNMG and the Federation of Patients in the Netherlands explicitly mention this.¹³⁷ However,

132 The Dutch DPA reacted in the current affairs programme *EenVandaag*, broadcast on 23 February 2016, *Eenvandaag*, 'Medische info delen via Whatsapp', *eenvandaag.nl*. Source: <https://eenvandaag.avrotros.nl/binnenland/item/medische-info-delen-via-whatsapp/>. See also Van Noort, 'Artsen moeten stoppen met whatsappen over patiënten', *nrc.nl* 23 February 2016. Source: nrc.nl/nieuws/2016/02/23/artsen-moeten-stoppen-met-whatsappen-over-patienten-a1409107.

133 M. Kregting, 'KNMG wil gebruik WhatsApp door artsen niet verbieden', *ICT&health*, *icthealth.nl* 25 March 2016. Source: icthealth.nl/nieuws/KNMG-wil-gebruik-WhatsApp-door-artsen-niet-verbieden/.

134 'About KNMG', *knmg.nl*. Source: knmg.nl/over-knmg/about-knmg/about-knmg.htm.

135 For supervision see Art. 55 and Art. 58 GDPR, for provision of advice see Art. 36 Para. 4 GDPR. Also see Art. 14 UAVG.

136 *Aanhangsel Handelingen II* 2015/16, no. 2203, p. 2.

137 See the above in section 4.2 presented opinions of the KNMG and the Federation of Patients in the Netherlands: 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm and the Federation of Patients in the Netherlands, in: Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809 and Van Noort, *NRC Next*, 8 July 2015, p. 7.

the fact that the occurrence of a personal data breach is possible, should be reason enough to advise against using this application for tele-expertise. Moreover, many alternatives, that are said to meet the standards for safety and security more closely, already exist.¹³⁸ The single opportunity of a personal data breach means that WhatsApp is not an appropriate means for tele-expertise.

Another question is if and, if yes where the application saves images and other documents sent through the applications. If the application saves information that is transferred in a cloud or server, it is important to note where this cloud or server is and who can access it. For instance, it is important to note if the cloud or the servers are outside the European Union, meaning that it is unsure whether patients can derive protection from European statutes and regulations concerning privacy law. WhatsApp Inc., as a company located in the USA, will save messages – albeit for a short period in time – on a server outside the European Union. Moreover, sometimes applications require and have access to information on the user's device, including confidential patient information. When the application synchronises, this information can land on the servers outside the European Union. This is problematic because information on these servers might not benefit from the protection of European Union privacy regulations, such as the GDPR.¹³⁹ Privacy legislation in the USA differs from privacy legislation in the European Union. The USA has an Act that regulates privacy in health care – the Health Insurance and Portability and Accountability Act (HIPAA)¹⁴⁰ – but this Act does not cover all types of health data.¹⁴¹ Based on Article 45 Paragraph 1 GDPR, the Commission can adopt a decision that states that a certain third country provides an “adequate level of protection”¹⁴² with respect to personal data. In that case, personal data can be transferred to such a third country. The EU–US Privacy Shield¹⁴³ was such a decision. However, in *Schrems II* the CJEU declared this decision invalid.¹⁴⁴ As a consequence, transferring personal data to the USA by means of the EU–US Privacy Shield is no longer allowed.¹⁴⁵

138 Examples are mentioned in Lycklama à Nijeholt, Pal, Tebbes & Peters, *Medisch Contact* 2015, p. 2312-2315 and Kregting, ‘KNMG wil gebruik WhatsApp door artsen niet verbieden’, *ICT&health, icthealth.nl* 25 March 2016. Source: icthealth.nl/nieuws/KNMG-wil-gebruik-WhatsApp-door-artsen-niet-verbieden/.

139 Wiggelinkhuizen et al., *Medisch Contact* 2015, p. 2310-2311.

140 Health Insurance and Portability and Accountability Act (HIPAA), Privacy Rule, 45 CFR Part 160 and Subparts A and E of Part 164, *Federal Register*, Vol. 67, No. 157/ Wednesday, August 14, 2002/Rules and Regulations, p. 53182-53273.

141 Price & Cohen, *Nature Medicine* 2019, p. 39.

142 Art. 45 Para. 1 GDPR.

143 Commission Implementing Decision (EU) 2016/1250 of 12 July 2016 pursuant to Directive 95/46/EC of the European Parliament and of the Council on the adequacy of the protection provided by the EU–U.S. Privacy Shield (*OJEU* 2016, L 207).

144 CJEU 16 July 2020, C-311/18, ECLI:EU:C:2020:559, *Computerrecht* 2020/183, m.nt. Steenbruggen & Van Harten (*Facebook Ireland and Schrems*).

145 Steenbruggen & Van Harten, comment on CJEU 16 July 2020, C-311/18, ECLI:EU:C:2020:559, *Computerrecht* 2020/183 (*Facebook Ireland and Schrems*), Para. 5.

Of course, in exceptional cases, the use of WhatsApp should not be a problem. But this only applies during emergencies, when no other options exist and when not using WhatsApp will lead to a violation of the obligation to act as a conscientious health care provider as laid down in Article 7:453 BW. Yet, even in those situations, other applications are preferable. Awareness of the risks of the use of WhatsApp to transfer patient information should be created, even though many health professionals indicate that they already know the risks. Other, safer applications for tele-expertise have been developed.¹⁴⁶ Such applications are preferable to WhatsApp.

WhatsApp has gone through several updates and is reported to include more means to guarantee privacy of its messages. From 5 April 2016 on, WhatsApp uses end-to-end encryption, which means that only the sender and the recipient can read the message and that WhatsApp or its employees cannot view this.¹⁴⁷ In an interview, the founders of WhatsApp explicitly mention that it is now possible to communicate with a health professional without third parties reading along.¹⁴⁸ This means that the same goes for communication of health professionals between each other. However, according to Nouwt, policy advisor on health law at the KNMG, WhatsApp still does not meet all criteria for safe messenger apps. Therefore, alternatives are still preferable.¹⁴⁹ Some patients, however, indicate that they value efficient communication between their health care providers and they are willing to give up some of their privacy for it.¹⁵⁰ Nevertheless, this does not mean that every patient thinks like this. It is very well imaginable that not every patient will think this way and a lot of patients will value their privacy very much. This can be drawn from – among other things – the discussion in the Netherlands related to the possible implementation of a shared electronic patient record from 2008 to 2011.¹⁵¹ Moreover, as already mentioned, patients' own feelings about their privacy is not relevant for privacy protection: privacy must be protected even though the subject does not care for their privacy. Because of the end-to-end encryption, the chances of violating

146 These applications are mentioned in section 2.3 above.

147 See 'About end-to-end encryption', *whatsapp.com*. Source: <https://faq.whatsapp.com/general/security-and-privacy/end-to-end-encryption> and Nouwt, 'WhatsApp veiliger, maar nog niet veilig genoeg', *knmg.nl Nieuws* 8 April 2016. Source: knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/whatsapp-veiliger-maar-nog-niet-veilig-genoeg.htm and the interview with its founders in *Wired*: see Metz, *Wired* 5 April 2016, Metz, 'Forget Apple vs. the FBI: WhatsApp Just Switched on Encryption for a Billion People. This morning, WhatsApp made the scope of the Apple-FBI encryption battle look kinda small.', *wired.com* 5 April 2016. Source: wired.com/2016/04/forget-apple-vs-fbi-whatsapp-just-switched-encryption-billion-people/ (interview Koum and Acton).

148 Metz, 'Forget Apple vs. the FBI: WhatsApp Just Switched on Encryption for a Billion People. This morning, WhatsApp made the scope of the Apple-FBI encryption battle look kinda small.', *wired.com* 5 April 2016. Source: wired.com/2016/04/forget-apple-vs-fbi-whatsapp-just-switched-encryption-billion-people/.

149 Nouwt, 'WhatsApp veiliger, maar nog niet veilig genoeg', *knmg.nl Nieuws* 8 April 2016. Source: knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/whatsapp-veiliger-maar-nog-niet-veilig-genoeg.htm.

150 Jacobs, *Smarterhealth.nl* 14 April 2016, smarterhealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/.

151 *Kamerstukken II* 2007/08-2011/12, 31466.

medical confidentiality because information can be viewed by others, are slimmer. Although end-to-end encryption is an improvement regarding personal data protection, it still cannot guarantee a full protection of personal data in any situation. It is still unclear what happens with data that are in a cloud outside Europe, even though the data are only on that cloud for a short period of time. That being said, for any application that is to be used for tele-expertise, it should be assessed whether the developer of the application or the company behind the application has opportunities to access the information that is processed by means of the application. It is advisable to carefully select the applications to use and if possible, make appointments with the developers of the applications, such as a derivative obligation of medical confidentiality for those who might see personal medical information. For instance, the use of WhatsApp would require the health professional to conclude an agreement with this company to guarantee that the data processed via WhatsApp are not used for another purpose.¹⁵²

It is stated that it is best to use safer alternatives for tele-expertise that meet the security recommendations.¹⁵³ Both the data that is transferred, such as photos and the accompanying text, should be considered personal medical data. These data should be treated with the necessary care. Health care institutions and their management teams should take steps to advise health professionals within their institutions about the (im)possibilities and about which applications are appropriate to carry out tele-expertise.¹⁵⁴ The appropriate applications must, as a minimum, meet the standards for safety and security as laid down in the NEN7511, NEN7512, NEN7513 and NEN8028 standards. However, this does not mean that assessing the appropriateness of applications in relation to data protection is the sole responsibility of health care institutions and their management teams; health professionals still have their individual responsibilities to protect medical confidentiality based on Article 7:457 BW and Article 88 BIG Act and to act as conscientious health care providers based on Article 7:453 BW. In other words, the safety of applications used for tele-expertise is a shared responsibility of health professionals and health care institutions.¹⁵⁵

152 According to a representative of the Dutch DPA: as stated in Jacobs, ‘Wie weet nu echt of WhatsApp mag in de zorg’, *Smarterhealth.nl* 14 April 2016. Source: smarterhealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/.

153 Peters & Lowijs, ‘Hoe een second opinion de privacy niet schaad. ‘Appende’ artsen vragen elkaar om advies,’ *dutchcowboys.nl* 9 July 2015. Source: dutchcowboys.nl/media/hoe-een-second-opinion-de-privacy-niet-schaadt. and Dutij, ‘Whatsapp in de gezondheidszorg, gemak voor de zorgverlener of rampzalig voor de privacy?’, *ictrecht.nl* 24 February 2016. Source: ictrecht.nl/blog/whatsapp-in-de-gezondheidszorg-gemak-voor-de-zorgverlener-of-rampzalig-voor-de-privacy.

154 Peters & Lowijs, ‘Hoe een second opinion de privacy niet schaad. ‘Appende’ artsen vragen elkaar om advies,’ *dutchcowboys.nl* 9 July 2015. Source: dutchcowboys.nl/media/hoe-een-second-opinion-de-privacy-niet-schaadt.

155 As in Peters & Lowijs, ‘Hoe een second opinion de privacy niet schaad. ‘Appende’ artsen vragen elkaar om advies,’ *dutchcowboys.nl* 9 July 2015. Source: dutchcowboys.nl/media/hoe-een-second-opinion-de-privacy-niet-schaadt.

When a health professional uses a personal cloud for a backup of their device and this cloud has an inappropriate security system or the device itself is not adequately protected, then, in spite of end-to-end encryption, the data which are being transferred will not benefit from a solid protection.¹⁵⁶ Moreover, the device itself is a hazard. When the device that is used for tele-expertise is not appropriately protected, an invasion of privacy can still occur.¹⁵⁷ Thus, no matter what kind of other safe and secured applications are used for tele-expertise, a risk of violation of privacy will remain when health professionals do not take precautions to secure and protect their devices with extra safety measures. Consequently, the issue is wider than the application that is used for tele-expertise alone. Physicians must therefore carefully consider which device they use for the purpose of tele-expertise and where to save the data. Using personal clouds where data can blend with the physician's personal data is also not advisable.

In the discussion on the safety of WhatsApp for tele-expertise it was also mentioned that the practicability of other applications might disappoint; it is not likely to find an application with as many users as WhatsApp. Moreover, when a certain application is only used within one health care institution it cannot facilitate contact between health professionals of various health care institutions.¹⁵⁸ This kind of contact however, is one of the main advantages of tele-expertise, to enable health professionals who are not in the same location to contact each other in a fast and efficient manner, such as tele dermatology.

4.3 Medical confidentiality and informational privacy during tele-expertise – the requesting physician

Tele-expertise takes place within an existing relationship for medical treatment: the physician who requests the tele-expertise has a contract for medical services with the patient they are asking tele-expertise for.¹⁵⁹ This means they should comply with the patients' rights following from the WGBO, including the obligation of medical confidentiality. All this depends on whether the contract is concluded between the patient and the physician or between the patient and the health care facility. When a health professional is not in the employ of a health care facility, the contract is concluded with the health professional. When the physician is in employment,

156 Santifort, 'End-to-end-encryptie & privacy bij WhatsApp: waarom je toch moet oppassen', *frankwatching.com* 11 May 2016. Source: frankwatching.com/archive/2016/05/11/end-to-end-encryptie-privacy-bij-whatsapp-waarom-je-toch-moet-oppassen/.

157 J. Jacobs, 'Wie weet nu echt of WhatsApp mag in de zorg', *Smarthealth.nl* 14 April 2016. Source: smarthealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/ and Santifort, 'End-to-end-encryptie & privacy bij WhatsApp: waarom je toch moet oppassen', *frankwatching.com* 11 May 2016. Source: frankwatching.com/archive/2016/05/11/end-to-end-encryptie-privacy-bij-whatsapp-waarom-je-toch-moet-oppassen/.

158 J. Jacobs, 'Wie weet nu echt of WhatsApp mag in de zorg', *Smarthealth.nl* 14 April 2016. Source: smarthealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/.

159 Art. 7:446 BW.

however, the contract will be concluded with the health care facility.¹⁶⁰ Such a construction means that the health care facility has a responsibility with respect to the patients' rights laid down in the WGBO as well as the physician.¹⁶¹ This means that the health care facility must take steps to protect medical confidentiality as well. In academia, consensus exists about the fact that the physician and the health care organisation where they provide health care are responsible for protecting the confidentiality of the patient's information, based on the WGBO.¹⁶²

This obligation of medical confidentiality entails that health professionals do not provide information about the patient and their health to others. This information includes, among other things, spoken communication by the patient and information that the health professional obtained while treating the patient. The latter includes information following lab test results, radiological images and diagnosis.¹⁶³ This means that photos of the patient, such as the photos taken on behalf of the tele-expertise, are subject to the obligation of medical confidentiality as well.¹⁶⁴ Exceptions are possible, such as the patient's consent¹⁶⁵ or other health professionals involved in the patient's treatment.¹⁶⁶ Consent will be discussed in section 6.

According to the explanatory memorandum to the WGBO, a colleague who provides the health professional with advice concerning the treatment of a particular patient can be considered a person involved in this patient's treatment. The obligation of medical confidentiality does not apply against these individuals.¹⁶⁷ This means that the physician can provide information about this patient to the colleague they are asking advice from, albeit only the information that the colleague needs in order to provide appropriate advice.¹⁶⁸ The only difference with tele-expertise is that the tele-expert is located at a distance from the health professional. As such, tele-expertise will not result in a breach of medical confidentiality if the requesting physician only provides the information that is necessary for the advice to the tele-expert.¹⁶⁹ On the contrary, providing the tele-expert with the necessary advice is in line with conscientious health care provision.¹⁷⁰ In the case of teledermatology for instance, this results in sending a picture of the part of the skin concerned, along with other information a teledermatologist might need to diagnose the patient or to consider whether a referral is needed.

160 Wijne 2017a, p. 9-10.

161 Wijne 2017a, p. 10-11.

162 See, for instance Krabben 2012, p. 87. Following from Art. 7: 446 BW in conjunction with 7:457 BW.

163 Buijsen et al. 2012, p. 37 and 81; Leenen/Dute & Legemaat (eds.) 2017, p. 153 and Wijne, in: *GS Bijzondere overeenkomsten*, Art. 7:457 BW, note 4 (online, updated to 17 June 2020).

164 Accordingly, KNMG Guidelines for dealing with medical data 2020, p. 24.

165 Art. 7:457 Para. 1 BW.

166 Art. 7:457 Para. 2 BW. More exceptions can be found in Art. 7:457 Para. 3 BW and Art. 7:458 BW.

167 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39 and *Kamerstukken II* 1989/90, 21561, no. 6, p. 39. Accordingly, KNMG Guidelines for dealing with medical data 2020, 19-20.

168 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39 and *Kamerstukken II* 1989/90, 21561, no. 6, p. 39. Accordingly KNMG Guidelines for dealing with medical data 2020, p. 20.

169 Dans & Van der Vorst, *TvGR* 2008, p. 193-194.

170 *Kamerstukken II* 1989/90, 21561, no. 6, p. 39.

4.4 Medical confidentiality and informational privacy during tele-expertise – the tele-expert

Not only is the physician who is asking for tele-expertise (the requesting physician) bound by the obligation of medical confidentiality, the physician who is asked a question (the tele-expert) is obliged to comply with the obligation of medical confidentiality as well. As presented in section 3, a contract for medical services exists between the requesting physician and the patient. No contract for medical services between the tele-expert and the patient is established during tele-expertise. Nevertheless, the tele-expert still has obligations towards the patient they are consulted about.

The tele-expert has responsibilities as they are involved in the treatment of the patient as soon as they start to provide tele-expertise because a colleague who is asked for advice about the treatment of a particular patient is considered to be involved in this patient's treatment.¹⁷¹ It is interesting to consider how we should place the tele-expert. They will receive information, providing this information to them will not result in a breach of the requesting physician's obligation of medical confidentiality, but the question is whether the tele-expert has an obligation of medical confidentiality. Certain categories of people have a so-called derivative obligation of medical confidentiality. This means that they have an obligation based on the physician's obligation – the health professional who entered into a contract for provision of medical services with the patient – following from Article 7:457 BW. However, the derivative obligation of medical confidentiality concerns people who are not health professionals.¹⁷²

The obligation of the tele-expert, as a health professional, can be found in the BIG Act. The tele-expert, as a professional with a BIG registration according to Article 3 of the BIG Act, has an independent obligation of medical confidentiality based on Article 88 BIG Act. This obligation is imposed on every health professional with a BIG registration as in Article 3 of the BIG Act, also if – for whatever reason – they are not in a relationship for medical services with the patient and there is somehow no reason to assume the WGBO's applicability. Thus, during tele-expertise, the right to medical confidentiality should be protected by both the requesting physician and the tele-expert, in order to keep on protecting the patient's right to access a health professional without having to fear that their information will be carelessly disseminated. Such a fear will infringe their right to access to health care, one of the main human rights that the right to medical confidentiality aims to protect.¹⁷³

171 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39. As presented in section 3.

172 *Kamerstukken II* 1989/90, 21651, no. 6, p. 39.

173 For instance, Leenen/Dute & Legemaate (eds.) 2017, p. 151.

4.5 Medical confidentiality and informational privacy during tele-expertise – third parties

In order not to violate the duty of medical confidentiality, health professionals and health care institutions should not only ensure that the applications are safe and secure, they should also pay attention to the question of whether the people behind the application, i.e. the developer and/or the company behind the application, have access to conversations through the application or to other information shared by this application, such as photos. The problems related to tele-expertise and the applications that are used are already presented in section 4.2. It is important to note that a personal data breach, caused because of the use of an inappropriate device for tele-expertise, constitutes a violation of the obligation of medical confidentiality as laid down in Article 7:457 BW.¹⁷⁴

The second group of third parties that might have access to the information that is disseminated by means of ICT is the IT workers who are employed within the health care institution. IT workers are likely to view information that was transferred during tele-expertise when they are monitoring the system or carrying out system maintenance. Moreover, it is probable that they gain access to certain information when they assist during system failure, especially if this occurs when one of the physicians (this can be the requesting physician or the tele-expert) is still providing input. As opposed to e-consultation, the information provided during tele-expertise will probably be more limited. Where e-consultation deals with an entire conversation with a patient, tele-expertise only deals with one question or situation. However, this information can still be visible to employees of the IT department when they assist the health professional. This means that the obligation of medical confidentiality must be extended to all employees of the health care institution.¹⁷⁵ This should include both the IT workers within the requesting physician's practice and the IT workers within the tele-expert's practice.

Finally, remarks should be made on medical confidentiality for IT workers who are hired externally. As for IT workers who work within the health care facility, they might view patients' personal medical data while assisting health professionals during tele-expertise. Similar to what has been stated in chapter 4,¹⁷⁶ it is recommended to make a provision on the derivative obligation of professional confidentiality in the contracts of IT workers who are hired externally.¹⁷⁷ Even though chapter 4 mentioned that it was stressed in academia that although in most cases no doubt exists as to the applicability of an derivative obligation of medical confidentiality, it is still recommended to include this obligation in the contract of

174 KNMG Guideline for dealing with medical data 2020, p. 24.

175 The KNMG made a similar recommendation in its Guideline for online Physician–Patient Contact 2007, Para. 8.3, p. 11-12 and even added an illustrative clause to include in the contract of employment: KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, appendix 5, p. 17-18.

176 See chapter 4, section 4.3.

177 Schalken et al. 2010, p. 121.

third parties who deal with personal medical data, especially when these third parties are not health professionals themselves.¹⁷⁸

5. TELE-EXPERTISE AND SPATIAL PRIVACY

The right to spatial privacy can be found in Article 7:459 BW. This privacy right implies a right to treatment without the presence of third parties and aims to realise the right to privacy as laid down in Article 10 Gw.¹⁷⁹ In a situation of a face-to-face consultation in the physician's practice, this means that the physician should ensure that others cannot oversee or overhear the consultation. During tele-expertise, however, typically a third person becomes involved – the tele-expert. Following from the text of Article 7:459 BW and the explanatory memorandum to the WGBO,¹⁸⁰ the patient's permission is needed to let others overlook the consultation. This means that the requesting physician should ask permission before they can ask the tele-expert to take a look. This might be obvious in a situation where a physician asks a colleague face-to-face for advice but this obligation has to be honoured no less when the colleague is asked for advice over distance; the right to spatial privacy applies over distance as well.¹⁸¹ According to the ECtHR, photos or other visual material of the patient is protected under the right to privacy as laid down in Article 8 ECHR as well.¹⁸² This means that the photo taken by the GP in a case of teledermatology is protected by the right to privacy; others are not allowed to view this material since this would entail viewing details of patients' treatment. Hence, it is possible to oversee someone's treatment by viewing images of this person. The explanatory memorandum to the WGBO expressly mentions that the patient's consent is necessary even for students and interns who wish to attend the consultation and that a tacit consent is not enough to assume the patient's consent. On the contrary, this consent should be explicit.¹⁸³ However, in literature it is mentioned that in practice, health professionals often seem to assume a tacit consent and allow students and assistants to be present during the consultation or treatment as long as the patient does not explicitly object to this.¹⁸⁴ The evaluation of the WGBO in 2000 showed a similar image.¹⁸⁵ However, according to interns in a university hospital, consent is asked and at times their presence is denied.¹⁸⁶ Based on the legislators' intention when drafting Article 7:459 BW, the principal rule should be asking consent before involving any other person during the treatment or consultation.

178 Duijst 2012, p. 22.

179 *Kamerstukken II* 1989/90, 21561, no. 3, p. 16-17.

180 *Kamerstukken II* 1989/90, 21561, no. 3, p. 41.

181 Ploem, *TvGR* 2008, p. 319.

182 ECtHR 15 January 2009, ECLI:CE:ECHR:2009:0115JUD000123405, *RvdW* 2009/991 (*Reklos and Davourlis v. Greece*).

183 *Kamerstukken II* 1989/90, 21561, no. 3, p. 41. In that sense, also Wijne 2017b, p. 274 and the ECtHR case law cited there.

184 Sluijters & Biesart 2005, p. 118.

185 Dute et al. 2000, p. 412.

186 The author learned this from the students while lecturing at the Erasmus Medical Center.

Paragraph 2 of Article 7:459 BW however, states that such a permission of the patient is not necessary when others are needed for the performance of the medical treatment or examination. This raises the question of whether a tele-expert is such ‘another’ person. The criterion mentioned in Article 7:459 Paragraph 2 BW differs from the criterion used in Article 7:457 Paragraph 2 BW about medical confidentiality.¹⁸⁷ Article 7:457 Paragraph 2 BW states that the obligation of medical confidentiality does not apply against “those who are directly involved in the performance of the contract or treatment (...)”¹⁸⁸ Article 7:459 Paragraph 2 BW states that Paragraph 1 does not apply for “persons whose cooperation in the performance of the activities is professionally necessary”.¹⁸⁹ In the original draft the exceptions used to be formulated in the same words.¹⁹⁰ Later, however, the provision on medical confidentiality was rephrased in order to include more people because, according to the legislator, non-medical professionals sometimes need information about the patient, too.¹⁹¹ Consequently, Article 7:459 Paragraph 2 BW is stricter; this exception only applies to people who are necessary in carrying out the contract for provision of medical services.

Where the obligation of medical confidentiality does not apply against a colleague who is consulted about a patient,¹⁹² spatial privacy must be interpreted in more restrictive terms. Spatial privacy relates to the moment where the tele-expert becomes involved: if the patient refuses to consent to the tele-expertise, the tele-expert will not be involved in the performance of the contract for medical services. Medical confidentiality only comes up when the patient gives permission and the tele-expert is involved. Since the tele-expert is involved in the performance of the contract for medical services from that moment on, medical confidentiality does not apply against them.¹⁹³ Even more so, they need some information about the patient to perform their task.¹⁹⁴ Permission should be asked before a tele-expert is involved in the patient’s treatment. The tele-expert is asked for their advice about the treatment or diagnosis of a patient but their involvement is usually not strictly necessary, unlike assistants who are necessary in conducting the treatment. Moreover, numerous reasons for which the patient will not consent to tele-expertise are possible, such as a fear of violation of privacy¹⁹⁵ or general lack of trust in ICT.¹⁹⁶ Such a patient should get the opportunity to visit the tele-

187 Wijne, in: *GS Bijzondere overeenkomsten*, Art. 7:457 BW, note 5 (online, updated to 17 June 2020).

188 Warendorf et al., Warendorf Legislation/457 CC Bk 7, 2015.

189 Warendorf et al., Warendorf Legislation/459 CC Bk 7, 2015.

190 *Kamerstukken II* 1989/90, 21561, no. 2, Art. 1653l Para. 2, p. 4 and art. 1653n Para. 2, p. 5.

191 *Kamerstukken II* 1989/90, 21561, no. 6, p. 39.

192 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39, KNMG Guidelines for dealing with medical data 2020, p. 20 and Wijne 2017b, p. 258.

193 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

194 *Kamerstukken II* 1989/90, 21561, no. 6, p. 39 and Wijne, in: *GS Bijzondere overeenkomsten*, Art. 7:457 BW, note 9 (online, updated to 17 June 2020).

195 Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980-984.

196 For instance Selwyn et al., *Ageing & Society* 2003, p. 575 and Zajicek 2007, p. 35 and 37.

expert by themselves instead of having their information transferred by means of ICT. This is in accordance with the legislator's intention, which shows a restrictive notion of spatial privacy.¹⁹⁷

6. TELE-EXPERTISE AND THE RIGHT TO INFORMED CONSENT

6.1 Introduction to tele-expertise and the right to informed consent

Tele-expertise invokes different questions with respect to the right to informed consent than those discussed in chapter 4 in relation to e-consultation and the right to informed consent. For carrying out tele-expertise, informed consent based on Article 7:448 in conjunction with Article 7:450 BW is needed. This section will discuss how the right to informed consent can and should be protected during tele-expertise. Similar to what was done in the previous chapter, informed consent will be separated into the right to information (section 6.2) and the right to give consent (section 6.3).

6.2 Tele-expertise and the right to information

The health professionals who conduct tele-expertise are each other's contracting parties and the health professional who is asking for tele-expertise related to the treatment of a patient should comply with the patient's rights in the WGBO in relation to this patient. Based on the right to information as laid down in Article 7:448 BW, the physician should inform the patient about the examination they will conduct and based on that information, make a joint decision with the patient. Because tele-expertise can be applied to obtain another health professional's advice on the diagnosis or treatment of a particular patient, tele-expertise can be considered a part of the medical examination. This means that the patient should be informed about the tele-expertise. The right to information prescribes that the health professional should inform the patient about the examination.¹⁹⁸ This means that a health professional who wants to consult another colleague via tele-expertise should inform their patient about this plan. Whether the tele-expertise takes place in the presence of the patient or after they left the health professional's practice, is irrelevant.

An important further question is what exactly should the patient be informed about, apart from the tele-expertise itself. As with any treatment, information must be provided about the nature and purpose of the treatment or examination, the consequences and potential risks of this as well as possible alternatives and the health expectations relating to or following from

¹⁹⁷ *Kamerstukken II* 1989/90, 21561, no. 3, p. 41.

¹⁹⁸ Art. 7:448 BW.

this particular treatment or examination.¹⁹⁹ In the case of tele-expertise, this means that the physician must explain why they want to request tele-expertise, for instance because they want to consult a colleague to diagnose the patient or because they want to know whether the colleague thinks a referral is necessary in this situation. Information should also be provided about the differences between tele-expertise and a regular second opinion.²⁰⁰ These differences will mainly relate to the distance, data collection and data protection. It might not be possible to diagnose a patient over distance, leading to the necessity of a referral after all. In principle, tele-expertise does not differ from a regular face-to-face second opinion or any other type of face-to-face health care provision, except for the handling of personal medical data, i.e. transferring these data by means of ICT and the related privacy risks. The patient should be informed about these potential risks as well. Because ICT is used to transfer personal medical data – during tele-expertise in many instances this includes a photo – a personal data breach can occur, in spite of the best safety measures.²⁰¹ If the tele-expertise includes photos or other personal medical data, information should be provided to the patient about the way their data are protected.²⁰² This means that during teledermatology, for instance, the patient should be informed about the possibilities of tele-expertise: the consulted teledermatologist can only diagnose the patient from a distance and diagnosis will not be possible all the time. At times, a referral will still be necessary. Moreover, in this example, the patient has to be informed about the fact that the photos are sent through a secured system and that the consulted dermatologist will use these photos to diagnose the patient or to provide advice to the physician who asks for tele-expertise. Also, they should be informed about which health professional stores and keeps the data. Most of the times this will be the physician who requested the tele-expertise; they have a contract for medical services with the patient and thus have a duty to keep a medical record about this patient.²⁰³

Moreover, the health professional should provide the patient with information on the expertise of the consulted specialist.²⁰⁴ When the tele-expertise only aims at asking whether a referral is necessary, it seems a little farfetched to provide all kinds of information on the tele-expert's background. When the purpose of the tele-expertise is e-diagnosis, however, it is useful to explain why the specialist is consulted and what they can do in this situation.

If the patient, after having received information about tele-expertise and its benefits, refuses to give their consent, they should be able to choose an alternative method of diagnosis or examination. Therefore, the right to information includes the right to receive information

199 Art. 7:448 Para. 2 BW.

200 Dreezen, *Med Law* 2004, p. 544, cited by Callens, *TvGR* 2006, p. 271.

201 See section 4 of this chapter on safety measures and precautions health professionals must take when transferring personal medical data.

202 Dreezen, *Med Law* 2004, p. 544.

203 Art. 7:454 BW.

204 Dreezen, *Med Law* 2004, p. 544 cited by Callens, *TvGR* 2006, p. 271.

about alternatives.²⁰⁵ Thus, information about the pros and cons of a referral to the specialist instead of tele-expertise should be given as well. Finally, the patient has to be informed about the health expectations and the possible outcomes. Tele-expertise can for instance lead to the prescription of medication or a referral. In these situations tele-expertise does not have a direct effect on the patient's health.

6.3 Tele-expertise and the right to give consent

The right to give consent is laid down in Article 7:450 BW. Based on this right, the patient needs to give their explicit consent for actions the health professional undertakes to carry out the contract for medical services. Tele-expertise invokes two questions with respect to the right to give consent. First, it is important to know whether tele-expertise is an action to carry out the medical services contract.

In the explanatory memorandum to the WGBO, the provision on consent (Article 7:450 BW) is explained as follows. The fact that the patient has given their consent to enter into the contract for medical services does not mean that the patient automatically gives consent for every act within this contract.²⁰⁶ Referring to case law, the explanatory memorandum states that this right directly relates to the right to physical and mental integrity.²⁰⁷ On the other hand, the physician can reasonably expect that the patient will allow acts that belong within the treatment contract that parties agreed on.²⁰⁸ However, not every act necessary to perform the contract for medical services is foreseeable. Thus, based on the right to respect of bodily and mental integrity, the patient should give their consent before they undergo a medical procedure or examination.²⁰⁹

In order to figure out whether explicit consent is needed for tele-expertise, a closer look should be taken at exactly what tele-expertise's place is within the treatment of a patient. Tele-expertise takes place within an existing contract for medical services.²¹⁰ In the case of teledermatology, a patient consults their GP about a problem with their skin. The GP, in turn, consults a dermatologist over distance. This dermatologist can indicate whether a referral is required in this situation or maybe they can, based on the material that was sent by the GP, already give a diagnosis. This is the same when WhatsApp is used for tele-expertise: the patient visits a health professional, with whom they conclude a contract for the provision of medical services. This consultation is a part of the performance of the contract for medical

205 Art. 7:448 Para. 2(c) BW.

206 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

207 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12, referring to Rb. Breda 27 April 1953, *NJ* 1954/41 and Medisch Tuchtcollege 's Gravenhage 7 December 1972, *MC* 1973, p. 261.

208 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

209 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

210 Art. 7:446 BW.

services because it belongs to the examination and diagnosis of the patient, and these can be classified under provision of medical services.²¹¹ Therefore, tele-expertise is an action that requires consent based on Article 7:450 BW.

An exception to this rule is possible though. According to Article 7:466 Paragraph 2 BW, for certain non-invasive actions consent can be considered given together with entering into the contract for medical services. These actions do not require specific consent. This should be weighed case by case, depending on the action, the possible consequences of this action and the patient's nature.²¹² It is important to note whether tele-expertise is an action of a major nature or an action of a minor nature that does not need explicit consent based on Article 7:466 Paragraph 2 BW. When comparing tele-expertise to consulting a colleague face-to-face, at first sight it does not seem invasive. The physician's colleague who is asked for their opinion will only take a look at the patient or a picture and give their advice to the requesting physician. Taking a photo and sending this photo to another health professional is not likely to be a physical invasion i.e. a violation of bodily integrity. However, it can be a violation of privacy because of the nature of tele-expertise. Tele-expertise will include transferring information about the patient digitally, and personal medical data are sensitive data.²¹³ Consequently, these data should be handled with the best possible care. Therefore, it is advisable to always ask patients for their consent with respect to tele-expertise. A patient might not object to one of the physician's colleagues taking a look face-to-face, but they might object when this involves a transfer of information by means of ICT. The patient and their circumstances have to be taken into account. It is possible that they do not want their information transferred through ICT because of a fear of violation of their privacy, or because they do not have confidence in ICT.²¹⁴ Since the patient has a relationship for medical treatment with the physician who requests tele-expertise, this physician should ask and obtain the patient's consent based on Article 7:450 BW.²¹⁵

The nature and character of tele-expertise lead to another aspect of giving consent. As well as the tele-expertise itself, consent should be given about the processing of medical data because tele-expertise entails transferring personal medical data and carries the risk of a personal data breach. Moreover, the number of people able to access the data will inevitably be higher than during a face-to-face consultation with a colleague.²¹⁶

211 Art. 7:446 Para. 2 BW.

212 *Kamerstukken II* 1989/90, 21561, no. 3, p. 49.

213 ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*); ECtHR 17 July 2008, ECLI:CE:ECHR:2008:0717JUD002051103 (*I. v. Finland*) and ECtHR 4 December 2008, ECLI:CE:ECHR:2008:1204JUD003056204, *NJ* 2009/410, m.nt. Alkema (*Marper and S. v. United Kingdom*), as cited by Verhey & Raijmakers, *Regelmaat Kwartaalblad voor wetgevingsvraagstukken* 2013, p. 186. The ECtHR bases its decision on Art. 6 of the Strasbourg Convention.

214 For instance Selwyn et al., *Ageing & Society* 2003, p. 575 and Zaijcek 2007, p. 35 and 37.

215 Accordingly, Dreezen *Med Law* 2004, p. 546.

216 Callens & Cierkens 2012, p. 134.

Finally, in some cases the patient might want to use their right not to know as laid down in Article 7:449 BW. This means that patients should be asked whether they want the specialist's opinion before the physician contacts the tele-expert.

In sum, the exception of Article 7:466 Paragraph 2 does not apply in the case of tele-expertise. At first sight, asking for explicit consent for tele-expertise does not seem necessary. The action itself cannot be seen as very invasive and it is a part of the treatment to which the patient gave their prior consent. However, because of the nature of tele-expertise, which requires dissemination of personal medical data – i.e. sensitive data – and the fact that more people might be able to view the data²¹⁷ and the data might be saved on multiple devices and perhaps in a cloud, explicit consent must be obtained in this situation. However, this should not go so far as to infringe the health professional's obligation to act as a conscientious health care provider.

217 For instance Callens & Cierkens 2012, p. 134 and Dreezen *Med Law* 2004, p. 544.

6





Telemonitoring and patients' rights

1. INTRODUCTION

This chapter will discuss telemonitoring and patients' rights. As presented in chapter 2, telemonitoring is the use of ICT to monitor a patient over distance. The patient is at home, or at least not within the health care facility, while their health values are transferred to a health professional. The health professional acts when the results give a cause for concern.¹ The health values can be measured by the monitoring device² but it is also possible that the patient themselves does the monitoring.³

In chapter 2, eHealth that facilitates health care provision was referred to as eHealth care provision. eHealth care provision, the topic of this study can, in turn, be divided into three subcategories: e-diagnosis (diagnosis over distance), e-therapy (online therapy) and e-care (monitoring and advising over distance).⁴

As such, telemonitoring seems to have a similarity to e-consultation, because in both situations the patient and the health professional are not in the same location. The difference, however, is that telemonitoring requires an even more active patient than e-consultation. During e-consultation, the patient has to ask the health professional a question to start the electronic consultation. Telemonitoring requires more continuous action by the patient, because they measure their own health values and must focus more on their health in general. The health professional checks these values and acts when these indicate a deterioration of the patient's health.⁵ At first sight, this seems to take place within the patient's private life because the patient is measuring and recording their own health values. This shows a resemblance to consumer eHealth, which is carried out by the patient without the involvement of a health professional. Yet, as soon as the health professional receives and reviews these values, i.e. when the actual monitoring starts, telemonitoring becomes e-care; the moment of involving a health professional marks the transition from consumer eHealth to professional eHealth. Also, telemonitoring does not always have to start as consumer eHealth. Numerous situations are imaginable where the health professional is involved from the beginning: for instance, when the physician prescribes a certain (web)application or device for monitoring or when the monitoring devices are provided or installed by the health care facility. The University Medical Center Utrecht for instance lists various applications that are used for telemonitoring on its website.⁶

1 Beuscart et al. 2014, p. 411-412 and Wouters et al. 2017, p. 74.

2 Beuscart et al. 2014, p. 411.

3 Krijgsman & Klein Wolterink 2012, p. 6-7 and 10; Beuscart et al. 2014, p. 412 and Wouters et al. 2017, p. 74.

4 Classifications in: RVZ 2002, p. 16-17.

5 Wouters et al. 2017, p. 74.

6 'eHealth toepassing', *umcutrecht.nl*. Source: umcutrecht.nl/nl/ehealth-toepassing.

In short, telemonitoring means that a patient measures their own health values and electronically transfers them to a health professional, who monitors them and provides feedback.⁷ It is a tool for the physician to keep track of the health of their patient, by using data measured and filled in by this patient themselves.⁸

Telemonitoring, as a type of e-care that is used in the relationship between the patient and the health professional, is most regularly utilised in health care provision for patients who are chronically ill.⁹ It can be carried out by means of an app or a website. Based on what was stated earlier, telemonitoring can be classified as e-care, which literally includes monitoring over distance. However, we can wonder whether it can, at times, also qualify as e-diagnosis, for instance when the health professional interprets the results from the data sent in by the patient and establishes a diagnosis based on this information.

Looking at the way telemonitoring is carried out, several variants are feasible. First, it is possible that the telemonitoring is combined with the patient's PHR.¹⁰ A PHR was explained in chapter 2 as a health record kept, written and organised by the patient themselves.¹¹ A PHR is a tool that can be used very well for a patient to monitor their own health status. If a patient shares (a part of) their PHR with their physician, the latter can monitor the patient over distance and give advice if necessary. A PHR as such can be categorised as e-care support because the PHR is not an act of health care provision but, comparable to an electronic patient record kept by a health professional, a means to support health care provision. A PHR will result in health care provision when used for telemonitoring. An example of a PHR that can be used for telemonitoring is the *Gezondheidsmeter PGO*¹² [Health Indicator Personal Health Portal].¹³ On this secured platform, patients can monitor and share their information with physicians as they wish. The health professional, in turn, can discuss these results during an e-consultation or a regular, face-to-face consultation. At times, health professionals can advise their patients with forms especially designed for this purpose. Moreover, *Gezondheidsmeter PGO* contains additional information, such as information on *thuisarts.nl* on a specific, custom-made platform for certain health problems.¹⁴ *Gezondheidsmeter PGO* offers about

7 *Kamerstukken II* 2013/14, 27529, no. 130, p. 3 and 10; Krijgsman et al. 2015b, p. 11 and Wouters et al. 2017, p. 74.

8 Krijgsman et al. 2016a, p. 104.

9 Krijgsman & Klein Wolterink 2012, p. 4.

10 Examples are mentioned in Van Duivenboden 2015, p. 21.

11 Hooghiemstra & Ippel 2011, p. 14.

12 PGO stands for *Persoonlijke Gezondheidsomgeving*, which means Personal Health Portal.

13 This example is mentioned by Van Duivenboden 2015, p. 21. 'Gezondheidsmeter PGO', *gezondheidsmeter.nl*. Source: gezondheidsmeter.nl/landing/landing.html. More examples are mentioned in Van Duivenboden 2015, p. 21. Also: Cunningham et al. 2014, p. 24.

14 For instance about COPD: 'COPD', *gezondheidsmeter.nl*. Source: gezondheidsmeter.nl/site/informatie/mijn-copd-online/meer-informatie-zorgverlener/96,5.html.

50 modules, each related to a specific disease or problem.¹⁵ The platform can be used on a personal computer, a tablet or a smartphone, making it accessible at any time.

Another example of such a platform is *patient1.nl*, a PHR that can be shared with (multiple) health professionals. In this PHR, patients agree on a plan for treatment with one or more physicians. Those health professionals will be able to view the information the patient records in their PHR. If necessary, the health professional can contact the patient or send them a questionnaire. This way, the physician can intervene in an early stage and prevent deterioration. Needless to say, this is only possible when the patient has given the health professional explicit consent for access to their information.¹⁶ In the Netherlands, patients can use a *persoonlijke gezondheidsomgeving* [personal health environment] (PGO), a personal health record in which they can collect and update their medical information. If they wish, they can share information from the PGO with their health professionals.¹⁷ PGOs that comply with safety and security standards receive a *Medmij-label*.¹⁸ Medmij awards this label to PGO applications after it is established that the PGO complies with the safety and security standards.¹⁹

Second, telemonitoring can be carried out by means of sensors that measure a person's health values and transfers them to a physician. Wearables, special kinds of sensors worn by the patient, can also be used for this type of telemonitoring.²⁰ Third, telemonitoring can be conducted by means of apps that can be installed on a smartphone, tablet or personal computer.²¹ Patients can transfer the information they record to the health professional within this application, but collecting the values by means of the app and transferring them later while using another means is possible as well. This does not seem preferable though.²² Fourth, telemonitoring can be combined with video communication. In that case, the results of the self-measurements done by patients are discussed during a video consultation.²³ Fifth, telemonitoring can be carried out by means of a secured web application that is connected with various devices the patient has at their home. Serrano and Holthe describe an example of

15 See 'eCoaches', *gezondheidsmeter.nl*. Source: gezondheidsmeter.nl/site/informatie/algemeen/-/261,1.html.

16 'Patiënt 1 Persoonlijk Gezondheidsdossier', *patient1.nl*. Source: patient1.nl/.

17 'Bruins: iedereen kan kosteloos gebruik gaan maken van een persoonlijke gezondheidsomgeving', *Rijksoverheid.nl Nieuws* 12 March 2019. Source: rijksoverheid.nl/actueel/nieuws/2019/03/12/bruins-iedereen-kan-kosteloos-gebruik-gaan-maken-van-een-persoonlijke-gezondheidsomgeving and 'Persoonlijke gezondheidsomgevingen', *medmij.nl*. Source: medmij.nl/pgo/.

18 'Persoonlijke gezondheidsomgevingen', *medmij.nl*. Source: medmij.nl/pgo/ and Hendriks, *NJB* 2019, p. 1110.

19 'Persoonlijke gezondheidsomgevingen', *medmij.nl*. Source: medmij.nl/pgo/. By July 2020, 29 PGOs had received the *Medmij-label*.

20 Krijgsman & Klein Wolterink 2012, p. 7 and 10.

21 Krijgsman & Klein Wolterink 2012, p. 6 and 10.

22 This will be elaborated on in section 2.4 on Quality.

23 Krijgsman & Klein Wolterink 2012, p. 7 and 10.

telemonitoring where a patient is measuring certain values daily. What needs to be measured differs from patient to patient. After measuring, the values are automatically transferred to the secured web application. Then, the patient transfers their values to the health care facility's cloud by means of a secured email application, along with the answers to a questionnaire about their well-being. This is viewed by a health professional, who will respond if necessary for instance if the values are anomalous.²⁴

Domotics and robots can also be deployed for telemonitoring.²⁵ Domotics, or home electronics as applications that can be installed in a person's environment, will not be discussed in this chapter. Some kinds of domotics can be classified as eHealth while others are not related to health per se. Domotics are broader than eHealth care provision and therefore exceed the scope of this thesis. The same applies to robots. Likewise, their scope can surpass eHealth care provision and therefore they will not be discussed in this chapter and this thesis.

This chapter will start with presenting the effects of telemonitoring on the right to health and under what conditions this type of eHealth care provision can make a positive contribution to the realisation of this human right (section 2). This will be done according to the AAAQ framework. Thereafter, the application of the WGBO to telemonitoring will be presented (section 3), followed by a discussion on the rights to privacy and medical confidentiality (section 4), the right to spatial privacy (section 5) and the right to informed consent (section 6).

2. TELEMONITORING AND THE RIGHT TO HEALTH

2.1 Availability

Equal to the other types of professional eHealth telemonitoring, as a potentially useful tool to improve health, is subject to high expectations.²⁶ From a legal perspective, it is important to consider whether and how telemonitoring affects the availability, accessibility, acceptability and quality of health care and thus whether it enhances the right to health and under what conditions it can do so.

As a part of their obligation to fulfil the right to health, governments should ensure the availability of health facilities, goods and services throughout the country.²⁷ In certain countries, such as Canada, telemonitoring is a useful tool to facilitate health care over long

²⁴ Serrano & Holthe 2015, p. 311-315.

²⁵ Krijgsman & Klein Wolterink 2012, p. 7 and 10.

²⁶ For instance *Kamerstukken II* 2013/14, 27529, no. 130 on the expectations of eHealth.

²⁷ CESCR General Comment no. 14 (2000) on Health, Para. 12(a).

distances.²⁸ Of course, in the Netherlands telemonitoring also facilitates health care provision over distance, enabling patients to transfer their results directly to the physician instead of travelling to the health care facility but because the distances in the Netherlands are small compared to those in Canada, the benefits for improving availability of health care throughout the country seem smaller as well. Nevertheless, telemonitoring has the potential to enhance the availability of health care within the Netherlands because it enables health care at any place and any time. For instance, a patient might even measure their health values when they are enjoying a holiday. Unless the data give cause for concern, the health professional and the patient do not necessarily have to interact. This can wait until the patient has returned from their holiday.

Another advantage of telemonitoring is that a patient does not have to wait until the next appointment with their physician to have their results measured, nor do they have to wait until the consultation in order to hear whether the results are good. Telemonitoring makes health care independent from time and place, and enables people to live independently for a longer period of time.²⁹ Because of this, telemonitoring seems to make a positive contribution to the availability of health care.

However, in spite of these positive expectations of telemonitoring's potential to increase the availability of health care, the annual eHealth-monitor, a study on the use of eHealth in the Netherlands conducted among patients and health professionals, shows that its use is not widespread yet. This means that telemonitoring does not seem to contribute to increasing the availability of health services at this point. For instance, in 2013 13% of GPs used telemonitoring for patients with diabetes; in 2017 this was 9% for diabetes, heart failure, COPD or asthma. 14 % of specialists applied telemonitoring in the care of one or more groups of patients in 2013, while in 2017, 11% of specialists used telemonitoring in the care for the patients in their department.³⁰ This indicates that the availability of telemonitoring itself is problematic. A possible explanation given in the 2017 eHealth-monitor is that little evidence related to the effectiveness of telemonitoring exists.³¹ This will be further elaborated on in the section on quality. In 2019, however, the goal set by the Minister for Health, Welfare and Sport – 75% of the chronically ill (diabetes, COPD) and the elderly are enabled to perform self-measurements in combination with telemonitoring, if they wish³² – was reached.³³ One-fifth of physicians indicate that they offer their patients telemonitoring.³⁴

28 Alvarez, *EHealth International* 2002, issue 1, no. 4, p. 4.

29 *Kamerstukken II* 2013/2014, 27529, no. 130, p. 11.

30 Krijgsman et al. 2013, p. 81 and Wouters et al. 2017, p. 76-77.

31 Wouters et al. 2017, p. 82, referring to a study by Hanlon et al., *JMIR* 2017, issue 5, available at jmir.org/2017/5/e172/.

32 *Kamerstukken II* 2013/2014, 27529, no. 130, p. 10.

33 Wouters et al. 2019f, p. 4.

34 Wouters et al. 2019f, p. 4.

Yet, room for improvement still exists as telemonitoring is not fully embedded in health care provision.³⁵ Less than 50% of patients in the Netherlands measure their health values.³⁶

Another drawback in eHealth care provision's potential to contribute to the availability of health care is computer illiteracy, i.e. the inability to use ICT.³⁷ Telemonitoring, too, can only be beneficial for patients who can measure their health values and subsequently transfer them to the physician. Telemonitoring is not suitable for every patient.³⁸ How and why will be discussed below in the sections on non-discrimination and acceptability, but it can already be mentioned that telemonitoring cannot contribute to increasing the availability of health care for those unwilling or unable to use such a tool.

Another possible disadvantage of eHealth care provision was noted by the International Society for Mental Health Online (ISMHO) together with the Psychiatric Society for Informatics (PSI) in their suggested principles of professional ethics for the online provision of mental health services;³⁹ availability in case of emergencies.⁴⁰ Although these principles relate to e-mental health and not necessarily telemonitoring, this observation can be extended to the situation of telemonitoring: measuring health values can lead to a faster notification of emergencies, but a health professional cannot always respond immediately and adequately over distance. Especially when the distance between the health professional and the patient is great, this can be a problem. When a patient is telemonitored by their GP who has a practice in the town where the patient lives, they can visit the patient in case of emergencies and the problem seems smaller. For longer distances, ISHMO and PSIs suggested principles provide an idea as well: the physician should keep contact with a health professional who lives or holds a practice closer to the patient and who can respond in emergencies.⁴¹ However, it is conceivable that a patient will not use telemonitoring to contact a health professional in case of emergencies. Consequently, the fact that telemonitoring cannot be of use in case of emergencies is not a major drawback for its effects on the availability of health care.

Finally, directly related to the extent telemonitoring can contribute to the availability of health care is the availability of ICT itself. The availability of ICT is not evenly spread worldwide. This is referred to as the digital divide.⁴² According to the *Centraal Bureau voor de Statistiek* [Statistics Netherlands] (CBS) and Eurostat, 98% of households in the Netherlands

35 Wouters et al. 2019a, p. 21.

36 Wouters et al. 2019f, p. 7.

37 Also discussed in chapter 4 above.

38 See, for instance Buijsen, *Medisch Contact* 2012, p. 1609, who mentions that those who are computer illiterate might experience problems accessing health care when eHealth is used more frequently.

39 ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

40 Art. 3(a) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

41 Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

42 For instance Cunningham et al. 2014, p. 26

had access to the Internet in 2017.⁴³ In 2019 this had not changed.⁴⁴ According to CBS this is 97% in 2019 though.⁴⁵ Therefore, the availability of ICT and Internet connections does not seem to be an issue in the Netherlands. This means that telemonitoring can in principle be applied within the care for most patients in the Netherlands and thus has the potential to increase the availability of health services. A digital divide, however, does not necessarily have to exist between countries. It can exist within countries as well, for instance between different groups in the population. For example, between older and younger people or between higher and lower educated people. According to the data from the CBS, a greater number of younger people than older people had access to the Internet in 2017. However, the differences seem rather small and not likely to cause an issue for the ability to integrate telemonitoring in health care provision for elderly people. The data show that in 2019, 99.8% of people aged 18–25 had access to the Internet and 100% of people aged 25–35, as opposed to 94.5% of people aged 65–75 and 77.2% of people aged 75 and older.⁴⁶ Also, the differences between the groups with different levels of education are small. In 2019, 92.4% of people with a lower level of education as opposed to 99.8% of people with a higher level of education had access to the Internet.⁴⁷ Although access to the Internet does not necessarily mean that people possess the skills required to measure their health values and transfer them to a health professional, at least the availability is secured. Internet skills will be further discussed in the following sections on accessibility and acceptability.

To sum up, integrating telemonitoring in health care provision can contribute to the availability of health care because it is a type of health care provision that is independent from time and place. Since ICT is sufficiently available in the Netherlands and most people have access to the Internet, this should not be a barrier to availability. However, according to the annual eHealth-monitor telemonitoring is not fully integrated in health care provision so far.⁴⁸ This makes it difficult to contribute to the availability of health services or to anything at all. Time and practice must show what telemonitoring's real contribution is to the availability of health care. It seems to have the potential, though.

43 'Nederland koploper in Europa met internettoegang', *cbs.nl* 3 February 2018. Source: [cbs.nl/nl-nl/nieuws/2018/05/nederland-koploper-in-europa-met-internettoegang](https://www.cbs.nl/nl-nl/nieuws/2018/05/nederland-koploper-in-europa-met-internettoegang).

and Eurostat, 'Level of internet access – households', *ec.europa.eu*. Source: ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&plugin=1&pcode=tin00134&language=en.

44 Eurostat, 'Level of internet access – households', *ec.europa.eu*. Source: ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&plugin=1&pcode=tin00134&language=en.

45 'Internet; toegang, gebruik en faciliteiten', *cbs.nl*. Source: opendata.cbs.nl/statline/#/CBS/nl/dataset/83429NED/table?dl=91F4, last modified 8 October 2019.

46 'Internet; toegang, gebruik en faciliteiten', *cbs.nl*. Source: opendata.cbs.nl/statline/#/CBS/nl/dataset/83429NED/table?dl=91F4, last modified 8 October 2019.

47 'Internet; toegang, gebruik en faciliteiten', *cbs.nl*. Source: opendata.cbs.nl/statline/#/CBS/nl/dataset/83429NED/table?dl=91F4, last modified 8 October 2019.

48 Wouters et al. 2019a, p. 21.

2.2 Accessibility

Available health care services alone are not enough to ensure the right to health care for a population. Availability has little value when the services offered are not accessible for all. Accessibility, as the second requirement according to GC14,⁴⁹ will be presented in this section. In GC14, accessibility is subdivided into four conditions: non-discrimination, physical accessibility, affordability and accessibility of information.⁵⁰

2.2.1 Non-discrimination

According to GC14, accessibility of health services means, among other things, that these health services are free of discrimination.⁵¹ This section will consider whether telemonitoring contributes to health care provision to everyone without discrimination. Although most households in the Netherlands have access to the Internet, this does not automatically mean that everyone in these households has the right skills to perform self-measurements and transfer the results to a health professional.⁵² This requires some additional skills, including a certain level of health literacy.⁵³ The ability to read and write emails is not comparable to conducting measurements and transferring the results to a physician by means of a special application or a PHR. Perhaps some of the people who use the Internet to maintain social contacts are uninterested in measuring and tracking their health values or incapable of doing so. The first group is referred to as the digitally self-excluded: people who are unwilling to use ICT.⁵⁴ The second group, who cannot perform complicated ICT operations or who cannot work with ICT at all, are called the computer illiterate. It is very possible that a person belongs to both of these groups, but an individual can belong to only one of them as well. These groups do have one thing in common: they are not likely to use telemonitoring. Thus, telemonitoring will not contribute to enhance access to health care without discrimination for these groups. On the contrary, they risk becoming the subject of discrimination by means of exclusion. This should be prevented and opportunities for the computer illiterate and the digitally self-excluded to keep receiving health care without discrimination should be provided. For instance, the part of these groups that is able and willing to perform self-measurements can still do this and then bring the results to the health professional's practice during their next consultation. Another option is that the physician keeps on measuring these patient's results instead.

It is sometimes stated that even though a group of patients is not interested in using eHealth or perhaps even incapable of doing so, the group of patients that is able and willing to use

49 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

50 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

51 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

52 As addressed in section 2.1 above.

53 See, for instance Ossebaard and Idzardi 2013, p. 4.

54 Zajcek 2007, p. 35 and 37.

eHealth should not be hindered, if only because this will result in more time for face-to-face care for those who really want and need it.⁵⁵ Although this makes sense, we should not forget that it is undesirable to force people who – for whatever reason – feel uncomfortable in using eHealth, such as telemonitoring, to use it. Doing so might result in these people not receiving the (amount of) health care they need.

Efforts have been made to involve the computer illiterate or the digitally self-excluded in using ICT, for instance by designing applications that can be used on devices that people already know.⁵⁶ This will be further elaborated on in the section on acceptability (section 2.3). Although designing applications according to the needs of patients is a good idea, people who are not willing to use telemonitoring should still not be forced to do so, no matter how user-friendly the applications are. Fortunately, eHealth applications, including telemonitoring, are still delivered in combination with regular, face-to-face care nowadays. This is referred to as blended care.⁵⁷

In summary, telemonitoring's contribution to delivering health care without discrimination is unclear. Risks of exclusion of patients who are computer illiterate or digitally self-excluded exist. Hence, telemonitoring should not be a substitute for a visit to the physician's practice. Those patients who prefer or need to see the health professional in person to measure their health values, should keep this opportunity. If not, the accessibility of health care is at stake.

2.2.2 Physical accessibility

Accessible health care without discrimination is only accessible when it is also physically accessible. According to GC14, health services should be physically accessible to everyone.⁵⁸ At first sight, telemonitoring seems to make a positive contribution to the physical accessibility of health care because a part of the health care provision takes place within the patient's home. This means that travelling to a health care facility is not necessary. This is especially beneficial for patients who experience difficulties in travelling to the health professional's practice and for those who would have to visit their health professional very often, saving both the physician and the patient a lot of time (and perhaps money). In fact everyone, including the patients who do not have mobility-issues or who do not have to travel to their health professional's practice that much, will benefit from an increased physical accessibility. Easily exchanging health data with a health professional over distance, who will only respond when this is needed, results in immediate accessibility at any place and at any time, making all physical barriers to accessing health care lose importance.

55 L. Engelen, 'Brengt 2016 eindelijk een volwassen debat over digital health?', Trendition, *smarthealth.nl* 29 June 2016. Source: smarthealth.nl/trendition/2016/06/29/debat-digital-health-ehealth/.

56 See, for instance Coleman et al. 2010, p. 175-178; cited by Bakx, *RGD Magazine* 2017, issue 2, p. 34-39 and Kokabisaghi, Bakx and Zenelaj, *ELR* 2016, p. 146-160.

57 See, for instance Van Duivenboden 2015, p. 31; Voorham et al., Tsg, 2015, p. 41 and Baardman, *Tsg* 2015, p. 44.

58 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

2.2.3 Affordability

Another condition of accessible health care according to GC14, is that health services should be economically accessible, meaning that they should be affordable for everyone.⁵⁹ Whether telemonitoring can contribute to the affordability of health care depends on two factors. First, telemonitoring itself should be affordable. This means that it should be investigated whether it is reimbursable by health insurance. Second, the effects of telemonitoring on the affordability of the health care process as a whole should be considered. Related to this is the question of whether telemonitoring really results in the cost savings it is expected to. Finally, the implementation costs on both sides should be taken into account before statements on the effects that telemonitoring has on the affordability of health care can be made.⁶⁰

As to the first, the *Nederlandse Zorgautoriteit* [Dutch Healthcare Authority] (NZA), published its *Wegwijzer bekostiging eHealth* [Guide on funding eHealth] in 2020.⁶¹ This guide intends to advise health professionals and health insurers in pointing out whether a certain way of eHealth care provision is reimbursable.⁶² Certain means of eHealth care provision such as e-consultation are reimbursable, while this remains unclear for other types of eHealth.

According to the NZA, eHealth that is applied as the law stands (Wkkgz, WGBO) and in accordance with existing guidelines such as the KNMG Guidelines for dealing with medical data, is reimbursable.⁶³ This means that telemonitoring, in order to be reimbursable, should be applied as the law stands and with respect to professional standards, guidelines and protocols. Now that telemonitoring is usually conducted within an existing relationship for medical treatment based on Article 7:446 BW, this precondition must be met in most instances. The health professional will still review the patient's results, even though they do this over distance instead of in their practice in the presence of the patient. According to the *Wegwijzer bekostiging digitale zorg 2020* [Guide on Funding eHealth 2020], face-to-face contact is not a requirement for health care provision to be reimbursable.⁶⁴ Another difference between telemonitoring and face-to-face health care provision is that contact is only sought when the results indicate a need to do so. A more striking difference with the situation where the patient is monitored in the physician's practice, is who is measuring. During telemonitoring, this is either the patient themselves or the device that is used.⁶⁵ This leads to a change in the way health care is provided. The responsibility is shifted towards the patient. When the way health care is provided changes, the NZA suggests that it should be assessed whether eHealth care provision in this case is a supplement to or a replacement of pre-existing health care

59 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

60 Van Duivenboden 2015, p. 7.

61 NZA 2019, appendix to *Kamerstukken II* 2018/19, 27529, no. 185-892379.

62 *Kamerstukken II* 2018/19, 27529, no. 185.

63 NZA 2019, p. 11.

64 NZA 2019, p. 11.

65 For examples and studies on telemonitoring see Peeters et al. 2013.

provision, in order to know whether this type of eHealth care provision is reimbursable.⁶⁶ Furthermore, the NZa stresses that eHealth care provision is only eligible for coverage by health insurance when this eHealth care provision is based on an existing contract for medical services, based on the WGBO.⁶⁷

With respect to cost savings, an NHG survey shows that GPs are unsure whether eHealth can meet the expectations of costs savings.⁶⁸ Additional research on cost-effectiveness of telemonitoring is recommended. An example of a telemonitoring application that has resulted in cost savings is the Health Buddy, a device that can be used to support patients suffering from chronic heart failure or diabetes.⁶⁹

A positive effect of health care over distance related to cost savings is the lack of travel expenses for patients or health professionals, depending on the situation.⁷⁰ During telemonitoring a patient measures their health values and transfers them to the physician, who in most instances can contact the patient over distance, for example by e-consultation via chat or by means of a video e-consultation. This saves costs on both sides. Moreover, the health professional will save time and costs because they do not have to organise face-to-face consultations with every patient who keeps their health values; they will only see those patients who have irregular values.

Yet, implementation costs can be a barrier to start with telemonitoring. An example mentioned during the *ZonMw-mini-symposium*⁷¹ on eHealth and described in a summary in the *Tijdschrift voor gezondheidswetenschappen* [Journal for Health Sciences] (Tsg) shows that patients sometimes have to purchase the devices they need for the telemonitoring.⁷² However, not everyone is able or willing to pay this. Perhaps the affordability of telemonitoring itself is suboptimal and still leaves room for improvement.

2.2.4 Accessibility of information

According to GC 14, accessible health services are services that include accessibility of information.⁷³ Another expectation of eHealth is that it also contributes to the accessibility

66 NZa 2017, p. 5.

67 NZa 2017, p. 6.

68 Van Duivenboden 2015, p. 7.

69 Vaccaro et al., *Disease Management* 2001, p. 137; Van Rijen, De Lint & Ottes 2002, p. 71-73 and Ploem 2012, p. 116-117.

70 Rauwerda & Krijgsman 2015, p. 11, presenting the advantages of health professional–patient communication by means of video contact.

71 ZonMw is the Netherlands Organisation for Health Research and Development.

72 Van Bodegraven, *Tsg* 2015, p. 61.

73 CESC General Comment no. 14 (2000) on Health, Para. 12(b).

of information.⁷⁴ Telemonitoring is, of course, inextricably linked to information. Telemonitoring makes a positive contribution to the flow of information between the health professional and the patient. Especially when it is linked to a PHR that is shared with a health professional, patients can more easily share information with their physician, who in turn has more information about them. If telemonitoring is carried out by means of wearables, this will contribute to an even more constant flow of data, of course depending on the frequency the information is transferred and how often the health professional interprets these data.

In contrast to these advantages of telemonitoring for the accessibility of information, there is also a downside to this constant flow of data. It is true that telemonitoring leads to more information, but it is important to consider whether telemonitoring always leads to better information as opposed to regular, face-to-face care, where the physician is measuring the patient's health status themselves. During telemonitoring, a device or the patient themselves are taking the measurements instead. When the health professional chooses a device, they can be surer of the quality than in the situation where the patient chooses the device.⁷⁵ For instance, when the patient uses their own smartphone to carry out the self-measurements, in combination with an application that is not accurate for serious medical purposes, this will have effect on the quality of care because of telemonitoring. A 2016 report by the *Nationaal ICT Instituut in de Zorg* [National ICT Institute in Health Care] (Nictiz) and the Netherlands Institute for Health Services Research (NIVEL) shows that patients sometimes list the results of their measurements on paper instead of having them recorded by an application, device, wearable or insideable and then take these results to their next consultation with their health professional to discuss them.⁷⁶ In 2019, the percentage of patients who brought the results of their self-measurements to the health professional was still greater than the percentage of patients who transfer their results to a health professional.⁷⁷ When patients gather the data by themselves and bring them to the physician later, inaccuracies in the data might occur due to the time between measuring and the analysis by the health professional, or due to mistakes in copying the data. In this case, the quality of the information is at stake because of telemonitoring.⁷⁸ In sum, telemonitoring can contribute to increasing the flow of information, if the quality of the information is assessed regularly.

74 See, for instance: 'eHealth: Digital health and care, overview', ec.europa.eu. Source: ec.europa.eu/health/ehealth/home_en.

and COM(2012) 736 final, p. 3 and 5 and, for instance, *Kamerstukken II 2013/14, 27529*, no. 130, p. 1 and 9-10.

75 This leads to interesting questions on the topic of medical liability in case of damage. However, this exceeds the scope of this study.

76 Krijgsman et al. 2016c, p. 39.

77 Wouters et al. 2019f, p. 8.

78 For instance, medical students told me that during their internship, they sometimes see patients who use their own smartwatches for self-measurements and come to the practice because they are worried. Most of these times, the patient can be reassured because not all functions on their smartwatches are as accurate as medical devices.

Second, the question is what the actual contribution of telemonitoring to the accessibility of information is. In the Netherlands, in spite of the expectations of telemonitoring and its potential to improve the flow of information, the actual use of telemonitoring lags behind. The aforementioned report by Nictiz and NIVEL shows that telemonitoring currently does not add much to information-related accessibility in the Netherlands. The monitor shows, for instance, that people who measure their health values do not always share them with their physician.⁷⁹ Digitally transmitting information to a health professional rarely occurs. Nor did people mention that a physician has access to information from a device or an application; 17% of the elderly who were interviewed and only 6% of the chronically ill patients who were interviewed on behalf of this study mentioned that telemonitoring was a part of their treatment.⁸⁰ Because telemonitoring seems not to occur very often (yet), it cannot fulfil its potential to contribute to the flow of information and thus does not contribute to information accessibility; it goes against the positive expectations at this point.

In summary, telemonitoring is all about information and certainly has the potential to contribute to improving the accessibility of information: information is disseminated between the health professional and the patient faster and perhaps more often, too. However, the positive effects are not perceived yet because the use of telemonitoring is lagging behind. Another pitfall of telemonitoring's positive influence on information accessibility is the quality of this information, especially when it is gathered by means of non-professional devices or when the patient is collecting and recording the information manually, which increases the occurrence of errors.

2.3 Acceptability

Perhaps telemonitoring falls short of its expectations because not everyone experiences this type of eHealth care provision as acceptable health care. Acceptability, which is the third condition for health services to realise the right to health,⁸¹ can be a barrier for telemonitoring in achieving its expectations of enhancing health and health care for everyone. According to GC14, acceptable health care provision is divisible in two more specified conditions: acceptable health services respect medical ethics and are culturally acceptable.⁸²

Applied to telemonitoring, this means the following. According to the first precondition of acceptable health care provision, health services should be provided with respect for medical ethics. This means that telemonitoring should be provided as the law stands. In other words, during eHealth care provision by means of telemonitoring, the health professional

79 Krijgsman et al. 2016c, p. 39.

80 Krijgsman et al. 2016c, p. 39-40.

81 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

82 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

should comply with the patients' rights as laid down in the WGBO. Furthermore, they should observe the laws and regulations related to privacy, data protection and dealing with personal medical data, such as the European Commission's GDPR, the Wabv pz and the EU Regulation on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation).⁸³ Moreover, guidelines and protocols by the professional group, such as the KNMG Guidelines for dealing with medical data⁸⁴ must be observed. And finally, the NEN standards, standards for data protection in health care,⁸⁵ should be complied with.⁸⁶ Some of these obligations, for instance following from the WGBO and the KNMG Guidelines for dealing with medical data will be discussed in section 4 and further below. For now, it will suffice to say that acceptable eHealth care provision by means of telemonitoring means that this eHealth care provision should be carried out in accordance with the mentioned regulations, statutes, guidelines and standards. As long as telemonitoring is provided as the law stands, it is acceptable in this respect.

The second part of acceptability, cultural acceptability, will be presented at this point. Culturally acceptable health services are health services that are able to take cultural and social differences into account.⁸⁷ As noted in the previous chapters, eHealth care provision, including telemonitoring, is pre-eminently appropriate to deliver culturally appropriate care; results can be transferred over distance and thus a health professional who shares the same language and/or cultural background can be reached. Moreover, telemonitoring is highly likely to take place asynchronously. This means that time zones are irrelevant. The physician will review the results of the self-measurements when they have the time to do so. For instance, a person who is living abroad can have contact with a health professional who resides in their country of origin and thus receive care in their own language, and within the context of their own culture. Moreover, the recent amendment to the WGBO introduced shared decision-making, which is suitable for health care provision appropriate to a patient's cultural background. In sum, telemonitoring seems to be able to contribute to culturally appropriate health care provision. But here too, several nuances can be made.

The question is whether patients perceive telemonitoring itself as an acceptable type of health care provision. Studies and reports have shown that patients in the Netherlands are not really interested in telemonitoring.⁸⁸ A group of patients in a 2016 study by Nictiz and NIVEL

83 Regulation (EU) 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (*OJEU* 2014, L 257).

84 KNMG Guidelines for dealing with medical data (2020).

85 Art. 1(d) Ministerial Regulation on the use of Citizens' Service Number in Health Care.

86 Art. 2 in conjunction with Art. 1(e) Ministerial Regulation on the use of Citizens' Service Number in Health Care.

87 CESC General Comment no. 14 (2000) on Health, Para. 12(c).

88 For instance Krijgsman et al. 2016c, p. 39-41 and Wouters et al. 2019f, p. 7.

has indicated that they consider measuring their health status as the health professional's task and not their own responsibility.⁸⁹ Others stated that they prefer not to measure and record their health values because it reminds them of their disease or inconvenience.⁹⁰ Others fear that health care provision by means of telemonitoring will make health care impersonal because it decreases the actual contact time with the physician. In 2019, 4 out of 10 patients with a chronic disease reported that they felt telemonitoring might be convenient⁹¹ and 15% of patients who do not conduct self-measurements would like to do this in the future. About 30% of patients do not want to measure health values.⁹² Perhaps people need some time to get used to the idea of telemonitoring and will use it more over time, because people tend to dislike things that are unknown or new to them as opposed to what they already know and are used to. In a study on self-management and eHealth for patients with a chronic disease, for instance, a group of patients indicated that elderly people are in general less familiar with the Internet.⁹³ This can explain why telemonitoring is used so little. Perhaps the user acceptance will grow over the coming years and people will gradually see telemonitoring as acceptable. The computer illiterate and the digitally self-excluded⁹⁴ are more of a concern with regard to acceptance of telemonitoring by patients because these groups are unlikely to consider telemonitoring as acceptable health care provision in the future. The first group is not able to perform the self-measurements needed for telemonitoring, therefore this is not an acceptable way of health care provision to them. The second group will not think of telemonitoring as an acceptable means of health care provision. This should be considered when offering telemonitoring. Fortunately, eHealth is usually offered as part of blended care, i.e. a combination of eHealth and regular, face-to-face care.⁹⁵ Telemonitoring should not be the only option; patients who do not find this an acceptable type of health care provision should not be excluded; other possibilities must be offered to them

Another important point to consider with respect to acceptability of telemonitoring as a means of health care provision, is acceptance by health professionals. For telemonitoring – or any other eHealth application – to be successful, physicians should accept it as a proper means of health care provision. Not only will this lead to them using it, it will also enable health professionals to play a role in breaking the barrier for acceptance by patients. The 2017 eHealth-monitor shows that the acceptance by health professionals overall is higher than the acceptance by patients. For instance, 44–49% of nurses indicate that they think of

89 Krijgsman et al. 2016c, p. 41.

90 Huygens et al., *BMC Health Services Research* 2016, issue 16, no. 232, p. 7 and Wouters et al. 2018, p. 88.

91 Wouters et al. 2019f, p. 9.

92 Wouters et al. 2019f, p. 7.

93 Huygens et al., *BMC Health Services Research* 2016, issue 16, no. 232, p. 8.

94 As explained in section 2.2.1 above.

95 See, for instance Van Duivenboden 2015, p. 31; Voorham et al., *Tsg* 2015, p. 41 and Baardman, *Tsg* 2015, p. 44.

telemonitoring as desirable or even necessary.⁹⁶ In 2019, 58% of nurses in inpatient care and 79% of nurses in general practice reported a positive attitude towards telemonitoring.⁹⁷ In 2017, GPs reported that they see telemonitoring as a desirable tool but yet the actual use of telemonitoring by GPs remained limited.⁹⁸ In 2019, 60% of the interviewed GPs considered telemonitoring useful.⁹⁹ Finally, in 2017 48% of specialists mentioned that they do not think that telemonitoring has any significance and only 11% of medical specialists actually used it at the time.¹⁰⁰ In 2019, one-third of specialists considered telemonitoring useful, for (some of) their patients.¹⁰¹ Hence, health professionals' acceptance seems not to be a barrier for the application of telemonitoring. Perhaps the acceptance of telemonitoring by patients is more of a barrier. It is not the acceptance but the actual use rate that seems to be the problem. Perhaps in the future they can play a greater role in winning acceptance by patients to use telemonitoring.¹⁰²

2.4 Quality

A final important condition for health care provision to contribute to realising the right to health, is quality.¹⁰³ This might be the most problematic for statements from a legal point of view. Quality is pre-eminently a condition that should be measured by means of empirical studies. However, in the previous sections on availability, accessibility and acceptability, several remarks that are also linked to quality have been made.

First, the availability of health care over distance can lead to quality-related problems. Telemonitoring usually takes place over distance, which extends the range over which health care can be delivered.¹⁰⁴ The expanded range can be an impediment to quality at the same time. For instance, when immediate help is required during emergencies and the health professional is too far away. This can be overcome by finding patients who transfer the results of their self-measurements to a physician over (long) distance an emergency contact. This emergency contact should be a health professional who is able to visit the patient when necessary.¹⁰⁵ The patient, in turn, should get the opportunity to visit this health professional when the distance to their own physician cannot be covered on time and face-to-face consultation is necessary at short notice.¹⁰⁶ When patients measure their own health values for telemonitoring, risks related to the quality

96 Wouters et al. 2017, p. 76.

97 Wouters et al. 2019f, p. 9.

98 Wouters et al. 2017, p. 76-77.

99 Wouters et al. 2019f, p. 9.

100 Wouters et al. 2017, p. 77.

101 Wouters et al. 2019f, p. 9.

102 Accordingly, Wouters et al. 2019f, p. 5.

103 CESCR General Comment no. 14 (2000) on Health, Para. 12(d).

104 As explained in section 2.1 above.

105 Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

106 Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

of this information can occur, especially when it is collected and disseminated manually.¹⁰⁷ When the patient enters the results into the system manually, errors might occur. Patients do have the ability to perform self-measurements and they should not be mistrusted or considered unable to conduct these measurements, but physicians should look carefully at the results and recognise incorrect measurements or data that is incorrectly recorded. Typos, for instance, become a risk. These errors can be classified as man-introduced risks; risks that are related to the way people use technology.¹⁰⁸ This concept was coined in a 2013 study by RIVM and Nictiz.¹⁰⁹ Although the study does not seem to include human errors, I think there is reason to do so. In the study, man-introduced risks mainly have to do with digital literacy, general literacy or acceptability. However, even people who possess (digital) literacy and who find ICT an acceptable means for health care provision, can make mistakes while using these means. These kinds of mistakes directly impact on the quality of the health care provision by the health professional, because they depend on the data provided to them by the patient during telemonitoring. Mistakes in the information interfere with the possibility of eHealth care provision of good quality. Obviously, when in doubt contacting the patient is strongly recommended. This must be elaborated in good practice guidelines on telemonitoring. Furthermore, the difference between devices chosen by the patient and devices selected by the health professional should be considered.

Another possibility is that patients conduct self-measurements with their smartphone or with a smartwatch without entering them manually into a system. While these devices can certainly be helpful when a person wants to get insight into their lifestyle, they are not medical devices and not all of the measurements are equally reliable, nor is it always known whether these apps are evidence-based.¹¹⁰ Practice shows, however, that patients do use them and sometimes show their results to their physician who often conducts these measurements again, with a medical device.¹¹¹ For reliable results and data of good quality, it is best that the health professional chooses the device that the patient uses for their measurements. For the quality of those devices, they should comply with the Council Directive Concerning Medical Devices (hereinafter: Medical Devices Directive),¹¹² implemented into the Dutch *Wet op de medische hulpmiddelen* [Medical Devices Act] (Wmh).¹¹³ The directive was replaced by the

107 As briefly addressed in section 2.2.4 on the accessibility of information.

108 Ossebaard & Idzardi 2013, p. 4.

109 Ossebaard & Idzardi 2013.

110 Croonen, *Medisch Contact* 2011, p. 579 and Hooghiemstra & Nouwt, *Computerrecht* 2011/152, p. 9.

111 As I was told by a medical student who experienced this during his internship.

112 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (*OJEU* 1993, L 169), replaced in 2007 by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (*OJEU* 2007, L 247).

113 *Stb.* 2017, 303. Implementation directive: *Stb.* 2008, 391.

European Union Medical Device Regulation of 2017 (MDR).¹¹⁴ The MDR will enter into force on 26 May 2021.^{115,116} In anticipation of the entry into force of the MDR, reference will be made to this regulation. Devices designed to monitor a disease, an injury or a disability fall within the scope of the MDR.¹¹⁷ Hence, when manufacturers develop devices for health professionals to conduct telemonitoring, these devices fall within the scope of the MDR. The regulation sets rules for quality and safety of medical devices and sets rules for awarding a CE certification mark to devices that comply with it;¹¹⁸ different rules apply for different categories of medical devices.¹¹⁹ Health care facilities should play a role in assessing and deciding which medical devices are appropriate for telemonitoring.

Applications that are downloaded and used by patients – for instance on a smartphone or a tablet – without the involvement of a health professional cannot be classified as medical devices under the MDR, because they are not designed for use in health care but for use to monitor a person's condition in general.¹²⁰ The quality of these apps should be assessed another way, such as awarding suitable applications a quality mark. Such quality marks do not exist up to now but until they do, health professionals can use *Medische App Checker* [Medical App Checker] developed by the KNMG.¹²¹ This quality check contains questions which help the physician to assess the quality of the app they or their patient wish to use.

Health professionals and patients should check together whether the application that the patient wishes to use is of good quality. A quality mark might be an indication of the applications quality. In the end, the physician will be responsible when they rely on inappropriate applications without verifying whether this application gives reliable results.

Wearables and insideables pose their own risks in case of failure or defect. It is imaginable that a failure or defect in these devices poses a great risk. For (legal) solutions, investigating the way failure or defects of other medical devices that are implanted in the human body,

114 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (*OJEU* 2017 L 117).

115 Communication from the Commission Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745 (*OJEU* 2020, C 171/01) and Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (*OJEU* 2020, L 130).

116 For more information on the Wmh and the MDR and an elaboration on liability for medical apps, see Sewalt & Lavrijssen, *Computerrecht* 2020, p. 243-249.

117 Art. 2 Para. 1 MDR.

118 Art. 2 Para. 43 MDR, Art. 20 MDR and annex V MDR. In order for a device to obtain a CE certification mark, a conformity assessment procedure has to be carried out first. See Art. 52 et seq. MDR.

119 Annex VIII, Chapter III MDR.

120 Art. 2 Para. 1 MDR.

121 KNMG – Medical App Checker: Evaluation of Mobile Medical Apps 2016.

such as pacemakers, are handled can be an inspiration for the way to handle this issue for wearables and insideables. That being said, for an indication of the quality of the various types of telemonitoring, empirical studies are necessary.

In sum, telemonitoring, despite the positive expectations related to realising the right to health, is not yet fulfilling its potential to do so. It seems that telemonitoring does not yet have the intended effect on the availability of health care. Questions remain as to why the actual use of telemonitoring remains behind. Before telemonitoring can make its contribution to the right to health, several conditions have to be met. Discrimination of groups that cannot or will not use ICT within their personal health care should be avoided. This means that they should either be monitored in another way or they should be taught and convinced to use user-friendly telemonitoring applications. The affordability of telemonitoring as well as the information about the affordability of telemonitoring needs to improve to break the barrier that is caused by uncertainty about the costs. Moreover, attention should be paid to the pitfalls of possible misinformation. Acceptance of telemonitoring seems to be rather low, considering its use rate. This means that information and education about this type of eHealth care provision is needed in order to increase the acceptance by patients and their health care providers. Finally, questions and problems related to quality should be investigated in empirical studies. Only when these conditions are met, can telemonitoring really live up to its potential to enhance patients' right to health care.

That being said, health care delivered against patients' rights is detrimental to health care provision according to the right to health, too. Therefore, the discussion on the applicability of the Dutch patients' rights framework will continue in the next section.

3. THE APPLICABILITY OF THE WGBO TO TELEMONITORING

The first step in considering the effects of telemonitoring on patients' rights laid down in the WGBO and how to conduct telemonitoring according to these rights should therefore be considering whether this Act applies to telemonitoring.

According to Article 7:446 BW, the WGBO applies to medical services contracts, where a natural person turns to a health professional for medical services and the health professional provides these medical services.¹²² This includes cure or prevention of disease or illness as well as examination and everything else a health professional does while providing health care to a specific patient.¹²³ Given the fact that telemonitoring will normally take place in

122 Art. 7:446 Para. 1 BW.

123 Art. 7:446 Para. 2 and 3 BW.

the context of an existing treatment, it can be assumed that a medical services contract based on Article 7:446 BW already exists. Telemonitoring can be used as a means for conducting check-ups between (face-to-face) consultations. Patients or the monitoring devices transfer health values to the physician the patient is seeing because of their illness or disease. In this case, the physician already has a contract for medical services with this patient and the WGBO is applicable.¹²⁴

When considering the text of Article 7:446 Paragraph 2 and the clarification provided in the explanatory memorandum to the WGBO on this legal provision, we can find that a medical services provision includes all actions the physician undertakes to cure a person, to prevent them from falling ill and to assess their health status. These actions must concern an individual person. Moreover, all actions taken in a person's capacity as health professional that are directly related to an individual are considered provision of medical services in the sense of the WGBO.¹²⁵ This person does not necessarily have to be ill.¹²⁶ This means that telemonitoring is medical services provision in the sense of the WGBO. That is to say, during telemonitoring the health status of an individual is assessed by the health professional when they review the data transferred to them. Telemonitoring can also be conducted with (relatively) healthy patients, although it is usually seen as mostly relevant for chronically ill patients.¹²⁷ Since the physician and the patient already have a contract prior to the start of the telemonitoring, telemonitoring can be seen as a continuation of the contract for medical services; medical services provision is continued by means of telemonitoring. So far, this does not seem to differ too much from the situation where a health professional collects and assesses the patient's health status during a regular, face-to-face consultation. There is, however, one striking difference: the distance. The explanatory memorandum to the WGBO explains that direct contact is not required to perform a medical services contract and can include research on material from the patient's body and assessing the results of such an examination.¹²⁸ This resembles telemonitoring in a way because in that situation, the results are assessed when the patient themselves is not present. Although the WGBO and its explanatory memorandum seem to give scope to include health care provision over distance in general and telemonitoring over distance, and the KNMG *Standpunt Niet-aangaan of beëindiging van de geneeskundige behandelingsovereenkomst* [hereinafter: KNMG Viewpoint on not entering into or terminating a contract for medical services] provides an escape clause to declare the WGBO applicable when in doubt,¹²⁹ it is advisable to include a legal provision in Article 7:446 BW that specifically declares the WGBO applicable to health care

124 Art. 7:446 Para. 1 BW, which states that a contract for medical services is formed when a patient asks a health professional for advice and the health professional starts providing this advice.

125 Art. 7:446 Para. 2(a) and Art. 7:446 Para. 2(b).

126 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

127 Wouters et al. 2017, p. 76-78.

128 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

129 KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

over distance. Article 7:446 Paragraph 2 BW, which defines health services provision, is the correct place to do so. A clause that states that health services provision over distance is also considered health care provision as meant in the WGBO would be the appropriate manner.

The equal applicability clause in Article 7:464 BW seems less appropriate for this purpose because this legal provision concerns situations where the patient does not consult a health professional on their own initiative.¹³⁰ Article 7:464 BW also concerns situations where the patient is somehow obliged to do so,¹³¹ contrary to the situation reflected in Article 7:446 BW where the patient contacts a health professional and thus initiates the contract.¹³² Moreover, telemonitoring is not related to any duty nor does it involve a situation where the patient cannot choose their own health care provider because they are unconscious or in a situation where they have restricted freedom, such as detention under a hospital order.¹³³

Another reason to include a legal provision on the applicability of the WGBO on health services provision over distance in Article 7:446 BW instead of assuming this situation falls within the scope of Article 7:464 BW, is that the use of ICT in health care will only increase along with the possibilities to deliver health care over distance. This development is ongoing and unstoppable, while patients' rights should be protected in this changing environment of health care. eHealth care provision such as telemonitoring will be an important branch of health care in the near future and therefore deserves a prominent position in patient's rights legislation: it should be clear from the beginning that eHealth care provision equals health care provision. The fact that it is carried out in a less traditional way does not change this.

Even more so, a specific legal provision that declares the WGBO applicable to eHealth will make it clear for physicians that they, without any doubt, should respect the patient's rights included in this statute, such as (spatial) privacy, medical confidentiality and informed consent.¹³⁴ It is a pity that the legislator does not touch on this in the recent amendment to the WGBO.¹³⁵ The amendment acknowledges that the relationship between health professionals and patients is changing and that documents and data are handled differently compared to

130 Examples of such situations are mentioned in the explanatory memorandum; *Kamerstukken II* 1989/90, 21561, no. 3, p. 46.

131 Stolker & Sombroek-van Doorn, in: *T&C BW* 2019, Art. 7:464 BW, note 1 (online, updated to 1 August 2020).

132 KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

133 *Kamerstukken II* 1989/90, 21561, no. 3, p. 46 and Stolker & Sombroek-van Doorn, in: *T&C BW* 2019, Art. 7:464 BW, note 2 (online, updated to 1 August 2020).

134 Art. 7:459 BW, Art. 7:457 BW and Art. 7:448 BW in conjunction with Art. 7:450 BW respectively.

135 *Stb.* 2019, 224.

the era in which the WGBO was originally developed.¹³⁶ Acknowledging that ICT plays an important role in the health care process is a step in the right direction. Unfortunately, a direct reference to eHealth care provision is not made. The amendment would have been a great opportunity to regulate and enhance patient's rights in this changing way of health care provision.

4. TELEMONITORING AND THE RIGHT TO PRIVACY

4.1 Telemonitoring and informational privacy: introduction

When asking people what they think the legal implications of eHealth care provision are, informational privacy is mentioned almost immediately. Most people assume that a study on eHealth and patients' rights is about privacy, or that privacy at least constitutes a large part of the research. Those people are right.

Privacy is a human right and is as such laid down in countless international human rights treaties and declarations such as Article 12 UDHR, art 17 ICCPR, article 8 ECHR, and Articles 7 and 8 CFREU. The right to informational privacy has a strong connection to processing personal data. Processing personal data and the right to protection of these data is laid down in the GDPR, a European regulation based on Article 8 ECHR, elaborated in the UAVG.¹³⁷ During telemonitoring, personal data are being processed in the sense of this regulation.¹³⁸ This means that the rules stemming from the GDPR apply in the case of telemonitoring. The GDPR classifies medical data as a special category of data, of which processing is in principle not allowed.¹³⁹ An exception can be made, however, in case the data need to be processed for health care provision and the data are being processed by a health care provider who is subject to medical confidentiality.¹⁴⁰ This is the case for telemonitoring since the WGBO applies to this type of eHealth care provision, and the WGBO includes the obligation of medical confidentiality.¹⁴¹ Processing of personal health data, which is

136 See for instance Art. 7:448 Para. 1 BW where a reference to electronic provision of information to comply with the duty to provide information is made and the explanatory memorandum (*Kamerstukken II* 2017/18, 34994, no. 3, p. 24) or the fact that "to documents" is replaced with "the data" at several points to include digital data, such as in Art. 7:455 BW, Art. 7:456 BW, Art. 7:457 Para. 1 and Para. 2 BW, Art. 7:458 Para. 1 BW and Art. 7:464 Para. 2(a) BW (*Kamerstukken II* 2017/18, 34994, no. 3, p. 24-25.)

137 *Stb.* 2018, 144.

138 Art. 4 Para. 1 and Art. 4 para 2 GDPR.

139 Art. 9 Para. 1 GDPR.

140 Art. 9 Para. 2(h) in conjunction with Art. 9 Para. 3 GDPR.

141 Art. 7:457 BW.

processing of sensitive data, must take place with extra care.¹⁴² When using telemonitoring, the health professional also comes across personal data that are not medical data, such as a person's living situation. The GDPR as well as the WGBO apply to these data.¹⁴³ Both these regulations allocate rights to the patient (WGBO) or data subject (GDPR). These rights will be presented below.

4.2 Rights related to informational privacy in the WGBO and the GDPR applied to telemonitoring

Comparable to the WGBO, the GDPR assigns several rights to the data subject, such as the right to access personal data, the right to correction of data and the right to be forgotten.¹⁴⁴ Informational privacy recurs, or plays an important role, in several legal provisions of the WGBO as well. Examples include the obligation for the health professional to keep a medical record, the patients' right to deletion of such a record, the patient's right to access their medical file and the physician's obligation of medical confidentiality.¹⁴⁵

Some of these rights included in the GDPR and the WGBO seem to have a certain level of overlap. For instance, both regulations include the right to access personal data, the right to correction of these data and the right to delete data. Moreover, medical confidentiality is explicitly mentioned as a prerequisite for processing personal medical data in Article 9 Paragraph 2(h) in conjunction with Article 9 Paragraph 3 GDPR. Although some differences in nuance exist between these rights provided in the GDPR and the WGBO, they all have in common that they exist to protect the data subject¹⁴⁶/patient.¹⁴⁷ The GDPR and the WGBO concur in some instances but since the last amendment to the WGBO took the entry into force of the GDPR into account, the concurrence will most likely not lead to many problems in the future.¹⁴⁸

Since the various rights have already been presented in detail in chapter 4, the focus will be directly on the aspects of these rights that are relevant for telemonitoring. First, the health

142 As confirmed in ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*); ECtHR 4 December 2008, ECLI:CE:ECHR:2008:1204JUD003056204, *NJ* 2009/410, m.nt. Alkema (*Marper and S. v. United Kingdom*) and ECtHR 17 July 2008, ECLI:CE:ECHR:2008:0717JUD002051103 (*I. v. Finland*), as cited by Verhey & Raijmakers, *Regelmaat Kwartaalblad voor wetgevingsvraagstukken*, 2013, p. 186. The ECtHR bases its decision on Art. 6 of the Strasbourg Convention.

143 Schalken et al. 2010, p. 144 discuss the Wbp, the Dutch Personal Data Protection Act, replaced by the GDPR. It can be assumed that what has been said will equally apply to the GDPR. About medical confidentiality: Wijne 2017b, p. 256 and the case law cited there, and Buijsen et al. 2012, p. 37 and 81, and the case law cited there.

144 Art. 15, 16 and 17 GDPR.

145 Art. 7:454, 7:455, 7:456 and 7:457 BW respectively.

146 Art. 4 Para. 1 GDPR.

147 Art. 7:446 Para. 1 BW.

148 *Kamerstukken II* 2017/18, 34939, no. 2; *Kamerstukken I* 2017/18, 34939, A and *Stb.* 2018, 247.

professional is obliged to keep a medical record during telemonitoring.¹⁴⁹ This is a part of the performance of the contract for medical services that the physician concluded with their patient. According to Article 7:454 BW the health professional should include the patient's health data along with everything they carry out to provide medical services, and everything else that needs to be included in order to provide the care of a conscientious health care provider. According to the explanatory memorandum to the WGBO this includes, among other things, results of lab tests.¹⁵⁰ During telemonitoring, the physician receives health data. These data and how the health professional responds to them should be included in the medical record because they are data about the patient that are relevant for this treatment. The recent amendment to the WGBO changes the wording of Article 7:454 Paragraph 1. The sentence that says that the health professional has to include everything else that needs to be recorded in order to provide the care of a conscientious health care provider, is replaced by "other data".¹⁵¹ The rationale behind this is that most relevant data are digital nowadays and thus already fit within the scope of the first sentence of the article, which refers to "data concerning the patient's health". According to the legislator, all data concerning the patient belong in the medical record notwithstanding their form.¹⁵² Thus, under the new legislation, data retrieved from telemonitoring is considered "data concerning the patient" as in Article 7:454 Paragraph 1 BW.

Second, patients have a right to access their medical record based on Article 7:456 BW. They also have such a right based on Article 15 GDPR. The right to access in the WGBO is (more or less) an absolute right.¹⁵³ When the patient asks the health professional for access to their medical file, this request should in principle be granted, unless the file contains information about third parties. In that case, access should be provided without that particular information.¹⁵⁴ The GDPR contains a similar regulation.¹⁵⁵ Article 7:456 BW also entails the obligation that the data which the patient has access to, are explained to them.¹⁵⁶ This means that the health professional should explain the health values they received through telemonitoring their patient. It should be noted that the legal provision on the right to access the medical record in relation to telemonitoring is only useful insofar the patient did not see the data for themselves yet. When the patient conducts the measuring of health values manually, then they will already have seen them and do not need to effect their right to access in order to view the data. Simply asking the physician to explain them would be enough. The right to access can be useful when the patient is using an application that directly transfers

149 Art. 7:454 BW.

150 *Kamerstukken II* 1989/90, 21561, no. 3, p. 17 and 34.

151 *Kamerstukken II* 2018/19, 34994, A, p. 2.

152 *Kamerstukken II* 2018/19, 34994, no. 3, p. 24-25.

153 *Kamerstukken II* 1989/90, 21561, no. 3, p. 37.

154 Sluijters & Biesart 2005, p. 97.

155 Art. 15 Para. 4 GDPR.

156 *Kamerstukken II* 1989/90, 21561, no. 3, p. 37 and Sluijters & Biesart 2005, p. 94.

values to the health professional without sending a copy of the results to the patient. Examples include wearables and insideables.

Third, patients have a right to have their medical record deleted based on Article 7:455 BW. A health professional should comply with this request, unless this is prohibited by law or the medical record contains relevant information about third parties that cannot be destroyed. It should be noted that in the current time, in which technology plays a large role, such a right can be difficult to execute. Sharing digital information equals multiplying it.¹⁵⁷ During telemonitoring, the information is not situated in one location to begin with. The patient will have the data themselves no matter what device they use for telemonitoring, or whether the device is a wearable or an insideable that directly transfers information to the health professional. The physician has the information on at least one location, too. Moreover, this information is recorded in the medical record.¹⁵⁸ Even though the record is successfully deleted, the information is perhaps still in the device that is used for monitoring or perhaps it is stored on a device owned by the patient. Moreover, the PHR, if the patient keeps one, has to be taken into account. This is another location where the patient will have to delete the information. This means that when a patient invokes their right to destruction of the medical file, they should take some actions to delete the data they personally gathered, whether intentionally or unintentionally, during telemonitoring as well. The health professional will probably have to delete the information on multiple locations as well, which makes this a very labour-intensive right. Yet it is very much an open question whether this can still be asked of health professionals, apart from the question of whether it is still possible to delete the information entirely. The GDPR also contains a provision on the deletion of personal data, for that matter.¹⁵⁹ This is even referred to as the right to be forgotten. Executing this right, however, will encounter the same problems.

Fourth, data subjects have a right to correction of data based on Article 16 GDPR. The WGBO does not contain such a right for patients. However, in the WGBO the right to add a declaration to the medical record has been granted to the patient in Article 7:454 Paragraph 2 BW. In practice, this means that the patient can give their opinion on the documents in the medical record and have the health professional add that to the medical file. The legislator did not consider a right to correction desirable because, among other things, this might disrupt the relationship between the patient and the physician.¹⁶⁰ In the literature it is stated that this legal provision prevails over the right to correction of personal data as laid down in the Wbp (now GDPR).¹⁶¹ For telemonitoring this will only play a role when the patient is measuring

157 For instance Kleve 2004, p. 193.

158 This is obliged according to Art. 7:454 BW.

159 Art. 17 GDPR.

160 *Kamerstukken II* 1991/92, 21561, no. 11, p. 29.

161 Sluijters & Biesart 2005, p. 76.

their health values on their own, without transferring them to the physician. If they or their device already do that, the information retrieved from telemonitoring will already be included in the medical file because this is part of the health professional's performance of the contract for medical services, and is thus recorded in the medical file according to Article 7:454 Paragraph 1 BW. When the patient is measuring their health values on their own, for instance by means of a smartphone or a smartwatch, these values are not automatically put in the medical file. If the patient wishes so, they should have to ask the physician to incorporate this information in the medical record based on Article 7:454 Paragraph 2 BW. However, regarding the doubts related to the accuracy of such applications, it is questionable whether health professionals will be very enthusiastic about this. A prerequisite of Article 7:454 Paragraph 2 is that the patient can have declarations added to their medical file when this is reasonable.¹⁶² When the health professional is not convinced of the quality of the data the patient presents to them, they can refuse to add them to the professional medical record and suggest (tele)monitoring with a device they trust instead. This patients' right must not conflict with the health professional's obligation to provide the care of a conscientious health care provider.¹⁶³

4.3 Informational privacy and security measures related to telemonitoring

Besides the various rights that are allocated to patients/data subjects, security measures are important for telemonitoring. Disseminating medical data might be more of a practical problem than a legal problem. Rights to protect patients' privacy are ubiquitous. Security of systems, however, is a challenge. Even though sufficient ways exist to protect these systems, hackers and others who mean harm find new ways to break into computer systems.¹⁶⁴ Without being too pessimistic, the section will now proceed with discussing some relevant security measures health care providers and/or individual health professionals can take to prevent violation of patients' privacy.

A lot of trouble can be avoided when using/prescribing appropriate devices to carry out telemonitoring and by protecting the devices that are used along with the data carrier the medical data are transferred to, such as a PC, according to the latest standards for safety and security. An example of such security standards are the NEN standards, good practice guidelines from the field of IT. Their importance for data protection is confirmed by the

162 Sluijters & Biesart 2005, p. 75.

163 Art. 7:453 BW.

164 L. Engelen, 'Brengt 2016 eindelijk een volwassen debat over digital health?', Trendition, *smarthealth.nl* 29 June 2016. Source: smarthealth.nl/trendition/2016/06/29/debat-digital-health-ehelth/.

Supreme Court of the Netherlands.¹⁶⁵ The NEN standards are referred to in Dutch legislation as well.¹⁶⁶ The standards NEN 7510, NEN 7512 and NEN 7513 are relevant for telemonitoring and contain rules on identification and authentication, digital dissemination of information and logging of medical records.¹⁶⁷

The KNMG Guidelines for dealing with medical data mention some general recommendations on digital medical data, referring to the necessary technical and organisational measures to safeguard these data, such as using secured computers.¹⁶⁸ Furthermore, the KNMG makes some recommendations on how to safely transfer data over distance, such as via email. For instance, the health professional should make sure that information is not sent to the wrong person; this will lead to a breach of medical confidentiality.¹⁶⁹ Unfortunately, hands-on practical information on how to deal with informational privacy in specific situations is lacking in the guideline. Moreover, telemonitoring is completely absent in the guideline, which is a missed opportunity in my opinion. When discussing eHealth care provision with physicians, the uncertainty concerning informational privacy is mentioned in almost every case. It turns out that in practice it is not always clear which devices or applications can be used for eHealth care provision without violating informational privacy, and under what circumstances health professionals are allowed to view certain data or to log in to a system containing data about patients without violating informational privacy.

The use of devices in eHealth care provision still has far to go. Within some health care institutions employees are allowed to use their own devices for work, while other organisations distribute devices, such as smartphones, for work-related communication. A certain amount of safety problems can be avoided when telemonitoring is only carried out on devices that are appropriate for that purpose and where the information cannot be mixed with personal information. Health care institutions should take the lead in resolving these problems by developing a uniform privacy policy and taking care of counselling health professionals who work within their institution about informational privacy. This is in line with the GDPR, which puts health care institutions under a similar obligation in Article 28. A first move can be distribution of devices to be used for work and when this is not possible, imposing obligations and restrictions on which applications to use for telemonitoring. Moreover, when health professionals work with their own devices, certain requirements that these devices

165 HR 22 June 2012, ECLI:NL:HR:2012:BW0393 (advisory opinion of Solicitor-General Langemeijer, ECLI:NL:PHR:2012:BW0393), *NJ* 2012/397 (*Knooble/Staat*), Para. 4.10. Even though this case did not relate to health care, but to the construction industry, this judgement is applicable to NEN standards related to health care as well.

166 See for instance, Art. 2 in conjunction with Art. 1(e) Ministerial Regulation on the use of the Citizens' Service Number in Health Care. Even though the regulation refers to NEN7510, NEN7511 and NEN 7512, Nouwt 2012, p. 29 assumes that health care providers should also comply with NEN7513.

167 For an explanation on the NEN standards and what they entail, see Ekker et al. 2013, p. 58-65.

168 KNMG Guidelines for dealing with medical data 2020, p. 23.

169 KNMG Guidelines for dealing with medical data 2020, p. 23.

have to fulfil can be imposed. An example is the possibility to only allow access to work applications when certain settings are active on someone's device, such as only allowing employees to install their work email on their smartphone when the device is secured with a PIN code.

As this section shows, a lot of legislation and rules about informational privacy are imposed on health professionals. Sometimes, however, the leak does not occur on the side of the health professional but on the side of the patient, for instance because the patient is not using a safe and up-to-date device or because they share their personal health information carelessly with other people or even publish it on social media. This can cause some friction. Imposing an obligation on patients to use a safe device that meets the latest security standards can be difficult with respect to the right to health since access to health care is a pivotal requirement of the right to health.¹⁷⁰

Finally, we should realise that the obligation to respect and protect someone else's informational privacy is something everyone has to deal with, especially health professionals. Legislation that imposes people to respect informational privacy should be complied with at any instance, even though the data subject themselves seem not to care too much about it. This means that the information the physician retrieves via telemonitoring should not be made public, not even when the patient will share all of it on social media. Patients cannot be obliged to respect their own privacy, because the degree to which something is experienced as an infringement of the right to privacy is subjective. The only thing a physician can do is explain the risks of publishing the data that is obtained through telemonitoring. The British Computer Society, the Chartered Institute for IT together with the Department of Health in the United Kingdom did a similar thing for residents of the United Kingdom by publishing a document on the Internet about people handling their own medical record.¹⁷¹ It would be appropriate to develop such documents in the Netherlands as well. Moreover, health professionals must discuss this with every patient who wants to be monitored over distance by means of telemonitoring. Patients should be urged to be very careful with the data they retrieve during telemonitoring. Physicians have the responsibility to verify whether the applications are safe and meet the standards for security and protection of personal data.

4.4 Telemonitoring, medical confidentiality and the PHR

Based on Article 7:457 BW, health professionals should not disclose any information about the patient to others, who are not involved in the patient's treatment. This obligation also

170 CESCR General Comment no. 14 (2000) on Health, Para. 12(b).

171 BCS The Chartered Institute for IT/NHS England 2013. On p. 13 sharing the medical record as a patient is discussed.

applies to health care institutions.¹⁷² Since the previous chapters already discussed a lot of implications related to this right, this section will present a topic that is particularly relevant during telemonitoring: the PHR.

Developments such as this can help in allocating more responsibility to patients.¹⁷³ A PHR is a health record kept, written and organised by patients themselves. Often, developments such as the PHR are seen as tools to transfer the ownership of their own health care process to patients.¹⁷⁴ A PHR cannot be considered a medical record for it can be incomplete or subjective. Medical records are kept by health professionals based on Article 7:454 Paragraph 1 BW. Patients can provide health professionals with access to their PHR or they can download and save health professionals' medical files (in part) into the PHR.¹⁷⁵ The PHR is managed by the patient themselves and even though the patient can grant their physician access to the PHR, it is not a replacement of a health professional's medical file. The health professional's medical record has the purpose of providing health care of good quality; the medical file contains information that can be consulted by physicians during the treatment. Moreover, in case of damages, the health professional can prove and explain what they have done and why.¹⁷⁶ A PHR, on the other hand, is a tool intended for patients to enable them to gather their health information at one central point.¹⁷⁷ A PHR can thus only serve as a supplement to the regular medical file and not as a replacement.

Patients can use a PHR for telemonitoring, for instance when they conduct self-measurements and manually insert them in the PHR. They can opt to share this data with one or more health professionals, who can then monitor the patient over distance. The patient can have their physician add information from the PHR to the medical record based on Article 7:454 Paragraph 2 BW.

Consequently, a PHR can contain a large amount of important health data. Since the PHR is managed by the patient and not by a physician, it is not protected by an obligation of medical confidentiality following from Article 7:457 BW or Article 88 BIG Act. This means that the data are not protected by legislation when third parties request them.¹⁷⁸ Therefore,

172 Based on Art. 7:446 Para. 1 BW which states that legal persons where health care is provided are also considered health care providers under the WGBO.

173 Hooghiemstra & Ippel 2011, p. 14.

174 Haan et al. 2017, p. 8. Both patients (Haan et al. 2017, p. 12) and health professionals (Haan et al. 2017, p. 14 and 15) acknowledge this.

175 Hooghiemstra & Ippel 2011, p. 14.

176 Hooghiemstra & Ippel 2011, p. 14 and Asser/Tjong Tin Tai 7-IV 2018/427 and Asser/Tjong Tin Tai 7-IV 2018/453.

177 Hooghiemstra & Ippel 2011, p. 14.

178 Examples include investigative services, insurers, financial institutions, ICT companies and other parties who might want to obtain patients' medical data, from accessing the medical record; see Hooghiemstra & Ippel 2011, p. 16 and RVZ 2014, p. 33.

the *Raad voor Volksgezondheid en Samenleving* [Council for Health and Society] (RVS) and the *Centrum voor ethiek en gezondheid* [The Netherlands Centre for Ethics and Health] (CEG) proposed a right to patient confidentiality, to give patients the right to refuse to share their data.¹⁷⁹ The Minister for Healthcare reacted to this idea by stating that although understandable, implementing patient confidentiality is not necessary because existing statutes and regulations provide sufficient protection.¹⁸⁰ It is true that medical confidentiality and patients' informational privacy are protected in various laws and regulations; medical confidentiality is protected in Article 7:457 BW, Article 88 BIG Act and Article 272 Sr. Article 218 Sv provides health professionals with a right to refuse to testify about information collected during health care provision. Others who work in the health professional's practice or department have an obligation of medical confidentiality derived from the health professional's own obligation.¹⁸¹ The obligation of medical confidentiality should be extended to IT workers hired externally as well.¹⁸² The GDPR protects patients' privacy by imposing strict rules on processors of personal data, including medical data. PGOs that comply with safety and security standards will receive a *Medmij-label*.¹⁸³ This means that information recorded in a PGO will be sufficiently protected as well.¹⁸⁴ However, none of these statutes and regulations apply to the patient themselves, and thus existing statutes and regulations do not provide sufficient protection. Therefore, an additional right of patient confidentiality, in the form of a right to refuse to provide medical data to third parties is needed, especially since the patient who uses telemonitoring or other types of eHealth will have more of their own medical data at their disposal as opposed to the years when eHealth had not yet emerged.¹⁸⁵ For as long as such a right does not exist, it is the duty of health professionals to inform their patients about their rights related to the PHR and to warn them not to share it too easily. Providing a *Medmij-label* to PGO with adequate safety standards leads to a digital environment where the same rules apply to everyone.¹⁸⁶ This is a good tool to use for PHRs and telemonitoring, and it can be a starting point for uniform rules related to eHealth care provision, including telemonitoring, the right to medical confidentiality and other patients' rights.

179 Hooghiemstra & Ippel 2011, p. 16; RVZ 2014, p. 33 and Patiëntenfederatie Nederland 2019.

180 *Kamerstukken II* 2019/20, 27529, no. 190.

181 *Kamerstukken II* 1989/90, 21651, no. 6, p. 39.

182 As stated in chapters 4 and 5.

183 'Persoonlijke gezondheidsomgevingen', medmij.nl. Source: medmij.nl/pgo/ and Hendriks, *NJB* 2019, p. 1110.

184 *Kamerstukken II* 2019/20, 27529, no. 190, p. 3.

185 Accordingly Patiëntenfederatie Nederland, 2019, p. 3.

186 'Persoonlijke gezondheidsomgevingen', medmij.nl. Source: medmij.nl/pgo/.

4.5 Telemonitoring, medical confidentiality and third parties

During telemonitoring, involving other parties is inevitable. This is inherent to the nature of eHealth care provision. It can be the case that the device that is used for telemonitoring is operated by a third party who is external.¹⁸⁷ It can also be the case that the devices that are used for telemonitoring are operated by the ICT department of the health care facility. Either way, third parties get to see the patient's data and these data should be protected under the obligation of medical confidentiality. In academia, it is recommended that patients should be informed and give their explicit consent about who has (or who can have) access to their data.¹⁸⁸ While I agree with this suggestion, I would like to add that the obligation of medical confidentiality should be extended to third parties.¹⁸⁹

The explanatory memorandum to the WGBO shows that the health professional can share information about the patient with people whose help is necessary for the performance of the contract for medical services, insofar as they need this information to carry out their jobs.¹⁹⁰ In academia, a derivative obligation of medical confidentiality for these people is derived from this comment.¹⁹¹ If these people are not subject to an obligation of medical confidentiality based on Article 7:457 BW (they do not, because they are not a party to the contract for medical services) or Article 88 BIG Act, they have a derivative obligation of medical confidentiality, i.e. their obligation is based on the health professional's obligation of medical confidentiality. By using the legislative history as the basis for interpretation, we can see that the legislator meant to include assistants, who are not health professionals and rather support the health care provision than conduct the health care provision, as people who are subject to a derivative obligation of medical confidentiality.¹⁹² ICT workers are at a greater distance from the health professional, and they may not even be at the same location. However, their work is essential for telemonitoring: without ICT professionals such applications cannot be installed and cannot be maintained or repaired in case of defects. Ploem rightly points out that telemonitoring cannot take place without involving ICT professionals.¹⁹³ Consequently, ICT workers should have a derivative obligation of medical confidentiality. The patient can be informed about this accordingly. This is consistent with the KNMG Guidelines for online Physician–Patient Contact 2007, where a derivative obligation of medical confidentiality for others within the health care facility, including ICT professionals, was recommended.¹⁹⁴

187 Ploem 2012, p. 123.

188 Ploem 2012, p. 123.

189 As I also recommended in chapter 4 on e-consultation.

190 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

191 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

192 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

193 Ploem 2012, p. 122.

194 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, p. 11. The guideline is now incorporated in the Guidelines for dealing with medical data 2020 but these guidelines do not contain this recommendation. I would advise that it does, though.

In chapter 4 I suggested that this should also be extended to ICT workers who are hired externally. This also applies to ICT professionals involved in telemonitoring. Again, it is a pity that the recent amendment to the WGBO does not pay attention to eHealth care provision in the amendment to Article 7:457 BW on medical confidentiality. Besides the fact that the word 'documents' is changed into 'data' to acknowledge that these data can also be digital, no attention is paid to health care provision by means of ICT.¹⁹⁵ In the digital era, in which more health data circulate at multiple places and the chance for personal data breaches is maybe bigger than ever, it is surprising that the legislator does not pay attention to this while regulating the obligation of medical confidentiality. It would have been better if a provision that reminds parties that the obligation of medical confidentiality applies online as well was added, along with a change in paragraph 2 that clearly states that individuals whose assistance is necessary to perform the contract for medical services are subject to a derivative obligation of medical confidentiality, even if they are located at a distance.¹⁹⁶

Finally, it is recommended to agree on this in the contracts the health care provider concludes with both internally employed and externally hired ICT workers.¹⁹⁷ There is a need to emphasise this because ICT professionals are relatively remote from the actual health care provision and therefore it might be harder for them to realise exactly what the obligations are derived from the duty of the derivative obligation of medical confidentiality.¹⁹⁸

5. SPATIAL PRIVACY

Spatial privacy means that the contract for medical services should be carried out without the presence of others, unless the patient gives their explicit consent for those third parties to overhear or oversee the performance of the contract concerning medical services.¹⁹⁹ Reviewing medical data retrieved during telemonitoring is a part of the performance of the contract for medical services, so the right to spatial privacy applies in this case.

Telemonitoring is suitable to protect the right to spatial privacy. Patients can carry out the measurements at home and at a time they choose for themselves, so they can pick a time when they cannot be disturbed. Problems arise when patients are not alone at home and the physician is unable to defend their right to spatial privacy over distance. When devices such as wearables and insideables are used, this will not be a problem because these devices

195 *Kamerstukken II* 2018/19, 34994, A, p. 2-3.

196 The KNMG Rules of Conduct for Physicians oblige health professionals to inform their support staff of their derivative obligation of medical confidentiality: KNMG Rules of Conduct for Physicians 2013, Para. II.15, p. 4.

197 Schalken et al. 2010, p. 121.

198 Duijst 2012, p. 22.

199 Art. 7:459 BW.

transfer the information unseen. This will perhaps only be a problem when the patient has to put the information into a system manually or when the device sends the information to a computer and the patient has to forward an email with the data. The physician should inform the patient about this right.²⁰⁰ Moreover, they should advise the patient to avoid using shared computers for telemonitoring as much as possible. During telemonitoring, it can occur that people other than the health professional and the patient can view the information, such as ICT workers. Patients should be informed about this potential breach of spatial privacy that is intrinsic to the nature of telemonitoring.²⁰¹

Health professionals have to realise that the right to spatial privacy also applies to telemonitoring. They have to adopt measures to protect this right, as is the case for e-consultation and other situations where patients' data is visible in their practice. This means, among other things, that they should lock their computer when they are not behind their desk and that they do not let others read along when they receive health data through telemonitoring. Third parties viewing the process of reviewing health data, third parties viewing the patient's health values in the physicians practice also relate to the obligation of medial confidentiality, which will be presented in the following section.

6. TELEMONITORING AND THE RIGHT TO INFORMED CONSENT

The last patients' right to be presented in relation to telemonitoring is the right to informed consent, consisting of the right to information (Article 7:448 BW) and the right to give consent (art. 7:450 BW).

When the patient and the physician start with telemonitoring, prior consent is necessary. This means that the health professional has to provide information before this type of eHealth care provision can start. Based on article 7:448 BW, this should be information about the treatment and the developments of this treatment, and the patient's health. Moreover, the patient must be informed about the nature and the aim of the treatment, the health risks for the patient when this method of treatment is applied, alternative treatment and the prospects of the patient's health in relation to the treatment.²⁰² Thus, the physician should inform the patient that they want to monitor over distance about the nature of telemonitoring. Information on the nature of telemonitoring must include the fact that it can be quite invasive in somebody's private life. Telemonitoring entails following someone all the time, after all. Furthermore, information has to be provided as to why the health professional thinks that monitoring is necessary. The explanatory memorandum adds to this that the patient should be informed at

200 Accordingly, Ploem 2012, p. 122.

201 Ploem 2012, p. 122.

202 Art. 7:448 Para. 2 BW.

any time that their situation changes.²⁰³ This means that, when the physician notes important changes in the data that they received through telemonitoring, they should notify the patient and inform them about the actions they, as a health professional, can take together with the patient to improve this patient's health.

In scholarly literature, additional suggestions about the provision of information are given. For instance, it is stressed that information about the nature of telemonitoring includes the fact that medical data are going to be processed for the purposes of the GDPR, especially because more actors are involved during telemonitoring than during a regular assessment of the patient's health in a face-to-face consultation.²⁰⁴ Information about who these actors are should be provided. At the same time, patients must be notified of the more proactive attitude they are expected to adopt during telemonitoring.²⁰⁵ Telemonitoring can require certain actions from the patient, varying from manually measuring and/or recording their health status to answering questions or measuring health values which are transferred automatically. Another suggestion is that the patient should be informed about the working of the telemonitoring application or device and the risks related to its use²⁰⁶ as well as the (health) risks of forgetting or neglecting to conduct self-measurements. Besides being informed about the risks of eHealth care provision, patients should also be informed about its benefits.²⁰⁷ Moreover, it is stated that patients should be informed about alternative telemonitoring applications and whether using those are reimbursable.²⁰⁸ Furthermore, patients should be told how and when they can pose questions about the use of telemonitoring and they must have opportunities to lodge a complaint about the telemonitoring. Finally, patients should be told what to do and who to turn to in emergencies.²⁰⁹ The suggested principles of professional ethics for the online provision of mental health services by the ISMHO and PSI recommend a local backup when the health professional who is providing health care over distance is too far away from the patient.²¹⁰

As a second part of the right to informed consent, the patient has to give their consent for the telemonitoring based on the information discussed.²¹¹ Because it is likely that the patient and the physician discuss the use of telemonitoring during a face-to-face consultation, the health professional is able to assess the patient's ability to consent; contrary to e-consultation, where a patient and a physician can have their first encounter online. Article 7:450 Paragraph

203 *Kamerstukken II* 1989/90, 21561, no. 3, p. 11.

204 Callens & Cierkens 2012, p. 134-135 and Ploem 2012, p. 119.

205 Ploem 2012, p. 119.

206 Ploem 2012, p. 119.

207 Art. 3(a) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

208 Ploem 2012, p. 119.

209 Ploem 2012, p. 119 and Art. 3(a) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

210 Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

211 Art. 7:450 BW.

1 applies to this situation: telemonitoring is an activity carried out to perform the contract for medical services, for which explicit consent is required.

The recent amendment to the WGBO changed Article 7:448 BW and endorses shared decision-making by stating that the physician informs the patient in a way that is understandable to this patient. Instead of proposing treatment, the new Article 7:448 BW urges the physician to confer with the patient, i.e. shared decision-making. Furthermore, the health professional must ask the patient if they wish to receive the information in writing, electronically or otherwise.²¹² This proposal fits into the picture of eHealth care provision, of which shared decision-making is also an important pillar. Moreover, this proposal can help in improving the acceptability of health care²¹³ because shared decision-making is ideally suited to adjust the health care to the situation and the needs of the patient related to their perception of their environment, their abilities and cultural background.²¹⁴ According to the explanatory memorandum, shared decision-making is a means to decrease the information inequality between the health professional and the patient.²¹⁵ I would like to add that, in the case of telemonitoring, the physician must verify whether the patient has understood the risks relating to invasion of privacy. Even though the patient is at their home, telemonitoring is there all the time. This results in an invasion of their private life. Moreover, risks related to privacy exist when medical data is processed over distance. In addition, telemonitoring, as said before, requires a proactive patient. The patient should understand this, agree to this and be able to do this. It is important that the patient understands that they give up some of their privacy and that an active stance is expected of them.

Finally, the explanatory memorandum states that the physician should keep informing the patient when the prospects of the treatment or the actions that need to be taken by the health professional change. Together they should decide what is the best way to proceed with the treatment, considering the patient's individual situation.²¹⁶ During telemonitoring, this should happen at any time the results indicate that the health professional should take action.

212 *Kamerstukken II* 2018/19, 34994, A, p. 1-2.

213 CESCR General Comment no. 14 (2000) on Health, Para. 12(c).

214 *Kamerstukken II* 2018/19, 34994, no. 3, p. 5.

215 *Kamerstukken II* 2018/19, 34994, no. 3, p. 6.

216 *Kamerstukken II* 2018/19, 34994, no. 3, p. 4.

Part III

Conclusion

7





Concluding remarks on eHealth and patients' rights

1. INTRODUCTION

This final chapter will provide an answer to the central question of this study:

How should patients' rights be applied in eHealth care provision and what are the challenges in this respect?

This will be done by formulating answers to the subquestions (section 2). Subquestions IV and V will be presented in the order of the chapters. After subquestion III, answers will be given to subquestions IV and V with respect to e-consultation. Thereafter, the same will be done for tele-expertise and telemonitoring respectively. Next, recommendations will be made (section 3) and to conclude recommendations for future study will be made (section 4).

2. ANSWERS TO THE SUBQUESTIONS

What is eHealth, what kinds of eHealth exist and how can they be categorised?

To answer this question, chapter 2 first started to review some definitions of eHealth coined by various actors, such as the WHO on the international level, the European Commission on the European level and the KNMG and the RVZ on the Dutch national level. Some definitions proposed in academia were mentioned as well. These definitions all included ICT but varied in terms of the purpose of eHealth: is it a means to improve health or health care, or is it only used to support health care provision? Moreover, definitions varied as to whether eHealth is used for health care provision or for health in general. Consequently, some definitions were broader than others. The following definition of eHealth was chosen: eHealth is the use of modern information and communication technology to support and improve health and health care.¹ Because this definition is still rather broad, some further explanation is required. eHealth is supposed to improve health, according to its definition. Therefore, an answer was sought to the question as to what health is. As a starting point, the only authorised definition of health from 1946 until nowadays was presented, the definition coined by the WHO: "Health is a state of complete physical, mental and social well-being

1 Building on the definitions formulated by WHO, KNMG and RVS. WHO 2011, p. vi; COM(2012)736 final, p. 3; 'eHealth', knmg.nl. Source: knmg.nl/advies-richtlijnen/dossiers/ehealth.htm and RVZ 2002, p. 13.

and not merely the absence of disease.”² This definition, known as the broad well-being definition, is criticised in academia. However, no new definition has been agreed upon so far. Various new definitions have been proposed. These varied from very narrow (“health is a state of physical well-being”³) to comprehensive (“one’s ability to fulfill one’s goals”⁴). Another definition that was presented in chapter 2 is the definition coined by Huber et al. in 2014: “The ability to adapt and to selfmanage, in the face of social, physical and emotional challenges.”⁵ This study chose to endorse the broad well-being definition of health because a narrow definition, purely describing an objective medical condition (so-called small health⁶) would not reflect other elements that are relevant for a person in order to feel healthy, such as a general feeling of well-being. The definition of health that states that health is “one’s ability to fulfill one’s goals” is perceived as too broad, because it might result in a view that health is an individual’s responsibility and a quality that can always be achieved by individuals as long as they possess certain skills. The definition by Huber et al. reflects developments in society and in health care, and suits eHealth because eHealth includes self-management and a patient with a more active role in their own health care process.⁷ This definition, however, also seems to view health as an ability that can be acquired if only a person tries hard enough. This is just not always a choice. Of course eHealth can help in dealing with chronic conditions, for instance, and can help the person to manage their health care process but this does not make them healthy; not even when their disease is bothering them very little. Therefore, the WHO’s broad well-being definition has been chosen as the definition of health for the purpose of this study. It includes the elements that are important for health: physical health, mental health and general well-being. This definition does justice to the fact that health is a human right by acknowledging that being healthy entails more than just not being ill.

Next, ICT was discussed. ICT, short for information and communication technologies, are

“technologies that are used for collecting, saving, editing, processing and transmitting information in various forms, such as data, images and sound.”⁸

2 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth, and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively. *Basic Documents*, Forty-fifth edition, Supplement, October 2006. The definition has not been amended since 1948.

3 Callahan, *The Hastings Center Studies* 1973, issue 3, p. 87.

4 Nordenfelt 1995, p. 88.

5 Huber et al., *BMJ* 2011, p. 237; also published as chapter 3 in Huber 2014. Definition coined in chapter 4 of Huber 2014, p. 57.

6 Van Spijk, *Med, Health Care and Philos* 2015, p. 246 referring to Nietzsche.

7 COM(2012) 736 final, p. 5.

8 SER 1996, p. 17.

Chapter 2 showed that eHealth has a longer history than might be expected in the first instance. It was shown that health care over distance began to develop when communication over distance became possible; it started in approximately the mid-nineteenth century.⁹ However, nowadays eHealth is associated with the use of modern information and communication technologies. Therefore, communication over the telephone cannot be classified as eHealth. The terms telemedicine and telehealth are often used as concepts that are interchangeable with the concept eHealth. This is not necessarily the case. Chapter 2 explained that eHealth is the most extensive of these concepts. Telemedicine mainly refers to health care provision over distance,¹⁰ whereas telehealth also includes public health.¹¹ eHealth, as the broadest concept, includes both telemedicine and telehealth as well as prevention and lifestyle advice. Also, not all kinds of eHealth require the involvement of a health professional.

Because eHealth is “best defined how it is used”¹² the chapter divided eHealth into subcategories according to the RVS. First, a distinction was made between professional eHealth and consumer eHealth. Professional eHealth includes all types of eHealth during which a health professional is involved, such as online consultation between patients and physicians, or keeping and sharing an electronic patient record within health care institutions. Consumer eHealth, on the other hand, refers to eHealth without the involvement of a health professional; this is the type of eHealth that is directly aimed at the patient by the manufacturer.¹³ Professional eHealth can be divided into three subcategories. These are: eHealth care provision, which refers to eHealth that directly takes place in the health care provision and relates to the care for a particular patient; e-care support, which includes eHealth applications that are not health care in themselves but aim to support health care provision, such as the electronic medical record; and e-Public Health, which is more related to monitoring, prevention and education of the population.¹⁴ Three types of eHealth care provision were central to this study. The first is e-consultation, online consultation between a patient and a health professional. This can take place synchronously or asynchronously, by (video)chat or email.¹⁵ The second is tele-expertise. Tele-expertise is a consultation over distance between two health professionals about the treatment of a particular patient. This

9 Examples are *South Australian Advertiser* 24 February 1874, as cited by Eikelboom 2012, p. 71 and Zundel, *Bull Med Libr Assoc* 1996, p. 72.

10 See WHO Group Consultation on Health Telematics 1998, p. 10; COM(2008) 689 final; Fatehi & Wootton, *Journal of Telemedicine and Telecare* 2012, p. 460 and Delzell, *Lermagazine* April 2012. Source: lermagazine.com/article/telemedicine-technology-propels-diabetic-foot-care.

11 See TeleSCoPE Project, European Code of Practice for Telehealth Services 2014, Part C: Glossary of definitions, p. 14 and Moore, *Future Generation Computer Systems* 1999, p. 245.

12 Part of a citation by Eysenbach, *J Med Internet Res* 2001, issue 2, available at: jmir.org/2001/2/e20/

13 RVZ 2015a, p. 19 and 20 and RVZ 2015b, p. 12.

14 RVZ 2002, p. 16-18.

15 For instance Van Meersbergen 2012, p. 99-100 and Timmer 2011, p. 77-78.

can include transferring patient information or a photo.¹⁶ The last type of eHealth care provision that is discussed in this study, is telemonitoring. This is a type of eHealth care provision during which a health professional monitors a patient over distance. The patient is conducting self-measurements and transfers those to the physician, or the patient is has a wearable or insideable that does this for them. The health professional only responds when the results indicate that they should do so.¹⁷

What are the right to health, the right to privacy, the right to medical confidentiality and the right to informed consent, where can they be found in legislation and what do they aim to protect?

The right to health is laid down in various national and international treaties and regulations, such as Article 22 Paragraph 1 GW, Article 35 CFREU and Article 11 RESC. The most important provision that includes the right to health is Article 12 ICESCR. In this treaty provision the right to health is described as “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.¹⁸ This does not entail a right to be healthy;¹⁹ hence the formulation “highest attainable standard of health”. The right to health should be progressively realised²⁰ which means that states should take measures to improve it steadily. Retrogressive measures are not allowed.²¹ The CESCR explained what the content of the right to health is in its General Comment no. 14.²² General Comments of the UN bodies are not legally binding, but are usually considered authoritative explanations of the human rights in the UN treaties.²³ General Comment no. 14 lists four elements that are essential in the realisation of the right to health according to the CESCR. These are availability, accessibility, acceptability and quality. Together, these elements are called the AAAQ framework.²⁴ This study used the AAAQ framework in order to determine whether eHealth care provision has the potential to contribute to the realisation of the right to health.

The right to informational privacy can be found in various treaties, regulations and statutes. Examples include Article 12 UDHR, Article 17 ICCPR, Article 8 ECHR and Articles 7 and

16 Although in literature this is often referred to as ‘teleconsultation’. See Krijgsman et al. 2014, p. 124 and Van der Heijden & Schepers, *Bijblijven* 2011, issue 8, p. 8. For this study, however, the term ‘tele-expertise’ was chosen, to avoid confusion with e-consultation.

17 Beuscart et al. 2014, p. 411-412.

18 Art. 12 Para. 1 ICESCR.

19 WHO & OHCHR 2008, p. 5.

20 Art. 2 paragraph 1 ICESCR.

21 CESCR General Comment no. 3 (1990) on the Nature of States Parties’ Obligations, Para. 9, CESCR General Comment no. 13 (1999) on the Right to Education, Para. 45; CESCR General Comment no. 14 (2000) on Health, Para. 32.

22 CESCR General Comment no. 14 (2000) on Health.

23 For example general comments on the Convention on the Rights of the Child (CRC) are regarded as authoritative in the advisory opinion of Solicitor-General Spronken, ECLI:NL:PHR:2015:1295, on HR 30 June 2015, ECLI:NL:2015:2465, *NJ* 2016/40, m.nt. Mevis.

24 CESCR General Comment no. 14 (2000) on Health, Para. 12.

8 CFREU. The GDPR, the European regulation that replaced the Wbp, is important in this respect. The GDPR is based on Article 8 ECHR and aims to protect people's personal data by regulating when, how and by who personal data are allowed to be processed. During eHealth care provision, personal medical data are processed. Because these are health data, extra care is required²⁵ since personal health data are a special category of data.²⁶

The rights to spatial privacy, medical confidentiality and informed consent can be found in the WGBO, where the majority of the Dutch patients' rights are laid down. The WGBO was drafted to protect patients in the unequal relationship with health professionals.²⁷ The right to spatial privacy is an aspect of the right to privacy²⁸ that relates to the right to receive medical treatment without anyone else present.²⁹ The right to medical confidentiality means that physicians are not allowed to provide others with information about the patient. This includes the medical record, the consultation and everything else the health professional comes to know about the patient while performing a medical treatment.³⁰ At first sight, this right also seems to protect informational privacy. This is true, however medical confidentiality aims to protect another human right as well: the fundamental right for everyone of access to health care.³¹ The right to informed consent is based on the right to mental and physical inviolability of the human body.³² The patient can only undergo treatment when they have given their explicit consent to this treatment.³³ They can only give their consent based on information given by the health professional.³⁴ This right is based on the fundamental right of physical and mental integrity.³⁵ In order to be able to give their consent, the patient must fully understand the information. The physician must confer with the patient; this process is referred to as shared decision-making and is expected to help patients in making better decisions.³⁶ Since these rights are all based on fundamental human rights, it is important that

25 As confirmed in ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*); ECtHR 17 July 2008, ECLI:CE:ECHR:2008:0717JUD002051103 (*I. v. Finland*) and ECtHR 4 December 2008, ECLI:CE:ECHR:2008:1204JUD003056204, *NJ* 2009/410, m.nt. Alkema (*Marper and S. v. United Kingdom*), as cited by Verhey & Raijmakers, *Regelmaat Kwartaalblad voor wetgevingsvraagstukken*, 2013, p. 186. The ECtHR bases its decision on Art. 6 of the Strasbourg Convention. See also Schalken et al. 2010, p. 144. Schalken et al. discuss the Wbp, the Dutch Personal Data Protection Act, replaced by the GDPR. It can be assumed that what has been said equally applies to the GDPR.

26 Art. 9 Para. 1 GDPR.

27 *Kamerstukken II* 1989/90, 21561, no. 3, p. 5-7.

28 Art. 10 GW. *Kamerstukken II* 1989/90, 21561, no. 3, p. 16-17.

29 Art. 7:459 BW.

30 Buijsen et al. 2012, p. 37 and 81; Leenen/Dute & Legemaate (eds.) 2017, p. 153 and Wijne, in: *GS Bijzondere overeenkomsten*, Art. 7:457 BW, note 4 (online, updated to 17 June 2020).

31 HR 21 April 1913, *NJ* 1913, p. 958; Buijsen et al. 2012, p. 25 and Leenen/Dute & Legemaate (eds.) 2017, p. 151.

32 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

33 Art. 7:450 BW.

34 Art. 7:448 BW.

35 Art. 11 GW. *Kamerstukken II* 1989/90, 21561, no. 3, p. 12 and the case law cited there.

36 *Kamerstukken II* 2017/18, 34994, no. 3, p. 3.

they are protected and that they remain protected during eHealth care provision. That is what this study investigated in the following research questions.

Considering the many expectations that exist about eHealth, to what extent can e-consultation, tele-expertise and telemonitoring live up to these expectations by contributing to the realisation of the right to health according to the AAAQ framework?

Availability

Because eHealth care provision is independent from time and place, e-consultation, tele-expertise and telemonitoring can make a positive contribution to the availability of health services, even within underserved areas.³⁷ Because e-consultation can be carried out anonymously, health care provision can be made available for a group of patients who would otherwise avoid seeking health care.³⁸ Tele-expertise enables contact with a specialist without the need for patients to travel. This means that the availability of the health services provided by these professionals increases. Studies showed a decrease in referrals because of tele-expertise,³⁹ which in turn expands the availability of face-to-face health care provision by these specialists for those who really need it.⁴⁰ As for telemonitoring, patients do not have to wait until their health values are measured by a physician nor do they have to wait for the consultation to get the results. The independence of time and place enables health care within the patient's private sphere, resulting in them being able to live on their own for a longer time.⁴¹

In order for e-consultation and telemonitoring to really fulfil their potential of contributing to the availability of health services, their actual application still has to grow. The eHealth-monitor shows that the use of these types of eHealth care provision, although slightly increased over the years, still is lagging behind.⁴²

Accessibility

E-consultation also seems to be able to make a positive contribution to the accessibility of health services without discrimination. This is mainly because e-consultation can at

37 COM(2010) 603 final, p. 8 and 9; SWD(2012) 414 final, p. 3; Van der Meer & Nouwt 2011, p. 295 and Beuscart et al. 2014, p. 415.

38 Art. 70a Zvw, elaborated in chapter 6, Para. 2 of the Health Insurance Regulation.

39 Van der Heijden & Witkamp, *NTvDV* 2013, p. 539 and the earlier study conducted by Van der Heijden et al., *NtVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

40 One of the purposes of the use of teledermatology was, among other things, to shorten waiting lists: Du Moulin et al., *Nederlands Tijdschrift voor Dermatologie en Venereologie* 2005, p. 155. Teledermatology is also mentioned in combination with the Dutch GP's function of gatekeepers: Van der Heijden et al., *NtVG* 2012, issue 4, p. 2, published before as Van der Heijden et al., *BJD* 2011, p. 1059.

41 *Kamerstukken II* 2013/14, 27529, no. 130, p. 11.

42 Wouters et al. 2019a, p. 21; Wouters et al. 2019b, p. 8-9; Wouters et al 2019f, p. 7 and Wouters et al. 2019c, table 2.27 and 2.28, p. 28.

times take place anonymously and can help patients who fear discrimination and would otherwise avoid seeking help.⁴³ On the other hand, attention should be paid to ensuring that e-consultation and telemonitoring do not pave the way towards discrimination instead. The computer illiterate and the digitally self-excluded are not likely to opt for these types of eHealth care provision, so they risk being discriminated against. Because eHealth is usually offered as blended care, i.e. as a combination of regular face-to-face care and eHealth care provision,⁴⁴ the risk of exclusion of these groups seems small.

E-consultation, tele-expertise and telemonitoring can all enhance the physical accessibility of health services, especially for patients who experience difficulties in travelling, because travelling is no longer necessary.⁴⁵

Regarding affordability, implementation costs and costs of training health professionals in using eHealth care provision and the related applications should be weighed against the benefits. E-consultation seems affordable because it is reimbursable under certain conditions⁴⁶ and a study on tele dermatology indicated tele dermatology's cost-effectiveness.⁴⁷ Telemonitoring that takes place within an existing contract for medical services is reimbursable.⁴⁸ This makes telemonitoring affordable. Moreover, both the patient and the health professional will save on travel expenses because the physician and the patient only contact each other when the results indicate that this is necessary.⁴⁹ The affordability of telemonitoring is counteracted by the fact that patients sometimes have to buy the devices they use for telemonitoring themselves.⁵⁰ Tele dermatology, a type of tele-expertise, is said to have led to a reduction in costs.⁵¹ Moreover, this type of tele-expertise is reimbursable under the condition that the applications that are used are appropriately secured.⁵² Thus, this type of tele-expertise has the potential to contribute to the affordability of health services.

43 An example is the possibility of anonymous e-mental health, see Art. 70a Zvw, elaborated in chapter 6, Para. 2 of the Health Insurance Regulation.

44 See, for instance Van Duivenboden 2015, p. 31; Voorham et al., *Tsg*, 2015, p. 41 and Baardman, *Tsg* 2015, p. 44.

45 For instance Schalken et al. 2010, p. 42 and Beuscart et al. 2014, p. 415.

46 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, section 1.2, Para. 4, p. 8.

47 Van der Heijden & Witkamp, *NtvdV* 2013, p. 538-541 and the earlier study conducted by Van der Heijden et al., *NtVG* 2012, p. 1-7.

48 NZa 2017, p. 5-6 and NZa 2019, p. 11.

49 Rauwerda & Krijgsman 2015, p. 11, presenting the advantages of health professional-patient communication by means of video contact and Rauwerda. However, this can equally apply to telemonitoring.

50 Van Bodegraven, *Tsg* 2015, p. 61.

51 Van der Heijden et al., *NtVG* 2012, issue 4, p. 5-6, published before as Van der Heijden et al., *BJD* 2011, p. 1063.

52 NZa Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REG-20622-04, Para. 4.11, p. 42.

Information accessibility is the final element of accessibility. At first sight, e-consultation does not seem to contribute to the accessibility of health information because it takes place between a physician and their patient in private. The Twitter consultation, however, is an exception. Due to its public nature, the Twitter consultation is a type of online consultation that can contribute to the accessibility of information. Twitter consultations, however, do not occur often. Tele-expertise revolves around information and a fast exchange of it. In that sense it facilitates the accessibility of information: on the Internet information can travel fast and patients and physicians will have the information that they need within a short time. Telemonitoring has the potential to contribute to accessibility of information as well because it facilitates a constant flow of information, especially when the information is transferred to the health professional automatically. Telemonitoring is not used that much.⁵³ Therefore, the accessibility of information will not increase. Moreover, not every patient who measures their health values shares them with a health professional.⁵⁴

Acceptability

eHealth care provision should also be acceptable. This means that it should be provided as the law stands. Thus, regulations, statutes and good practice guidelines should be taken into account during eHealth care provision. Examples are the WGBO and the GDPR and the good practice guidelines developed by the profession, such as the KNMG Guidelines for dealing with medical data.⁵⁵

E-consultation has the potential to help to offer health services that are culturally acceptable. It enables patients to contact a health professional who shares their background.⁵⁶ Telemonitoring is suitable for culturally acceptable health care provision as well because communication concerning telemonitoring usually takes place asynchronously. It is therefore not a problem when the monitoring health professional resides in another time zone.

Acceptance of e-consultation and telemonitoring as means for health care provision is not always there (yet). Some people are computer illiterate or uninterested in using ICT. E-consultation and telemonitoring will not be an acceptable way of health care provision to them. The low use rate of e-consultation and telemonitoring⁵⁷ indicates that people do not consider it as an acceptable means of health care provision though. Patients have indicated various reasons why they do not want to use telemonitoring. These include an unwillingness

53 Krijgsman et al. 2013, p. 81; Krijgsman et al. 2016c, p. 39-40 and Wouters et al. 2017, p. 76-77.

54 Krijgsman et al. 2016c, p. 39.

55 KNMG Guidelines for dealing with medical data 2020.

56 See, for instance Ye et al., *TELEMEDICINE and e-HEALTH* 2012 as cited by Kokabisaghi, Bakx and Zenelaj, *ELR* 2016.

57 Krijgsman et al. 2013, p. 81; Wouters et al. 2017, p. 76-77; Wouters et al. 2019a, p. 21; Wouters et al. 2019b, p. 8-9; Wouters et al. 2019f, p. 7 and Wouters et al 2019c, table 2.27 and 2.28, p. 28.

to be confronted with their disease on a constant basis, the opinion that a health professional should conduct the measurements and the lack of face-to-face contact with a physician.⁵⁸

With respect to tele-expertise, it is also possible that not every patient considers this an acceptable way of health care provision. Perhaps not every patient accepts that their information is transferred over the Internet because they fear that their privacy will be violated.⁵⁹

Quality

As for quality, positive as well as negative effects are conceivable, insofar as statements can be made from a legal point of view. Empirical studies must reveal what the exact contribution of eHealth care provision is to the quality of the health services that are provided.

This study presented several potential positive effects of eHealth care provision on quality. Tele-expertise, for example, allows patients to get advice from a specialist at an earlier stage, which means that they have a diagnosis sooner and that treatment can also start at an earlier stage and deterioration can be prevented. On teledermatology, a type of tele-expertise, some research has been conducted. Positive effects on the quality of health care because of tele-expertise were found. Moreover, an educational effect was perceived from teledermatology.⁶⁰ This contributes to the quality of health care as well. More studies on eHealth care provision, also on tele-expertise in other domains of health care are required to see the effects of this way of health care provision on quality.

Good practice guidelines can help in maintaining the quality of eHealth care provision by setting minimal standards. Several good practice guidelines have been developed with respect to e-consultation and the protection of personal data during (eHealth)care provision.⁶¹ These can help in offering eHealth services of good quality. Devices used for telemonitoring should comply with the Wmh. Health care institutions should take the lead in checking which devices are appropriate for telemonitoring. This should be discussed with the health professionals who work in that institution. Patients and health professionals can decide together which application they will use for telemonitoring but in the end the physician is responsible for the decision.

58 Huygens et al., *BMC Health Services Research* 2016, issue 16, no. 232, p. 7 and Wouters et al. 2018, p. 88.

59 See, for instance Gajanayake, Iannella & Sahama, *Studies in Health Technology and Informatics* 2014, p. 980-984, who found that patients were more likely to use eHealth applications when they did not fear that their privacy was violated.

60 Van der Heijden & Witkamp, *NTvDV* 2013, p. 538-541 and the earlier study conducted by Van der Heijden et al., *NtVG* 2012, issue 4, p. 1-7.

61 KNMG Guidelines for dealing with medical data 2020 and NHG-Checklist e-consult 2014.

Impediments for the quality of health care during eHealth care provision were presented as well. For e-consultation they are the absence of non-verbal and paralinguistic communication,⁶² the impossibility of physical examination, a possible limited literacy of the patient which causes problems for written consultations⁶³ and the fact that e-consultation can take place asynchronously, as a result of which the patient's condition can change before the health professional has had the time to reply. Another quality-related problem is the possibility of laymen posing as physicians on the Internet and provide patients with poor advice that can inflict damage.⁶⁴

For tele-expertise, the use of inappropriate applications can be detrimental to the quality, especially when photos of inferior quality are added to the information the tele-expert receives. This increases the chances for a misdiagnosis. Furthermore, quality of health care will not improve if the tele-expert has a long response time.

As for telemonitoring, mistakes can occur when patients are measuring their own data, especially when they record them manually. The health professional should pay close attention to this issue. Patients might use their smartphone for measuring their health values but in order to protect quality, physicians can pick the application or the device that the patient uses. Furthermore, failures and defects of insideables and wearables are a complicating factor for the quality of telemonitoring. Empirical studies on the quality of various applications and devices for telemonitoring are necessary.

Does the WGBO apply to e-consultation?

The WGBO applies to e-consultation. Two different situations can be distinguished. First, the situation in which a patient and a health professional who already have an existing relationship for medical treatment. For instance, when a GP holds an e-consultation with one of their own patients. In this instance, e-consultation is considered a continuation of the performance of the existing medical services contract based on Article 7:446 BW.⁶⁵ E-consultation between patients and physicians who do not know each other is possible as well, under certain conditions.⁶⁶ This will result in a contract for medical services. According to Article 7:446 BW a medical services contract is concluded when a health professional

62 Schalken et al. 2010, p. 21.

63 Meijman & Den Ouden, *Medisch Contact* 2014, p. 1585; Van Meersbergen 2012, p. 100 and KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, p. 15.

64 Capello & Luini 2014, p. 138.

65 Views as to whether a contract for provision of medical services is established as soon as the patient subscribes to the GP's practice or whether such a contract is established each time the patient actually consults their GP, differ in academia. The first view is endorsed by Asser/Tjong Tjin Tai 7-IV 2018/392 and Van Meersbergen 2012, p. 106. The latter view is endorsed by Van Wijmen, *NJB* 1985, p. 542-543; Brands 1997, p. 163 and Houben 2005, p. 140. This study endorses the first view.

66 KNMG Guidelines for dealing with medical data 2020, p. 27.

is providing medical services – in other words, when they are giving advice or help to a patient with the aim of diagnosis, care or cure of this particular patient. This is what happens during an online consultation. Therefore, a contract for medical services is concluded. The preparatory memorandum to the WGBO explains that provision of medical services can also take place over distance.⁶⁷ This is the first argument to consider e-consultation medical services provision and to accept the applicability of the WGBO to this means of medical services provision. Second, the KNMG indicated in good practice guidelines that, when in doubt, the existence of a contract for medical services and thus the applicability of the WGBO should be presupposed.⁶⁸ This way, the patient's rights can be protected. The KNMG explicitly assumes the applicability of the WGBO in their good practice Guidelines for dealing with medical data.⁶⁹ Moreover, according to case law, the scope of the WGBO is broad.⁷⁰

Only the Twitter consultation is an exception to this rule. The WGBO does not apply to Twitter consultation. Because of the public nature of Twitter and the restrictions on the amount of characters as well as restrictions due to obligations of confidentiality,⁷¹ questions and answers will remain general. Because of this, the criterion in Article 7:446 BW that the advice the physician gives should concern an individual will not be met. Moreover, the nature of the Twitter consultation and the WGBO seem irreconcilable. However, this does not mean that health professionals who offer Twitter consultations do not have any obligations at all.⁷²

How do the patients' rights to informational and spatial privacy, medical confidentiality and informed consent apply to e-consultation and how should they be applied?

The right to informational privacy is sufficiently protected by the WGBO and the GDPR. Both the GDPR and the WGBO set rules to protect personal data and to prevent personal data breaches. The outcome of enforcement of these regulations is different, however. The GDPR is actively enforced by the Dutch DPA, which has the authority to impose a fine in case of a personal data breach.⁷³ Based on a violation of patients' rights laid down in the WGBO, a civil suit is the appropriate means. Even though the WGBO and the GDPR overlap at certain points, problems are not to be expected in practice since the WGBO was amended when the GDPR entered into force.⁷⁴

67 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

68 KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

69 KNMG Guidelines for dealing with medical data 2020, p. 27-28.

70 HR 12 March 2013, ECLI:NL:HR:2013:BY4859, *NJ* 2013/424, m.nt. Legemaate and discussed by Hulst, *TGMA* 2013, issue 2, p. 55-56.

71 Even if the WGBO does not apply, health professionals still have an obligation of medical confidentiality based on Art. 88 BIG Act.

72 For instance, they can be held responsible in front of the disciplinary court. See Ekker, Nouwt & Legemaate in *Haarlems Dagblad* 5 April 2013.

73 Art. 51 in conjunction with Art. 58 Para. 1(i) and Art. 83 GDPR and Art. 32 in conjunction with Art. 83 Para. 2 introduction and (d) GDPR.

74 *Kamerstukken II* 2017/18, 34939, no. 2; *Kamerstukken I* 2017/18, 34939, A and *Stb.* 2018, 247.

During e-consultation, patients' data are being processed. Medical data are a special category of personal data which can only be processed under strict conditions.⁷⁵ An example of a right that both the WGBO and the GDPR allocate to the patient is the right to destroy their medical file. In spite of these possibilities, deleting information is difficult in the digital era. Information will remain on the devices that were used to view the information; even after the information is deleted from the device, traces of it might still be left behind.⁷⁶ Therefore it is often said that sharing information equals copying it. This is all the more relevant during e-consultation, because these consultations will leave traces themselves; that is if they are not saved on to the devices that are used for them to begin with.

Because e-consultation requires the travelling of data over the Internet, personal data breaches are more likely to occur. In practice, various norms and standards apply for the use of data in health care. The NEN standards are an example of such rules on data protection in health care. These standards are endorsed by case law.⁷⁷ Furthermore, several good practice guidelines give health professional a handle on this topic.⁷⁸ Concluding, sufficient statutes, regulations and good practice guidelines exist to protect patients' informational privacy during e-consultation. Health care facilities should take the lead to discuss these statutes, regulations and good practice guidelines with their employees⁷⁹ and discuss which applications and devices can be used for e-consultation. These are all enforced on health professionals and health care institutions. However, a personal data breach can also occur on the patient's devices. The aforementioned statutes, regulations and good practice guidelines all address the responsibilities of health care facilities and health professionals. However, it is difficult to impose a regulation that obliges patients to respect their own privacy. This means that health professionals should explain the privacy risks to patients and urge them to handle their medical data very carefully.⁸⁰ However, when a special application is used for e-consultation, it is possible to adjust the settings of the application so they only allow somebody to log on when the safety and security settings are adequate. In that case, the patient's right to access health care should be weighed against their right to privacy. This is possible, because denying access to e-consultation is not denying access to health care at all if the patient is invited to discuss their question during a regular consultation. Moreover, access to the e-consultation can be acquired as soon as some safety and security settings of the device are adjusted.⁸¹ This should not take too much time.

75 Art. 9 Para. 1 in conjunction with Art. 9 Para. 3(h) GDPR.

76 For instance Kleve 2004, p. 193.

77 HR 22 June 2012, ECLI:NL:PHR:2012:BW0393, *NJ* 2012/397 (*Knooble/Staat*), Para. 4.10.

78 NHG-Checklist e-consult 2014, Para. 4, p. 3 and the KNMG Guidelines for dealing with medical data 2020.

79 Also according to Art. 28 GDPR.

80 Accordingly, Schalken et al. 2010, p. 139.

81 The Erasmus University Rotterdam operates a similar system: employees can only have access to their work account on private devices when the safety and security settings of these devices are adequate.

Article 7:459 BW gives the patient a right to spatial privacy: others should not listen in or oversee the consultation. This is also the case when the consultation takes place over distance. At first sight, e-consultation seems to facilitate the right to spatial privacy. The patient can hold the consultation in their own home, where no one can interrupt them and at a time that is convenient for them. However, it is difficult for the health professional to assess whether the patient is really alone and if someone else is present during the online consultation. If someone else is present, it is harder for the physician to determine if the patient gave their consent for this. Whenever the health professional suspects that the patient cannot speak freely, they should end the e-consultation and invite the patient to their practice.

According to Article 7:457 BW, the health professional has an obligation to respect medical confidentiality. This means that they cannot share information about the patient with others, except for those who are involved in the patient's treatment.⁸² E-consultation extends the number of people who can see the consultation. First, these are assistants of the practice, but they already have a derivative obligation of medical confidentiality, derived from the health professional's duty of medical confidentiality. In some health care facilities, they filter the questions that are sent in for e-consultations, comparable to what is common practice over the phone. People whose assistance is necessary for the medical treatment have such a derivative obligation of medical confidentiality.⁸³ For e-consultation, ICT workers are necessary to carry out the medical treatment as well. Therefore, they should have a derivative obligation of medical confidentiality, too. To clarify this, the derivative obligation of medical confidentiality should be laid down in the contracts with ICT workers, both the ICT workers that are employed within the health care facility and those who are hired externally.⁸⁴

Article 7:448 BW obliges physicians to provide the patient with information in order for them to be able to give their explicit consent for the treatment, which is required based on Article 7:450 BW. During – or, in fact, before – the e-consultation, some additional information should be provided to the patient as well as the information about the treatment, the expected outcomes of this treatment and possible risk as well as alternatives to this treatment. For e-consultation, this information should include information on the opportunities and impossibilities of e-consultation. When e-consultation takes place asynchronously, the patient should be informed about the response time.⁸⁵ Moreover, information should be given about the way the data retrieved from the e-consultation are processed,⁸⁶ protected⁸⁷ and who

82 Art. 7:457 Para. 2 BW.

83 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

84 Accordingly, KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, appendix 5, p. 17-18.

85 KNMG Guidelines for dealing with medical data 2020, p. 28 and NHG-Checklist e-consult 2014, Para. 2, p. 1.

86 Art. 33 GDPR and Ploem, *TvGR* 2008, p. 317.

87 NHG-Checklist 2014, Para. 2, p. 1.

has access to the information.⁸⁸ Information about the risks should include information on risks specifically related to e-consultation, such as the risks of a personal data breach⁸⁹ and the fact that not every question can be answered by means of e-consultation. Information on the costs of the e-consultation should also be provided,⁹⁰ especially when the e-consultation is the first contact between this health professional and the patient. E-consultations that take place within pre-existing medical services contracts are usually covered by insurance.⁹¹ Finally, the health professional must offer the patient information about how they or, when they are located at a great distance from the patient, another health professional can be contacted in emergencies.⁹² Based on this information, the patient should give their explicit consent to receive treatment by means of e-consultation. The health professional must carefully assess whether the patient has understood the information. This can be difficult online and over distance. Still, an obligation to ascertain whether the patient really understood the information given by the physician is recommended.⁹³

Does the WGBO apply to tele-expertise?

During tele-expertise, the physician who is seeing the patient, the requesting physician, asks advice from a colleague over distance, the tele-expert. The patient and the requesting physician have a contract for medical services, because the patient is already in their practice.⁹⁴ This means that the WGBO applies in this relationship. The requesting physician asked the tele-expert for advice. Therefore, the requesting physician is the principal in the relationship with the tele-expert. This should not be a problem for the applicability of the WGBO, since Article 7:446 Paragraph 1 does not require that the principal and the patient are the same person. Yet, it is unlikely that a contract for medical services is established between the patient and the tele-expert. Establishing such a contract does not seem to be in line with parties' expectations and will also lead to some practical difficulties, such as the obligation for the tele-expert to start a medical record as soon as they advise a colleague by means of WhatsApp. The tele-expert can be considered as an auxiliary person to the requesting physician who enlists their help.

88 NHG-Checklist 2014, Para. 2, p. 1.

89 Turvey et al., (ATA Practice Guidelines for Video-Based Online Mental Health Services) 2013, p. 726.

90 Ploem *TvGR* 2008, p. 317; Siegal, *Otolaryngol Clin N Am.* 2011, p. 1380, citing Goldstein, *J Law Med Ethics* 2010; Turvey et al./ATA Practice Guidelines for Video-Based Online Mental Health Services 2013, p. 726; NHG-Checklist e-consult 2014, Para. 2, p. 1-2 and Para. 4, p. 3 and KNMG Guidelines for dealing with medical data 2020, p. 28-29 (and footnote p. 29).

91 NZa Tariff Decision General Practice and Multidisciplinary Health Care 2020, TB/REGCU-20622-04, section 1.2, Para. 4, p. 8.

92 Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000; Ploem *TvGR* 2008, p. 317; NHG-Checklist e-consult 2014, Para. 2, p. 2 and KNMG Guidelines for dealing with medical data 2020, p. 29

93 The legislator seems to imply this in the Explanatory Memorandum to the recent amendment to the WGBO: *Kamerstukken II* 2017/18, 34994, no. 3, p. 5.

94 Based on Art. 7:446 BW.

This does not mean, however, that the tele-expert does not have to comply with certain patient's rights. For instance, they are still subject to the rules related to processing personal medical data following from the GDPR and they have an obligation of medical confidentiality based on Article 88 BIG Act.

How do the patients' rights to informational and spatial privacy, medical confidentiality and informed consent apply to tele-expertise and how should they be applied?

Because tele-expertise requires transfer of information, more specifically personal health data, informational privacy deserves attention in this respect. During tele-expertise, physicians must comply with the rules on processing medical data as laid down in the GDPR, the rules related to informational privacy in the WGBO and with standards from the field, such as the NEN standards. Moreover, compliance with the KNMG Guidelines for dealing with medical data is required.

For informational privacy, the applications and devices that are used are relevant. They must meet the standards for safety and security. In the discussion on the use of WhatsApp for tele-expertise, a lot has been brought up about the requirements when disseminating patient information between colleagues.⁹⁵ During tele-expertise, the requesting physician must not send information that is easy to trace back to an individual patient. This means that no names or other personal details and no recognisable photos can be included in the message.⁹⁶ Metadata, data behind the actual data, such as information on the time and place a photo is taken, can also make the data retraceable to an individual.⁹⁷ Therefore, transferring patient data for tele-expertise should be carefully considered. Another recommendation is that the data is immediately deleted from the device that is used for tele-expertise.⁹⁸ Both the requesting physician and the tele-expert should do this. The requesting physician, however, might need to save the data in the medical file based on Article 7:454 BW.

95 For the initial news that was the cause for discussion among various stakeholders, see for instance Van Noort, *NRC Next* 8 July 2015, p. 7 and Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809. See chapters 1 and 5 and the citations there for the extensive discussion on this topic.

96 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm and the Federation of Patients in the Netherlands: They gave a reaction in Van Noort, 'Even een foto van jouw infectie heen en weer appen, mag een arts dat?', *nrcq.nl* 8 July 2015. Source: nrc.nl/nieuws/2015/07/08/even-over-jouw-infectie-heen-en-weer-appen-mag-dat-a1495809 and Van Noort, *NRC Next*, 8 July 2015, p. 7.

97 KNMG Guidelines for dealing with medical data 2020, p. 24.

98 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-een-arts-patientgegevens-uitwisselen-via-whatsapp.htm

Tele-expertise can also violate informational privacy when patients themselves give permission because sometimes, they prefer efficient and fast communication between physicians over their right to privacy.⁹⁹ However, this can never be a reason to employ applications that violate patient's informational privacy. Privacy is a fundamental right that must always be protected, even though the subject does not seem to value it that much.

Tele-expertise, comparable to e-consultation, allows more parties to view the information. Remarks on third parties such as ICT professionals have already been made in answering the subquestion on e-consultation. These remarks apply to tele-expertise as well. Therefore, at this point, the focus will be on another third party: the developer of the application that is utilised for tele-expertise. Health professionals and health care facilities should make sure that the applications they intend to use for tele-expertise meet the safety and security standards and thus cannot lead to a violation of the obligation of medical confidentiality.¹⁰⁰ This assessment should include discovering who has access to the information that is disseminated by means of the application. Furthermore, the assessment should include whether, and if so, where the application stores its information. It can be a complicating factor if this is outside the European Union; in this case it is difficult to verify what happens with the data that land on these servers and it is unclear whether the data protection of the GDPR can be easily enforced.¹⁰¹

Various applications for tele-expertise that claim to be more safeguarded are brought to the market.¹⁰² A problem with these applications however is that not all of them are well-known among health professionals and their use might vary from one health care facility to another.¹⁰³ This diminishes the initial advantage of tele-expertise which usually consists of contact between two health professionals who do not work within the same practice. Health care facilities are responsible for counselling their employees on the protection of informational privacy during tele-expertise.¹⁰⁴ Health professionals themselves do however still have their obligations to act as a conscientious health care provider; thus it is not the responsibility of health facilities alone.¹⁰⁵

99 J. Jacobs, 'Wie weet nu echt of WhatsApp mag in de zorg', *Smarthealth.nl* 14 April 2016. Source: smarthealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/.

100 Accordingly Peters & Lowijs, 'Hoe een second opinion de privacy niet schaadt. 'Appende' artsen vragen elkaar om advies,' *dutchcowboys.nl* 9 July 2015. Source: dutchcowboys.nl/media/hoen-eeen-second-opinion-de-privacy-niet-schaadt.

101 Wiggelinkhuizen et al., *Medisch Contact* 2015, p. 2311.

102 'Strijd om verovering markt medische WhatsApp', *telegraaf.nl* 23 May 2016. Source: telegraaf.nl/tech/409960/strijd-om-verovering-markt-medische-whats-app.

103 J. Jacobs, 'Wie weet nu echt of WhatsApp mag in de zorg', *Smarthealth.nl* 14 April 2016. Source: smarthealth.nl/trendition/2016/04/14/whatsapp-communicatie-zorg-artsen/.

104 Art. 28 GDPR and 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Praktijkdilemma 20 November 2015. Source: knmg.nl/advies-richtlijnen/artseninfolijn/praktijkdilemmas-1/praktijkdilemma/mag-eeen-arts-patientgegevens-uitwisselen-via-whatsapp.htm.

105 Art. 7:453 BW.

Noticeable in the discussion on the appropriate/inappropriate applications for tele-expertise is the difference between the KNMG and the Dutch DPA on, in that case, the use of WhatsApp for tele-expertise. Although the KNMG is not particularly in favour of the use of WhatsApp to consult colleagues, the organisation does not prohibit its use for tele-expertise.¹⁰⁶ The Dutch DPA on the other hand, is firmly against the use of this application and stated that the authority will impose a fine on offenders in case of a personal data breach.¹⁰⁷ This variation can be explained by the different interests that these stakeholders aim to protect. The KNMG puts health care of good quality first while the Dutch DPA, on the other hand, puts the protection of privacy first. From that point of view, it is very understandable that the KNMG sometimes allows a risk of a small personal data breach when this serves good professional conduct while the Dutch DPA aims to protect privacy in any situation.

As for medical confidentiality, the above-mentioned comment about informational privacy applies. In order to protect medical confidentiality, only applications that respect informational privacy and meet existing standards and good practice guidelines related to privacy must be used for tele-expertise. However, in case of an emergency, sometimes the fastest way of communication that is possible, is communication by means of a medium that has a poorer reputation regarding data protection. This is only possible during emergencies when no other options in the form of tele-expertise by means of another application are available, and not requesting tele-expertise will infringe the duty to provide the care of a conscientious health professional.¹⁰⁸ Emergencies can be grounds to breach the obligation of medical confidentiality.¹⁰⁹ Medical confidentiality based on Article 7:457 BW stretches out to all information about the patient and includes – among other things – written information as well as photos.¹¹⁰ The requesting physician can provide the tele-expert with information without violating their obligation of medical confidentiality because the latter can be classified as a person who is involved in the patient's treatment. Others who are involved in the patient's treatment should only receive the information that they need to carry out their part of the

106 KNMG Guidelines for dealing with medical data 2020, p. 24.

107 The Dutch DPA reacted in current affairs programme *EenVandaag*, broadcast on 23 February 2016, *Eenvandaag*, 'Medische info delen via Whatsapp', *eenvandaag.nl*. Source: eenvandaag.avrotros.nl/binnenland/item/medische-info-delen-via-whatsapp/. See also Van Noort, W. van Noort, 'Artsen moeten stoppen met whatsappen over patiënten', *nrc.nl* 23 February 2016. Source: nrc.nl/nieuws/2016/02/23/artsen-moeten-stoppen-met-whatsappen-over-patienten-a1409107.

108 Art. 7:453 BW.

109 Following from the grounds to breach the obligation of medical confidentiality as discussed in, among others, Leenen/Dute & Legemaate (eds.) 2017, p. 158-162 and Buijsen et al. 2012, p. 48-57 and the literature and case law cited there.

110 Wijne, in: *GS Bijzondere overeenkomsten*, Art. 7:457 BW, note 4 (online, updated to 17 June 2020) referring to Buijsen et al. 2012, p. 37 and 81 and Leenen/Dute & Legemaate (eds.) 2017, p. 153. Moreover, the obligation of medical confidentiality also stretches to non-medical information that came to the attention of the health professional while performing the contract for medical services as well as information to the health professional passed on by third parties. For further explanation, see Wijne, in: *GS Bijzondere overeenkomsten*, Art. 7:457 BW, note 4 (online, updated to 17 June 2020) and the case law she mentions, as well as references to Buijsen et al. 2012, p. 81.

treatment.¹¹¹ This means that the requesting physician can provide the tele-expert with the information they need to be able to provide tele-expertise, but no more.

The tele-expert themselves also has an obligation to respect medical confidentiality of the data they receive from the requesting physician and their own observations on the patient. They derive this obligation from Article 88 BIG Act.

Before a physician requests tele-expertise, they should provide the patient with information.¹¹² This means they should give the patient information about the fact that they are going to request tele-expertise and why. They should mention why they want to consult that particular tele-expert, based on this tele-expert's expertise.¹¹³ Moreover, the requesting physician should provide the patient with information on the alternatives for tele-expertise, such as a regular second opinion, where the patient will visit the specialist by themselves. Furthermore, they should inform the patient about the differences between tele-expertise and a face-to-face second opinion.¹¹⁴ Finally, the information that should be provided based on Article 7:448 BW must include information on how the requesting physician and the tele-expert handle data protection,¹¹⁵ whether the tele-expert will store the patient's information and for how long. Finally, the patient should, based on the information, give their explicit consent for tele-expertise. Asking for explicit consent for tele-expertise may not seem necessary because this is a part of the medical treatment for which the patient has already given their consent. However, giving consent for treatment does not entail giving consent in advance for every action to perform that treatment.¹¹⁶ Article 7:466 Paragraph 2 provides an exception to this rule, namely that consent is not required for actions that are not invasive. Since taking a photo or writing down information is in itself not invasive, it might seem that the patient's explicit consent is not needed for tele-expertise. However, the patient's data have to be transferred over the Internet and this brings along privacy implications as presented above. Since personal health data are sensitive data¹¹⁷ and tele-expertise involves a risk of a violation of privacy, explicit consent is required. The obligation to ask for explicit consent should not interfere with the obligation of conscientious health care provision.¹¹⁸

111 *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

112 Art. 7:448 BW.

113 Dreezen, *Med Law* 2004, p. 544 cited by Callens, *TvGR* 2006, p. 271.

114 Dreezen, *Med Law* 2004, p. 544 cited by Callens, *TvGR* 2006, p. 271.

115 Dreezen, *Med Law* 2004, p. 544.

116 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12.

117 ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*); ECtHR 17 July 2008, ECLI:CE:ECHR:2008:0717JUD002051103 (*I. v. Finland*) and ECtHR 4 December 2008, ECLI:CE:ECHR:2008:1204JUD003056204, *NJ* 2009/410, m.nt. Alkema (*Marper and S. v. United Kingdom*), as cited by Verhey & Raijmakers, *Regelmaat Kwartaalblad voor wetgevingsvraagstukken*, 2013, p. 186. The ECtHR bases its decision on Art. 6 of the Strasbourg Convention.

118 Art. 7:453 BW.

Does the WGBO apply to telemonitoring?

Telemonitoring takes place within an existing contract for medical services. A physician monitors their patient over distance and contacts the patient when the results of the self-monitoring indicate that they should do so. Assessing someone's health is considered health care provision by Article 7:446 Paragraph 2 BW. The explanatory memorandum adds that this is also possible for healthy people.¹¹⁹ Telemonitoring can also take place with relatively healthy people. In that situation, telemonitoring is provision of health services under Article 7:446 Paragraph 2 BW. This means that the WGBO applies to telemonitoring.

How do the patients' rights to informational and spatial privacy, medical confidentiality and informed consent apply to telemonitoring and how should they be applied?

A lot has been said about these patients' rights in answers to the questions about e-consultation and tele-expertise. Therefore, at this point only those observations that are different to the observations presented above will be mentioned. Insofar as there is overlap with e-consultation and tele-expertise, what has been said about those types of eHealth care provision applies to telemonitoring as well.

A point of particular interest related to telemonitoring and informational privacy is the application that is used for telemonitoring. Several situations are possible. First, the situation in which the health professional prescribes the application. This can be a wearable or an insideable, or an application to be used on the patient's personal computer or smartphone. Physicians and health care facilities are subject to various statutes, regulations and standards, such as the GDPR, the WGBO and the NEN standards. This means that applications prescribed by health professionals should meet the criteria posed by these regulations. Another situation that is possible is the situation that a patient chooses the application they use for telemonitoring and brings the results to the health professional. The health professional should always verify whether the application the patients uses meets the safety and security standards. If not, they should urge the patient to choose another application. The health professional can help the patient find an application that does meet the standards for safety and security as the law stands. Health care facilities together with health professionals should discuss which applications are appropriate for telemonitoring and which are not.

Because of telemonitoring, the patient possesses more health information about themselves. Health professionals should counsel patients on handling their personal medical data and explain the risks of sharing these data carelessly with others.¹²⁰ It can be asked of patient to

119 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

120 Accordingly BCS The Chartered Institute for IT/NHS England 2013, p. 13.

safeguard the devices that they use for telemonitoring, for instance by letting the application function only when certain security settings are adjusted.

The right to spatial privacy as laid down in Article 7:459 BW also applies to telemonitoring. This provision should be read to include health care provision over distance as well. Wearables and insideables are able to protect the patients' right to spatial privacy very well because they directly transfer the information to the health professional; this way spatial privacy cannot be violated when the health values are measured. Otherwise, especially when the patient is conducting self-measurements and puts the results into a system manually, violation of spatial privacy is possible. Even though it is difficult for the health professional to protect this right over distance, especially because telemonitoring is usually asynchronous, they should inform the patient about this right.¹²¹

A development related to telemonitoring is the PHR. This is a medical record that patients administer by themselves. They can insert information about their health obtained from various health professionals in this record. They can also add information they obtained by themselves, such as the results of self-measurements. Patients can choose to share their PHRs with health professionals but they can also decide to not share information with them. Such a PHR is not protected by the obligation of medical confidentiality as laid down in Article 7:457 BW and Article 88 BIG Act because the patient themselves is responsible for managing it. Therefore, the RVS and the CEG proposed a right to patient confidentiality that the patient can invoke when third parties request access to (parts of) the PHR.¹²² The right to patient confidentiality is proposed because fear exists that patients will provide access to their PHR to third parties because they might think they are obliged to do so, or because they think denying access is disadvantageous for them.¹²³ This is a good suggestion to protect the data in the PHR.

The role of third parties such as developers and suppliers of applications should be considered with respect to medical confidentiality. They cannot, unlike ICT workers who work for the health care facilities, be considered people whose assistance is needed to perform the medical services contract;¹²⁴ they are not bound by a derivative obligation of medical confidentiality. It is advisable to make arrangements with these parties on how they handle medical data.

121 Accordingly Ploem 2012, p. 122.

122 Hooghiemstra & Ippel 2011, p. 16 and RVZ 2014, p. 33.

123 Examples include investigative services, insurers, financial institutions, ICT companies and other parties who might want to obtain patients' medical data, from accessing the medical record; see Hooghiemstra & Ippel 2011, p. 16 and RVZ 2014, p. 33.

124 People whose assistance is necessary in the performance of the contract for medical services have a derivative obligation of medical confidentiality based on *Kamerstukken II* 1989/90, 21561, no. 3, p. 39.

Finally, before the physician can start with the telemonitoring, the patient has to give their explicit consent.¹²⁵ As well as the usual information, giving the patient some additional information on telemonitoring in order to be able to give their consent, is advisable. First, the patient should be informed about the way their data are processed.¹²⁶ Because certain kinds of telemonitoring require an active contribution from the patient, for instance when the patient has to conduct self-measurements manually, they must be informed what is expected of them. Furthermore, the patient should receive information on how to use the devices needed for telemonitoring¹²⁷ and who they can ask their questions to as well as what to do in case of emergencies.¹²⁸ The information about the risks must also include information related to neglect of the patient. Finally, patients should receive information about the costs of telemonitoring and alternative applications or devices that they can use.¹²⁹ The duty to provide the patient with information is an ongoing obligation. Every time the outcomes change or the health professional has to adjust their plan of treatment, the patient should be consulted based on Article 7:448 BW.¹³⁰ The recent amendment to the WGBO introduced shared decision-making; in other words the health professional must not propose treatment but consult with the patient instead. The amendment to Article 7:448 BW also involves a duty to ascertain; the physician must ensure that the patient has understood the information.

3. RECOMMENDATIONS ON EHEALTH AND PATIENTS' RIGHTS

Now that the questions central to this study are answered, recommendations on eHealth and patient's rights in general will be made (section 3.1), followed by recommendations specific to e-consultation (section 3.2), tele-expertise (section 3.3) and telemonitoring (section 3.4).

3.1 Recommendations on eHealth and patients' rights in general

Because of eHealth, patients possess more information about their own health. Not only does eHealth facilitate the patient's right to access to their own medical record¹³¹ because they are likely to obtain digital access, it also increases the amount of health information that patients have about themselves. Patients can for instance keep a PHR in which they might include health information and information received from health care providers, information by non-professionals, information as a result of self-measurements and personal notes on

125 Art. 7:448 in conjunction with Art. 7:450 BW.

126 Callens & Cierkens 2012, p. 134-135 and Ploem 2012, p. 119.

127 Ploem 2012, p. 119.

128 Ploem 2012, p. 119 and Art. 3(a) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

129 Ploem 2012, p. 119.

130 *Kamerstukken II* 2017/18, 34994, no. 3, p. 4.

131 Art. 7:456 BW.

their health. When a patient had an e-consultation with a physician, they might have the transcript of the consultation or the email if the consultation took place over email on their devices. Telemonitoring also typically increases the health information that patients possess themselves, because they either conduct self-measurements on health values or they carry a device which takes these measurements. Therefore, I support the idea to implement a right to patient confidentiality.¹³² Even though various statutes and regulations apply to this situation, it would be clear to regulate this in one specific place. The right to patient confidentiality should not only apply to the PHR, but should be extended to health information or (parts of) the medical file that the patient obtains in another way.

The right to information as laid down in Article 7:448 BW should be extended in the case of eHealth care provision. Because of eHealth care provision, other information besides the usual information that is provided at the start of a treatment, has to be provided, such as information on how the health professional and health care facility are handling and processing medical data,¹³³ the risks related to health care provision over distance and/or over the Internet, including privacy-related risks¹³⁴ and, in case of asynchronous eHealth care provision, their response time and whether other parties filter incoming questions first.¹³⁵ Moreover, information should be provided on who to contact during emergencies.¹³⁶

3.2 Recommendations on e-consultation and patients' rights

E-consultation should, in order to contribute to realising the right to health for all, be carried out in a way that is acceptable to all. This means that e-consultation should be offered as blended care – as a part of a medical treatment, but not as a replacement. This serves to prevent exclusion of those who are computer illiterate and those who do not show any particular interest in online consultation. Excluding this group would mean that they are discriminated against. In that case, another one of the elements of the right to health, accessibility,¹³⁷ is also not met.

In order to protect patients' informational privacy during e-consultation, applications used for e-consultation should have built-in safety and security features that detect whether the device the patients wants to use for the e-consultation is adequately safeguarded. If not, the

132 Hooghiemstra & Ippel 2011, p. 16 and RVZ 2014, p. 33.

133 Accordingly Ploem *TvGR* 2008, p. 317 and Art. 13 GDPR and NHG-Checklist e-consult 2014, Para. 2, p. 1.

134 Siegal, *Otolaryngol Clin North Am.* 2011, p. 1380, quoting Goldstein, *J Law Med Ethics* 2010.

135 NHG-Checklist e-consult 2014, Para. 2, p. 1 and KNMG Guidelines for dealing with medical data 2020, p. 28.

136 KNMG/Van Meersbergen Guidelines for online Physician–Patient Contact 2007, Para. 8.6, p. 12 and Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

137 CESCR General Comment no. 14 (2000) on Health, Para. 12(b). Accessibility includes accessibility without discrimination.

application should deny access to e-consultation from this device, stating the reason and explaining what the patient can do to gain access. This would be improving the protection of their device or using another device that is sufficiently safeguarded.

Article 7:459 BW on spatial privacy elaborates on third parties observing the performance of the contract for provision of medical services. This provision should be interpreted as follows: observing a consultation between a doctor and a patient does not only mean being in the physician's practice during this consultation or reading the screen in real time, it also means observing either the patient or the physician during e-consultation, i.e. reading along with one of them or viewing (some or all of) the e-consultation. The obligation to respect spatial privacy also applies over distance. Whenever a health professional suspects that the patient is not alone during the consultation, they must invite the patient for a consultation in their practice.

The WGBO also applies to e-consultation between physicians and patients who have not met each other before. An e-consultation between them leads to a contract for medical services according to Article 7:446 BW. The legislator intended for the WGBO to have a wide scope.¹³⁸ The wide scope of this statute also follows from case law,¹³⁹ and is endorsed in good practice guidelines.¹⁴⁰

E-consultation between patients and health professionals who have not met before is not prohibited but it is rather an exception. This should only happen when this is consistent with the duty to act as a conscientious health care provider.¹⁴¹ The decision and responsibility to hold e-consultations with unknown patients is the responsibility of the physician.¹⁴² Contract law (WGBO) as well as disciplinary law apply to this situation.

3.3 Recommendations on tele-expertise and patients' rights

At first sight, asking the patient for their explicit consent about requesting tele-expertise does not seem necessary. This act is a part of the performance of the contract for medical services. For these kinds of actions, usually explicit consent is not required because the patient agreed to undergo certain acts necessary to carry out the medical treatment contract when they gave their consent for that particular treatment.¹⁴³ This especially applies for non-invasive actions. Asking another health professional for advice does not seem invasive at a first glance, were it

138 *Kamerstukken II* 1989/90, 21561, no. 3, p. 28.

139 HR 12 March 2013, ECLI:NL:HR:2013:BY4859, *NJ* 2013/424, m.nt. Legemaate and Hulst, *TGMA* 2013, issue 2, p. 55-56.

140 For instance KNMG/Doppegieter & Van Meersbergen 2005, p. 4.

141 Art. 7:453 BW.

142 Accordingly KNMG Guidelines for dealing with medical data 2020, p. 27-28.

143 *Kamerstukken II* 1989/90, 21561, no. 3, p. 12 and 49.

not for the distance. Tele-expertise requires information to transfer digitally, which means that privacy risks are involved. Moreover, this information, as well as being disseminated, is likely to be stored in both the servers of the requesting physician and servers of the tele-expert. Since personal medical data are considered sensitive data,¹⁴⁴ tele-expertise is an invasive act in that sense. This is a striking difference between tele-expertise and asking a colleague who passes by for advice. Therefore, I would like to stress that tele-expertise requires the patient's explicit consent based on Article 7:450 BW.

The WGBO applies to tele-expertise; the patient has a contract for medical services with the requesting physician.¹⁴⁵ The patient does not have such a contract with the tele-expert, however. The requesting physician is the principal in this situation. This does not mean that the tele-expert does not have any obligations towards the patient at all. For instance, they also have an obligation of medical confidentiality, albeit based on the BIG Act¹⁴⁶ instead of the WGBO.

Both the requesting physician and the tele-expert should guarantee that the device and applications they use for tele-expertise meet the standards for safety and security, such as the NEN norms and compliance with the GDPR. Health care facilities should take the lead in discussing this with health professionals.¹⁴⁷ Article 28 GDPR imposes this on health care facilities as well. Not only should health care facilities discuss these issues with health professionals who are employed by them and the self-employed health professionals who offer services within their health care facility, they should develop uniform policies on the use of devices and applications for communication about patients. When providing work-only laptops or smartphones is not possible, the professional's own devices should comply with the standards for safety and security before they can be used for work-related purposes.

3.4 Recommendations on telemonitoring and patients' rights

In the case of telemonitoring it is possible that the patient is located at a great distance from the health professional who is monitoring them. Therefore, it is recommended that a health professional who holds their practice in the patient's neighbourhood is made an emergency contact. The patient should be able to rely on this health professional in case of emergencies.

144 As confirmed in ECtHR 25 February 1997, ECLI:CE:ECHR:1997:0225JUD002200993 (*Z. v. Finland*); ECtHR 4 December 2008, ECLI:CE:ECHR:2008:1204JUD003056204, *Nj* 2009/410, m.nt. Alkema (*Marper and S. v. United Kingdom*) and ECtHR 17 July 2008, ECLI:CE:ECHR:2008:0717JUD002051103 (*I. v. Finland*) as cited by Verhey & Raijmakers, *Regelmaat Kwartaalblad voor wetgevingsvraagstukken*, 2013, p. 186. The ECtHR bases its decision on Art. 6 of the Strasbourg Convention.

145 Art. 7:446 BW.

146 Art. 88 BIG Act.

147 In that sense, also 'Mag een arts patiëntgegevens uitwisselen via WhatsApp?', *knmg.nl* Federatienieuws 25 November 2015. Source: medischcontact.nl/nieuws/federatienieuws/federatiebericht/Praktijkdilemma-Mag-een-arts-patientgegevens-uitwisselen-via-WhatsApp.htm.

The physician who conducts the telemonitoring should also be able to contact this physician when necessary.¹⁴⁸

In order to start telemonitoring, patients should give their explicit consent. Telemonitoring, as an action that is taken to perform the contract for medical services provision, requires explicit consent because of its invasive nature. Telemonitoring can invoke someone's informational and spatial privacy because it is a continuous action. As well as the information the health professional is obliged to give their patient, based on Article 7:448 BW, information on these privacy risks and information on the health professional who can be contacted in emergencies, should be provided as well, as mentioned above.¹⁴⁹

4. RECOMMENDATIONS FOR FUTURE STUDY

This study examined the effects of eHealth care provision on patients' rights and revolved around the question whether eHealth, with its many expectations, can contribute to realising the right to health and how patients' rights must be protected in this situation. A phenomenon as comprehensive as eHealth always leads to more questions than can be answered in one study. Therefore, at this point some recommendations for future study will be made.

As much as this study aimed to assist in providing legal certainty on eHealth and patients' rights, not all eHealth applications could be discussed. This means that there is room for more study in the future. As chapter 2 showed, eHealth is a comprehensive concept and numerous types of eHealth care provision exist. Related to telemonitoring, but more invasive in the patient's personal life, is home telecare. Home telecare refers to technology installed within the patient's home with the aim of improving their quality of life.¹⁵⁰ Alarm buttons or motion sensors are examples. This invasive type of health care provision invokes questions on how to deal with patients' rights such as spatial privacy in that case. The question is whether spatial privacy is still feasible when home telecare is provided. Another question invoked by home telecare is the question of liability in case of malfunctioning. This would make a topic for a study on its own.

Another category of eHealth is consumer eHealth, the type of eHealth where health professionals are not involved but manufacturers sell their products directly to patients or, more appropriate in this situation, customers.¹⁵¹ The question is whether applications for consumer

148 In accordance with Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

149 In accordance with Art. 3(b) ISMHO/PSI Suggested Principles for the Online Provision of Mental Health Services 2000.

150 Timmer 2011, p. 45.

151 RVZ 2015a, p. 20; Boersma & Vermunt 2015, p. 8 and RVZ 2015b, p. 12.

eHealth can be considered medical devices as meant in the Wmh and whether developers of such applications can be held liable if their use inflicts damage. Another question in this respect is related to patients' rights. Manufacturers of health apps are not health professionals and therefore the WGBO might perhaps not be applicable to the relationship between them and the patient because the criteria in Article 7:446 BW are not met. On the other hand, the concept 'health care provider' is usually understood in broad terms.¹⁵² It should be examined how the patient can be best protected in this situation.¹⁵³

In literature, some attention has already been paid to the safety and quality of eHealth care provision.¹⁵⁴ An example is the uses of medical apps. For medical apps that can be seen as a medical device for instance, a CE marking is required.¹⁵⁵ Although the question of what such a CE marking means in case of liability is interesting. It is worthwhile investigating who is liable for damage suffered during eHealth care provision.¹⁵⁶ Even when damage is caused by medical devices during regular health care provision i.e. health care without the application of eHealth, it is difficult to establish who is responsible and thus liable. There is no consensus about this issue in the case of eHealth.¹⁵⁷ The physician as well as the hospital can be held liable for either owning or utilising a medical device with a defect,¹⁵⁸ or based on tort.¹⁵⁹ When the defect is caused by a manufacturing error, the producer can be held liable.¹⁶⁰ eHealth will further problematise this debate because in this new form of health care provision, even more parties are involved. New questions such as the question of whether network operators can be held liable in case of damage caused by a power outage will arise. Moreover, the question of what is the role of manufacturers of eHealth applications in the case of damage should be investigated.

152 HR 12 March 2013, ECLI:NL:HR:2013:BY4859, *NJ* 2013/424, m.nt. Legemaate and Hulst, *TGMA* 2013, issue 2, p. 55-56.

153 Van der Mersch 2018 pays attention to this question. See also the reaction by Dute in: Dute, *ZIP* 2018, issue 3 p. 19-22. Authors agree that this topic should get attention.

154 Van der Meer and Nouwt 2011, p. 310-311.

155 Art. 2 Para. 43 MDR, Art. 20 MDR and annex V MDR. In order for a device to obtain a CE certification mark, a conformity assessment procedure has to be carried out first. See Art. 52 et seq. MDR. The MDR entered into force on 26 May 2017 (Communication from the Commission Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745 (*OJEU* 2020, C 171/01) and Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (*OJEU* 2020, L 130).

156 Ploem, *TvGR* 2008, p. 325-326 and Dans & Van der Vorst, *TvGR* 2008, p. 194-198.

157 See, for example, Spradley, *Tulane Journal of Technology and Intellectual Property* 2011, p. 323-330 and p. 332 on the situation in the United States.

158 Respectively Art. 6:173 in conjunction with Art. 6:181 BW and Art. 6:77 in conjunction with Art. 7:462 BW.

159 Art. 6:162 BW.

160 Art. 6:185 BW.

Another, complicating factor for patients' rights is cross-border health care. This will be enhanced by eHealth.¹⁶¹ Cross-border eHealth care is worth investigating because it is likely to gain importance in the future. Cross-border eHealth care can lead to questions other than eHealth as a national phenomenon. Although cross-border health care raises various questions, in academia the focus mainly lies on the issue of reimbursement of the costs of cross-border health care.¹⁶² Nevertheless, some authors mention the importance of a uniform regulation on cross-border health care¹⁶³ while others emphasise the need for interoperability of the various eHealth services in Europe.¹⁶⁴ Others describe the fact that Dutch as well as European legislation concerning eHealth is divided over distinct laws and regulations, but do not propose a uniform legal framework.¹⁶⁵

As a final remark, eHealth is under constant and continuous development. New applications are brought to the market on an almost daily basis. In the future, eHealth care provision will gain increasing importance. It is necessary to anticipate to this by researching patients' rights.

161 Callens & Cierkens 2012, p. 132.

162 Van der Meer & Nouwt 2011, p. 302-304.

163 Callens *TvGR* 2006, p. 275.

164 Van der Meer & Nouwt 2011, p. 312.

165 Van der Meer & Nouwt 2011, p. 311.



A golden scale of justice is shown in a faded, background style. A diagonal blue band with a wavy edge runs across the center of the image. The word "Appendices" is written in white, bold, sans-serif font on the blue band.

Appendices

SUMMARY

In recent years, the use of modern technology in healthcare has been increasingly in the news. The use of ICT to support and improve health and healthcare is called eHealth. Much is expected of eHealth, for instance, that it can make a positive contribution to the quality of care.

An example is online contact between doctors and patients through specially designed platforms that in some cases made it possible for patients to seek advice from a health professional who had not seen them before. This is not an isolated example and it shows that the use of eHealth raises legal questions, for example, about the protection of patients' rights.

There is a great variety of eHealth applications. For this study, a choice was made for three types of eHealth: e-consultation (online interaction between a physician and a patient), tele-expertise (two health professionals consulting each other over a distance by means of ICT) and telemonitoring (monitoring patients' health over distance by means of ICT). E-consultation, tele-expertise and telemonitoring are all forms of eHealth care provision: e-Health applications that relate to direct care to the patient.

The research question is:

How should patients' rights be applied in eHealth care provision and what are the challenges in this respect?

Patients' rights cannot be separated from the right to health. This study, therefore, examines the possible effects of e-consultation, tele-expertise and telemonitoring on the availability, accessibility, acceptability and quality of care provision. These criteria form the AAAQ framework and give further substance to the right to health. In addition, the application of individual patients' rights from the *Wet op de Geneeskundige Behandelingsovereenkomst* [Medical Treatment Act] (WGBO) to e-consultation, tele-expertise and telemonitoring is being examined.

This study consists of three parts. The first part contains an introduction to the study (chapter 1) and an exploration of eHealth (chapter 2) and patients' rights (chapter 3). Chapter 2 first provides an overview of some commonly used definitions of eHealth, after which a definition is chosen for the continuation of the study. Because eHealth and health are inextricably linked, an explanation is given of the concept of health and the different views regarding the content of that concept. In addition, the chapter contains a brief review of the history of eHealth and some related concepts. Lastly, eHealth is divided into different categories, which are explained by means of examples. Chapter 3 discusses the right to health and the rights

of the patient. In addition to the WGBO, international and European regulations that are important for patients' rights are discussed. Moreover, attention is paid to the General Data Protection Regulation (GDPR).

The second part deals with the right to health and individual patients' rights with regard to the e-consultation (chapter 4), tele-expertise (chapter 5) and telemonitoring (chapter 6). These chapters start with an analysis of the possible effects of the relevant type of eHealth care provision on the right to health based on the AAAQ framework. Subsequently, the applicability of the WGBO to e-consultation, tele-expertise and telemonitoring is discussed. This is done by means of the question whether a contract for provision of medical services is established with the application of this type of eHealth care provision and, if so, who the parties of such a contract are. Subsequently, the rights to informational and spatial privacy, the right to medical confidentiality and the right to informed consent are discussed. Attention is also paid to the GDPR.

The third part contains the conclusion (chapter 7). The chapter starts with the answers to the sub-questions, after which recommendations are made. The chapter closes with recommendations for further study.

SAMENVATTING

De afgelopen jaren is het gebruik van moderne technologie in de gezondheidszorg steeds meer in het nieuws geweest. Het gebruik van ICT ter ondersteuning en verbetering van gezondheid en gezondheidszorg wordt eHealth genoemd. Van eHealth wordt veel verwacht, onder andere dat het een positieve bijdrage kan leveren aan de kwaliteit van zorg.

Een voorbeeld is het online contact tussen artsen en patiënten via speciaal daarvoor ontworpen platforms die het in sommige gevallen mogelijk maakten voor patiënten om advies te vragen aan een zorgverlener die hen nog niet eerder had gezien. Dit voorbeeld staat niet op zichzelf en laat zien dat het gebruik van eHealth juridische vragen oproept, bijvoorbeeld over de bescherming van patiëntenrechten.

Er bestaat een grote verscheidenheid aan eHealth toepassingen. Voor dit onderzoek is een keuze gemaakt voor drie vormen van eHealth: het e-consult (online contact tussen patiënt en zorgverlener), tele-expertise (online contact tussen zorgverleners met betrekking tot de zorg voor een patiënt) en telemonitoring (monitoring door de zorgverlener op afstand met behulp van ICT). E-consult, tele-expertise en telemonitoring zijn alle drie vormen van e-zorgverlening: eHealth toepassingen die zien op directe zorgverlening aan de patiënt.

De onderzoeksvraag is:

Hoe moeten patiëntenrechten worden toegepast tijdens e-zorgverlening en wat zijn de uitdagingen in dat opzicht?

Patiëntenrechten kunnen niet los worden gezien van het recht op gezondheid. In dit onderzoek wordt daarom gekeken naar de mogelijke effecten van het e-consult, tele-expertise en telemonitoring op de beschikbaarheid, toegankelijkheid, aanvaardbaarheid en kwaliteit van zorgverlening. Deze criteria vormen het *AAAQ-framework* en geven aan het recht op gezondheid een nadere invulling. Daarnaast wordt gekeken naar de toepassing van individuele patiëntenrechten uit de Wet op de Geneeskundige Behandelingsovereenkomst (WGBO) op het e-consult, tele-expertise en telemonitoring.

Dit onderzoek bestaat uit drie delen. Het eerste deel bevat een inleiding op het onderzoek (hoofdstuk 1) en een verkenning van eHealth (hoofdstuk 2) en patiëntenrechten (hoofdstuk 3). In hoofdstuk 2 wordt allereerst een overzicht gegeven van de verschillende definities van eHealth, waarna een definitie voor het vervolg van het onderzoek wordt gekozen. Omdat eHealth en gezondheid onlosmakelijk met elkaar verbonden zijn, wordt een uiteenzetting van het begrip gezondheid en de verschillende opvattingen met betrekking tot de inhoud van dat begrip gegeven. Daarnaast bevat het hoofdstuk een korte beschouwing van de

geschiedenis van eHealth en enkele verwante begrippen. Tot slot wordt eHealth ingedeeld in verschillende categorieën, die worden toegelicht aan de hand van voorbeelden. In hoofdstuk 3 worden het recht op gezondheid en de rechten van de patiënt besproken. Naast de WGBO worden internationale en Europese regelingen die van belang zijn voor de rechten van de patiënt besproken. Daarnaast wordt aandacht besteed aan de Algemene Verordening Gegevensbescherming (AVG).

In het tweede deel wordt ingegaan op het recht op gezondheid en individuele patiëntenrechten met betrekking tot het e-consult (hoofdstuk 4), tele-expertise (hoofdstuk 5) en telemonitoring (hoofdstuk 6). Deze hoofdstukken vangen aan met een analyse van de mogelijke effecten van de betreffende vorm van e-zorgverlening op het recht op gezondheid aan de hand van het AAAQ-framework. Vervolgens wordt ingegaan op de toepasselijkheid van de WGBO op het e-consult, tele-expertise en telemonitoring. Dit wordt gedaan aan de hand van de vraag of er bij de toepassing van die vorm van e-zorgverlening een geneeskundige behandelingsovereenkomst ontstaat en zo ja, tussen welke partijen. Daarna wordt steeds ingegaan op het recht op informationele en ruimtelijke privacy, het medisch beroepsgeheim en het recht op informed consent. Er wordt ook aandacht besteed aan de AVG.

Het derde deel bevat de conclusie (hoofdstuk 7). Het hoofdstuk vangt aan met de beantwoording van de deelvragen, waarna aanbevelingen worden gedaan. Het hoofdstuk sluit af met enkele suggesties voor nader onderzoek.

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Rb. Noord-Nederland 19 September 2014, ECLI:NL:RBNNE:2014:4489, *NTHR* 2014, issue 6, m.nt. Ernes, p. 301

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Regional disciplinary tribunals for the health care sector

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Regionaal Tuchtcollege voor de Gezondheidszorg Amsterdam 26 November 2006, 05/140, *JGR* 2007/34, m.nt. Schutjens

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PORTFOLIO

Publications

I. Bakx, 'Een zwarte lijst voor zwarte scenario's?' *RGD Magazine* 2015, issue 1, p. 24-34

F. Kokabisaghi, I. Bakx & B. Zenelaj, 'The Right to Mental Health in the Digital Era', *ELR* 2016, p. 146-160

I. Bakx, 'Ouderen en eHealth', *RGD Magazine* 2017, issue 2, p. 34-39

Teaching activities

Bachelor Health Policy and Management

Gezondheidsrecht – Workgroup teacher 2017-2018

Premaster Health Policy and Management

Gezondheidsrecht – Workgroup teacher 2017

Master Health Law

Thesis supervision 2014-2016

Kwaliteit van de Gezondheidszorg – Guest lecture 2015

Kwaliteit van de Gezondheidszorg – Guest lecture/workgroup 2016-2018

Conference presentations

Presentation at 'E-health: Grand challenges and Legal Concerns': 'eHealth and patient rights – a few challenges addressed', The Erasmus Observatory on Health Law, Erasmus University Rotterdam, the Netherlands, 2014

Presentation at 'Health Law and Cross Border Health Care in Europe' – 5th Conference of the European Association of Health Law: 'The right to (mental) health in the digital era' Prague, Czech Republic, 2015

Conferences attended

Symposium on the Influence of Cyberspace on Communication between Citizens – The Netherlands Institute of Human Rights (SIM), Utrecht University, the Netherlands, 2014

World Health Care Forum, World Forum, the Hague, the Netherlands, 2015

Najaarsvergadering 2017, ‘Het recht op zorg: de kosten van solidariteit en de prijs van de gelijkheid’, Vereniging voor Gezondheidsrecht, Rotterdam, the Netherlands, 2017

Lustrumvergadering 2018, ‘Nieuwe techniek, nieuwe zorg’, Vereniging voor Gezondheidsrecht, Rotterdam, the Netherlands, 2018

Congres, ‘eHealth, een blijvende belofte of realiteit? Wat betekent het voor arts en patiënt?’, KNMG District Zuidoost-Brabant, Eindhoven, the Netherlands, 2018

CURRICULUM VITAE

Iris Bakx (Nederlek, 8 November 1988) obtained her *VWO-diploma* (pre-university education) at the Krimpenerwaard College in Krimpen aan den IJssel. She holds a master's degree in Health Law (2013) and a master's degree in Private Law (2013). During her studies she was a student assistant at the Sanders Law Library. Moreover, she was involved in the foundation of the *Nieuwsblad RGDspuut* (now: *RGD Magazine*), the Magazine of the Rotterdam Health Law Students' Association. From 2014 until 2018 she held a PhD position in the department of Law & Health Care at Erasmus School of Health Policy & Management (ESHPM). From 2014 until 2017 she was a board member of Young ESHPM, an organization for PhD Candidates within ESHPM. Currently, she is a lecturer at Erasmus School of Law. In this position she guides workgroups for LL.B. students.

The use of modern information- and communication technology (ICT) to support and improve health and health care, known as eHealth, will inevitably play a role in health care provision in the future. It is impossible to imagine life today without ICT. This applies to health care provision as well.

This book elaborates on the application of patients' rights in health care provision by means of eHealth by discussing three types of eHealth care provision: e-consultation, tele-expertise and telemonitoring. Attention is paid to eHealth care provision's potential to contribute to the realisation of the right to health for everyone. For this purpose, opportunities and obstacles for eHealth care provision to contribute to the availability, accessibility, acceptability and quality of health care are discussed. Subsequently, the application of the rights to informational and spatial privacy, the right to medical confidentiality and the right to informed consent on e-consultation, tele-expertise and telemonitoring is presented.