

# eHealth, eLaw and ethics

WHICH CHALLENGES ARE WE FACING IN 2019?

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## Introduction

In the last decade, eHealth has increasingly been adopted by the Dutch healthcare system. During this process, it has become clear that the application of digital health technologies is not the end, but the means to provide better care. eHealth can, for example, contribute to making healthcare more secure, efficient and personalised. However, the implementation of eHealth in the daily clinical practice does not always run smoothly. The Dutch annual eHealth monitor, published by the Dutch Healthcare Research Institute (NIVEL) and the National Healthcare ICT Institute (Nictiz), showed that technical problems hinder the implementation of eHealth, but they are only part of the issue.<sup>1</sup> Other factors, such those related to ethics and legal compliance, also play a significant role. However, the specific challenges in these fields are not completely clear yet. To identify these challenges is a valuable asset for establishing future strategies and for finding solutions and new opportunities. In general terms, it may facilitate a more efficient and broader implementation of eHealth. Although there is wide expertise in the field of digital health, it is fragmented across the country. The goal of the National eHealth Living Lab (NeLL) is to bridge the scattered strengths to efficiently work together in building the healthcare of tomorrow.

### Expert Meeting

NeLL gathered fifty experts in the field of clinical implementation of eHealth to jointly explore which ethical and legal challenges are currently being faced. The meeting was held on March 18, 2019 in Leiden, the Netherlands.

The dialogue took place in three separate focus groups, comprised of fifteen to twenty experts. Each focus group was assigned one of the three main topics:

1. responsibility and liability;
2. governance and privacy;
3. good use of eHealth.

The topics were intended to serve as a guide, but it became evident that the challenges are broad and in some cases, they inevitably encompass more than one topic.

To facilitate the discussion, each group was assigned a moderator and an observant. The moderator introduced the topics through casuistry. Together, the experts formulated the most relevant challenges per subject. At the end, a plenary session was held to present the most important findings regarding the three topics to all participants.

### Follow-up

This first Expert Meeting will be followed by several follow-up activities. The final goal is to share the knowledge generated during this process and to make it accessible through scientific publications. In parallel, there are plans to engage in other strategies to reach a wider public, for example through the formulation of 'golden rules' or 'guidelines' for eHealth.

### This report

This report summarises the most important challenges identified during this first Expert Meeting.

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<sup>1</sup> Wouters M., et al. (2018). eHealth at different speeds. A brief outline eHealth-monitor 2018. Nictiz en het Nivel. <https://www.nivel.nl/nl/publicatie/ehealth-different-speeds-brief-outline-ehealth-monitor-2018> (English version), <https://www.ehealth-monitor.nl/wp-content/themes/nictiz/assets/pdf/ehealth-monitor-2018.pdf> (Dutch version).

## Topic 1: Responsibility and Liability

- Regarding the clinical practice, there seem to be inconsistencies between the daily practice and the (legal) theory; such as in the case of informed consent. For example, the Medical Treatment Agreement Act of the Civil Code (WGBO), which regulates the patient-doctor relationship, recognises among others, the patient's right to be informed and establishes the obligation and conditions to obtain informed consent. In practice however, clinical consultations are limited to ten minutes and informed consent as strictly as established in the WGBO, is difficult to obtain for each topic discussed with the patient and for each treatment.
- When an eHealth application is adopted, the distribution of responsibility among the different players involved (patient/consumer, healthcare professional, manufacturer) is not always clear. This issue is also relevant regarding the use of digital health within a healthcare relationship.
  - Should a difference be made between a service that is provided to a consumer (mostly happening in a private context) and healthcare provided to a patient (mostly happening in a healthcare context)? Do different legal frameworks apply to these two scenarios? Should other types of 'care relationships' be defined by the Dutch Medical Treatment Agreement Act?
  - Can/should a manufacturer of a digital health tool be considered a 'care provider' in some cases?
  - When adopting an eHealth application, who is responsible for supervising and analysing the stream of data generated? When speaking about responsibility, should there be a distinction between acute care, chronic care, or lifestyle coaching?
  - How could responsibility be efficiently established for all parties involved, e.g. through a contract or a general protocol?
- Software's explainability is still a challenge (specifically in the field of artificial intelligence, where this is also known as the 'black box problem'). However, the challenge generated by the lack of explainability is not necessarily new in healthcare. For example, the mechanism of action of many currently-used medicines is not completely understood.
  - In the face of eHealth systems with low explainability, how can all parties involved act responsibly?
- In the case of the use of algorithms and AI in healthcare, are there acceptable margins of error?
- Within a care relationship, shared decision-making is key for the implementation of digital health.
  - In order to achieve the successful implementation of eHealth, it is necessary to improve patients' and physicians' eHealth literacy.
    - To be entitled to a higher level of responsibility, patients need first to understand their data and the implications of its use. Where, how and from whom can patients get this knowledge?
  - Since there are different kinds of patients, how can a healthcare professional evaluate if a patient can appropriately use eHealth? Should patients be 'certificated' as 'suitable' to use a particular eHealth application?
  - Patients and healthcare professionals have expectations about eHealth. These expectations need to be explicitly discussed, before the adoption and during the care pathway. On a similar regular basis, it is important to evaluate the use of eHealth. What is the best way to carry out these assessments?
  - Also related to *Topic 3: Good use*.
- To implement eHealth in clinical practice, it is desirable to discuss the case or the business case with a legal expert and an ethicist, but these inquiries do not always take place. There may be scenarios when this recommendation may be unnecessary; for example, when the healthcare institution has a lot of experience with similar eHealth applications. Where can healthcare institutions find the knowledge they need in an efficient and timely way?

## Topic 2: Governance and privacy

- The legal frameworks and ethics regarding governance and privacy of eHealth are complex. There is a great demand for guidance, practical examples and support with the interpretation of these frameworks. In the field of eHealth, the feeling of legal insecurity sometimes leads to favouring the establishment of more and clearer rules. However, more rules do not necessarily improve the practical situation and can end up causing more harm than good. It is therefore necessary to find a balance in this regard quickly.
- The demand for guidance and interpretation of legal and ethical frameworks regarding eHealth seems to be (at least partially) the product of a gap of knowledge and/or fear of making a mistake, being held accountable or being fined. These same challenges are faced regarding the use of personal data and privacy protection.
  - Knowledge about legal frameworks and guidelines is often fragmented and it has become a challenge to bridge fields in order to learn from each other.
- A frequent issue is that efficient and clear governance systems for eHealth are still missing. For example, at an organisational level, adequate guidance and appropriate internal knowledge platforms are essential when adopting eHealth. Additionally, changes in the working practices and procedures are often necessary, which require the appropriate organisational support to guarantee an efficient adoption of eHealth.
- The decision-making systems based on health data need to generate and deserve consumers' and patients' trust.
  - In this regard, the 'bio-power' threat of digital giants such as Google and Amazon needs to be taken into account. The power held by these companies originates from the massive generation, storage and processing of data.
  - Ownership of personal data needs to be clearly established, giving certainty to all parties involved and giving clarity to their expectations.
    - Attention must be paid to the guarantees that are generally clear to data managers, but not always to consumers/patients (e.g. professional secrecy and right to silence).
    - Promote and guarantee patient empowerment.
  - The interchange of health data (how, with whom, when, for how long, etc.) needs to be clear to all parties involved, especially for consumers/patients.
  - According to the legal frameworks, the use of data for scientific research is allowed. Furthermore, under special conditions it is possible to use health data for scientific research without consent of the data subjects (e.g. when research is carried out for the greater good and 'disproportionate effort' is necessary for obtaining consent).
    - However, the conditions under which the use of personal health data is allowed to be used, are not always clear to researchers, and patients/consumers.
- How to balance the different forces and interests that are used to claim ownership of digital health data, or used to justify the right to process sensitive data?
- It is necessary to strive for reliable and good-quality data for eHealth (also related to *Topic 3: Good use*).
- When developing an eHealth application, how much data do we want and which data are we allowed to collect?
- From a purely legal point of view, it seems that legal frameworks suffice to regulate the use of personal data; as long as the conditions of collection, storage and processing are clearly established from the beginning. In practice however, it is still very complex to comply with the legal frameworks.

### Topic 3: Good use

There are challenges at different levels regarding the 'good use' of eHealth.

#### Devices and data

- It is necessary to strive for reliability and good quality of data, especially when used for:
  - provision of healthcare;
  - research purposes;
  - development of new digital health applications (e.g. for training deep learning systems).
- It is necessary to ensure data protection during storage, processing and use of personal data. Moreover, privacy must be guaranteed, and governance and ownership must be clearly established for all parties.
- The Medical Device Regulation will be effective shortly. The new Regulation represents a challenge because its content and related procedures are not simple nor clear for all parties. To improve this situation, simple and practical guidelines need to be produced and to be made accessible. These practical guidelines will be key for overcoming barriers that hinder the safe and evidence-based implementation of digital health applications in the daily clinical practice.
- Also related to *Topic 2: Governance and privacy*.

#### Infrastructure

- The sharing of patient data among healthcare providers, and between healthcare providers and patients is not optimal yet.
- Neither is the use of an interoperable and standard data language across the healthcare system the norm (e.g. the language used for recording the electronic medical records, which can be used to train algorithms).<sup>2</sup>

#### Professional

- Healthcare professionals often lack the right knowledge and skills to apply digital health in clinical practice, for example regarding:
  - practical knowledge (e.g. how does making an electrocardiogram via a smartwatch work?);
  - joint decision-making (e.g. how to decide together with a patient if he/she is capable of monitoring his/her heart rate at home?, what has to be taken into account by patient and physician to make this decision?, which advice needs to be given to the patient?);
  - data custody/governance.
- Additionally, healthcare professionals often lack the knowledge and skills to appropriately deal with massive amounts of data that are generated outside their own institution, or with data that is not generated with standard devices. For example, could we consider reliable the data generated at home by a patient with his/her own device that was purchased online? Could the use of consumer-driven eHealth devices cause a redundancy of efforts? If this is the case, is this an efficient use of resources?

#### Patient

- eHealth should not be imposed to patients, but it must be a choice instead (at least for the time being).
- Patients do not always have the right knowledge and skills to make use of digital health tools, for example, regarding:
  - practical knowledge (e.g. how does a blood pressure monitor work?);

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<sup>2</sup> SNOMED works tackling this issue.

- medical knowledge (e.g. which factors are relevant for taking one's own heart rate at home?);
- governance of one's own personal data, including practices to protect privacy.
- How can patients access the relevant information/knowledge they are lacking regarding eHealth?

#### Healthcare

- Attention must be paid to avoid eHealth leading to 'over-treatment'.
- The doctor-patient relationship may be influenced by the adoption of digital applications in healthcare.
- The access to healthcare, an important right in the Netherlands, needs to be continuously reviewed in order to be efficiently protected. For example, how to overcome low literacy, limited digital skills and language barriers? How could we, with the help of digital health, strive for patient empowerment in all layers of society?
- There is still no textbook example of 'good use' of eHealth. When is the application of digital health 'good'?
  - To pin down the practical meaning of good use of digital health, more and clearer practical examples of eHealth in the clinical practice need to be studied and shared. These examples will potentially serve as the basis to facilitate other eHealth initiatives and the appropriate implementation of eHealth.