

Electronic information for health and care services

Are we getting better?

Michiel Sprenger, PhD

LAWS & REGULATIONS

ORGANISATION POLICY

CARE PROCESS

INFORMATION

APPLICATION

IT INFRASTRUCTURE

Foreword

Physicists always strive to create structure in what might seem to be a confusing reality. My training ground was solid state physics, in which we try to discern the structure and chaos put there by nature herself. In 1986 I switched to a university hospital, where I was able to use my structuring skills for MRI, which was then a brand-new medical technology in healthcare. A technology that went on to more than fulfil its initial promise. Within that environment I also encountered aspects of healthcare other than the purely physical and technical ones, including care processes and decision-making, the structure and order of which were not immediately obvious to me. When I later became closely involved in clinical informatics it became clear to me that that this profession had even more variables and more types of people involved than those in medical technology. This fascinated me greatly and my move to the Dutch national centre of expertise for eHealth (Nictiz) in 2008 was certainly largely inspired by this complexity, which plays a major role at national level. Nictiz had just started to position itself as a centre of expertise for information solutions in health and care services, in addition to its development role for a national infrastructure. That expertise role also took me to the European level, where the number of variables can be even greater. In addition, it felt like a very logical step to me, along with others, to take the initiative and create the Clinical Informatics postmaster educational program at the Eindhoven University of Technology, where people are trained to work effectively within the complex reality of care institutions. They are trained to build bridges, to bring people together and to create order and understanding.

In this report I have tried to explain, as briefly and accessibly as I can, what I have learned and developed, mainly intended as a methodological contribution. A contribution for all those who have the task of developing, implementing, managing and evaluating complete and future-proof information solutions. To serve as an aid in realising the great expectations that exist about the use of electronic information for health and care services. A prominent part of my contribution is the Layer Framework, which facilitates the structuring process. For creating solutions within institutions and creating transparency across institutional boundaries. And, above all, to finally strengthen the position of the citizen when interacting with healthcare providers.

Naturally, I did not do this all by myself. Everyone stands on the shoulders of others and, together with many colleagues at home and abroad, lends their support to others in turn.

Michiel Sprenger

The Hague, June 1st, 2019

Contents

1	Introduction	8
1.1	Electronic information for health and care services: a world of expectations	8
1.2	Complexity	8
1.3	A short historical overview	9
1.4	Preview of this report	12
2	Expected benefits	13
2.1	For better equipped health professionals	13
2.2	For continuity of care	13
2.3	For better informed patients	13
2.4	For a better analysis of the situation in which (public) health and care services operate	13
2.5	For better business operations within the health care system	14
2.6	For economic activities related to healthcare	14
3	Structuring: The Layer Framework	15
3.1	The Layer Framework as a structuring tool over six areas	15
3.2	Why these layers?	16
3.3	Scaling	17
3.4	Vertical coordination between layers	18
3.5	The concepts of interoperability & intra-operability	19
3.6	Horizontal coordination between the domains	20
3.7	Information security	21
3.8	The international situation of the Layer framework (ReEIF in Europe)	22
4	Required agreements per layer	23
4.1	The importance of agreements	23
4.2	The care process as the core	23
4.3	Administrative agreements	24
4.4	Laws and regulations for setting out rights and obligations	24
4.5	The information layer as an important link to the care process	24
4.6	Applications and IT infrastructure	26
5	Governance in the light of the Layer Framework	27
6	Recommendations	30
6.1	Broad use of the Layer Framework	30
6.2	Design administration from the perspective of health and care policy	30
6.3	Increase attention for the information layer	30
6.4	Ensure that technical complexity can be controlled in broad outline	31
6.5	Design and implement the expertise function for horizontal and vertical coordination	31
7	Final word	32

1 Introduction

1.1 Electronic information for health and care services: a world of expectations

As technology advances, expectations about the many ways that the transition to digital information could benefit the health and care of patients and citizens have grown sharply. These benefits all arise directly or indirectly from the differences between digital information and the traditional forms of paper-based information. Put briefly, digital information can be:

- communicated on a large scale and in a finely branched network with many end points, partly due to the rise of the Internet, smartphones and tablets;
- shared instantaneously;
- edited in a multitude of devices, with a rapidly growing range of software;
- analysed at individual level and at group level.

These four properties create possibilities we could only dream of 30 years ago.

However, in real life things move more slowly, and to date not all the theoretical advantages of creating information electronically have been achieved in real-world situations.

This report discusses the progress made in recent years and indicates where further progress can be made, with focus on the methodology for creating clinically correct and desired solutions.

1.2 Complexity

It is often argued that healthcare does not progress as fast as other sectors, e.g. finance, travel and retail. In order to better understand the situation, it is worth noting several impacting issues:

- The **data model** for health and care services is extremely complex. By way of illustration, the number of concepts that are used to describe the human body, its illnesses and the actions we take in response runs into the many hundreds of thousands. In addition, while some parameters are more or less fixed (body height in adults), others are subject to strong fluctuations - often over the course of a single day or even less - such as body temperature or the glucose level in the blood. Further, the real meaning of many parameters depends heavily on the context.
- The most important actor is, of course, the **citizen/patient**. However, health and illness are strongly interwoven in the existence of the individual. As a result, it is not always possible for the individual citizen/patient to distance themselves sufficiently to make well-considered decisions. In other words, as a result of being ill you may become nervous, you start worrying, or, worse, the psychosomatic

aspects of diseases can obstruct good judgement directly. Culture also plays a role here as it has not been customary for patients to be actively involved in decisions about their own health. Access to information gives the citizen opportunities they have not yet learnt to fully use.

- Healthcare is characterised by the fact that many, often highly skilled, **professionals** are active in the direct implementation of care. These professionals have a high degree of autonomy. This professional autonomy is also necessary in healthcare as its complexity requires the judgment of the highly skilled professional to be applied on top of protocols. The action taken can therefore deviate from the protocol. Every such a deviation must then be documented separately.
- The **organisation** of healthcare is complex in all countries and varies widely. For instance, in the Netherlands healthcare is carried out by a large number of private-law organisations. They are not subject to direct hierarchical control from larger associations or the various levels of government. This makes it hard to manage collaboration, and agreements must be made by consensus. But in other countries where more direct control seems to be present, other complexities exist, e.g. due to the existence of largely independent regions or provinces in countries like Sweden, the United Kingdom and Spain.

1.3 A short historical overview

Electronic information first entered the world of healthcare in the 1970s. Back then it was not yet possible to separate information from systems. The systems were still primitive, mutual exchange was in its infancy and there was no Internet. In addition, the systems could not yet be flexibly configured to meet the needs of the users and institutions. The focus was on hospitals and the applications were mainly in the **business aspects** of the hospital, namely patient administration, invoicing and internal logistics. In short, the systems were mainly for administrators and managers.

Between 1990 and 2005, a second focus was added: attention was given to **healthcare-related information** for use in the care process itself. In the hospitals, this involved storing and distributing, for example, electronic images and laboratory data. That is, directly supporting professionals in carrying out their tasks. There was also a strong growth in these types of systems outside the hospital sector, such as in general practitioners' practices and pharmacies. Around the turn of the millennium, the term Electronic Health Record, EHR, came to be widely used for these institution-based, professional-oriented systems. This term is often still used, despite the fact that it refers to many different applications. It is certainly not just a record system, but rather the electronic work environment for the professional. Only recently (2010-2018) has there been a large wave of investment in the hospital world for implementing

modern EHR systems, however, the potential for exchanging information between institutions has never been an important motive for these implementations.

Nevertheless, around the year 2000 there was a strong focus on the **exchange of information**. It came to be realised that when we refer patients more and more often, especially for diagnostics and specialised treatment, it will in many cases be necessary for the information to 'accompany' the patient. When institutions change over to electronic information provision, the electronic transfer of data between these institutions is also required. This awareness was reinforced by the attention that was given to activities that go further than referral, namely multidisciplinary care (also known as network care) for patients, in particular those with chronic conditions such as diabetes and chronic obstructive pulmonary disease (COPD). This is referred to as 'Continuity of Care'. In short, the fact that there are physical and organisational boundaries between specialisms and institutions should not be an obstacle to achieving continuity of care. In most of the European countries the government has stimulated or developed "National Infrastructures" of different kinds for the health systems. In the Netherlands, there are many institution-transcending initiatives managed by organisations that promote cooperation between healthcare institutions. The attempt to channel many of these types of activities through a single national, government-led network ran aground in the Senate in 2011, which rejected the law that was needed to facilitate this. In particular, the active role of the government was rejected. Since then, a multitude of non-government-led initiatives have been developed to promote mutual cooperation via the use of digital information. Coherence between all these initiatives is not automatically guaranteed, and actions should be started to link those initiatives. This process may take many more years in the Netherlands, but also in other countries, even in those with central steering possibilities.

Since about 2008, attention for the **individual patient** has grown considerably. This is first and foremost the result of a societal trend: more assertive citizens want to be informed about their situation, decide for themselves on matters that affect their health and care and, increasingly, want to be seen as equal participants in the care process, in some cases even to have the main role in it. Since about ten years ago, this effort has been strongly supported by people's expectations of digital information. As a result, the patient, who is naturally not part of a care organisation, can always stay up to date. Digital information can also help the patient to fulfil many more roles, representing a real modernisation of the care process. Think, for example, of self-measurements and the patient's own observations and findings. This type of active involvement of the patient in their interaction with the care provider also fits

in well with the patient orientation that is one of the objectives of many healthcare institutions.

To conclude this historical overview: for many years the healthcare sector, along with governments and supervisory bodies, has needed the ability to **analyse** what is happening in the health and care sectors. These analyses go beyond the individual patient case and deal with groups of patients. The most important goals that are mentioned are quality of care, epidemiology, scientific research and accountability. These analyses should facilitate not only optimisations (small scale) but also innovations (large scale) in care processes. Again, expectations are strongly driven by the fact that healthcare has switched to using electronic patient information. So, in theory combining information from the EHRs of hospitals, for example, is a very powerful tool. However, this exposes all kinds of limitations, mainly due to insufficiently standardised information. Much attention has been paid to this issue in recent years as a result of the growing number of initiatives in these areas. The limitations are mainly due to the fact that these analyses are often not possible with one-off registration in or near the care process, and thus lead to separate registrations for specific purposes. That leads to a heavy registration burden for healthcare providers.

Figure 1 gives a schematic representation of these four areas, which have grown historically and are still under development.

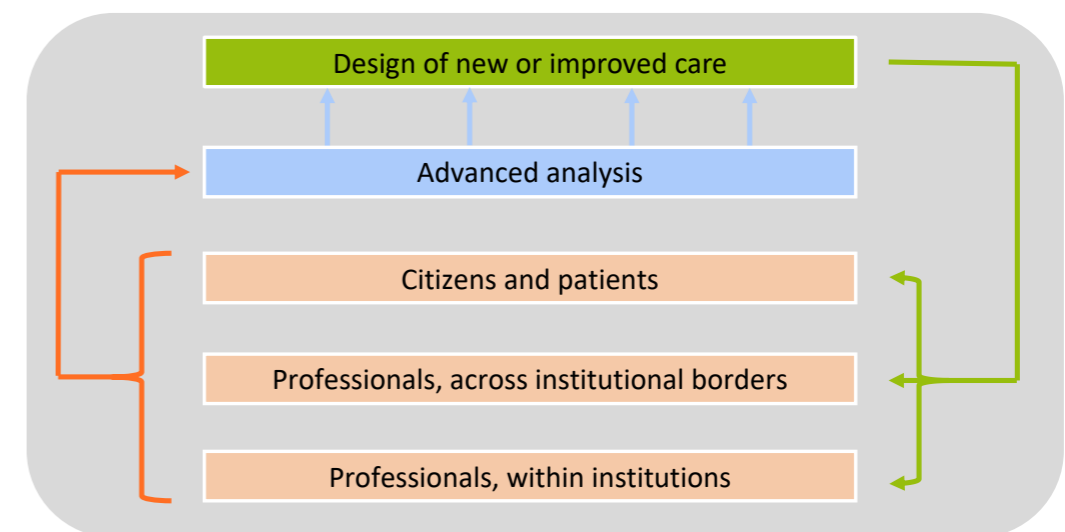


Figure 1 Information-driven healthcare system and historical overview.

1.4 Preview of this report

Section 2 discusses the expectations of various groups of actors involved. Sections 3 to 6 contain guidance for ways to meet these expectations. The Layer Framework is described in Section 3. This is a way to structure the complexity, that helps people to reach joint solutions on all facets and to provide a conceptual framework for this. Section 4 provides an overview of the types of agreements that have to be made within this conceptual framework. Section 5 offers guidance for the development of governance. Finally, Section 6 gives several recommendations for the way forward.

2 Expected benefits

This section describes the expectations in a number of areas and for a number of stakeholders in the field of electronic information for health and care.

2.1 For better equipped health professionals

The health professional is increasingly working in a field in which information plays a crucial role. Not only is the amount of literature published as knowledge increasing, patient care is being documented more and more consistently. In addition, there is an increasing demand for transparency and communication. Electronic communication will be needed to deal with this. Furthermore, the increasing quantity and variety of information leads to the need for intelligent processing to protect the professionals from overload and chaos.

2.2 For continuity of care

The developments needed to achieve continuity of care for the patient also require electronic communication of data and agreements. The traditional methods of communication are inadequate. Two things are important here: the information from one party must reach the other party. This requires a mechanism by which the information reaches both the computer and the person. Furthermore, the aim must be to ensure that meaning is preserved. Both the person and the computer receiving the information must be able to understand it in the way intended by the sender. In addition, the information must be processed at the receiving side in such a way that there is real continuity.

2.3 For better informed patients

From the patient's perspective, any ideas about being empowered only make sense if the patient and the health professional have mutually meaningful electronic communication. It also requires the patient to be connected to sources of knowledge about health and care, and these naturally need to be in a form and with content that is actually useful to the patient. It is then essential that the patient is accepted as a (self) care provider. It is also very important to healthcare providing institutions that the information they provide is quickly available and easily accessible to their patients, so that the specialised professional information reaches the media-wise citizens as quickly as the general online information from the outside digital world.

2.4 For a better analysis of the situation in which (public) health and care services operate

Insight requires analysis and analysis requires the availability of data. Electronic information is the only way. This is usually structured information (recorded in

care processes, for example), collected in registers. In some cases, less structured information is used. Often collected for a different purpose and used for analysis of care and health. This last area is called 'big data analysis'. Whereas big data analysis reveals unexpected perspectives and connections, but lacks individual precision, structured data provides a lot of precision. Provided that standards have been met beforehand.

2.5 For better business operations within the health care system

In addition to high ambitions, there are many concerns about the future of the healthcare system. Affordability, staff shortages and aging are common issues. Solutions are being sought that involve more activity on the part of the patient and their relatives and shifting care from expensive institutions (hospitals, etc.) to cheaper institutions (general practitioners' practices etc.) or to the home environment. This increasingly separates the patient from the location of the expert and from where the equipment is. Electronic information is also a precondition for the necessary flexibility to implement these changes.

2.6 For economic activities related to healthcare

Obviously, a great deal needs to be done to meet all these expectations, all of which generates economic activity. Of the greatest importance are:

- **Software** for healthcare. A lot of software is needed, for professionals, patients, for communication and for analysis. Moreover, a strong diversification of hardware takes place: Not only PCs and workstations within institutions and at home, but also software on mobile platforms, smartphones, tablets and wearables. There is also a growing market in software as a tool that lets the patient manage their own health.
- There is a great variety of **medical equipment** coming to the market, for professionals and citizens both, which needs to be integrated into the electronic environments.
- Various **services** come into the picture, for professionals and patients, for advice, analysis, trend watching, and more.
- **Consultancy**: to cope with the growing complexity, governments, institutions and other organisations increasingly need specialist advisors, especially for issues related to organising information solutions.

These business opportunities can be seen not only as opportunities for the domestic markets, but also for international trading.

3 Structuring: The Layer Framework

The field of health and care and, more specifically, the way that information is handled within it, is a complex area involving many responsibilities and interests. It has been known for years that proper and consistent analysis, discussion and design in this area require structure. The Layer Framework for information solutions is a model designed for this purpose within the health and the care domain. This framework accommodates concerned actors, their responsibilities and relationships, and hence facilitates structuring. This section will offer a short description of this framework, which was co-designed by Nictiz and is embedded in European developments.

It is not, in itself, a new framework. These frameworks have existed in one form or another for some years now, but their refinement and the focus on care and European convergence has largely been initiated by Nictiz.

3.1 The Layer Framework as a structuring tool over six areas

In the following we use the term 'information solution' for the situation within an organisational unit where care provision is supported by and/or based on electronic information. The term 'organisational unit' could refer to anything from a hospital or GP practice to a region or country. To develop an information solution of this sort, it is necessary to develop and coordinate matters in the following six areas:

1. **The laws and regulations** of the jurisdiction under which the organisation falls. The bodies responsible for these include governmental and supervisory authorities.
2. **Policy, management and administration** within the organisational unit, hereafter referred to, in brief, as 'organisation policy'.
3. **Care processes** within the organisational unit.
4. **Information** required to support the care processes, including the way it is structured and coded and how types of information relate to each other. What information do persons and devices need and what can they deliver.
5. **Applications** that store, structure, process, analyse or communicate information.
6. **IT infrastructure**, which provides the technical base on which the applications operate.

Figure 2 gives an overview of this layering and identifies the most important actors within those layers. It shows a (grey) box constituting the organisational unit, which contains the aspects that projects for generating solutions need to work on. This immediately implies a special position for the 'Laws and regulations' layer, which, as shown in Figure 2, sometimes lies within the box and sometimes outside it. A project

within a hospital, for example, will start with the policy of the Executive Board (EB) or its delegates. In a project of that type, laws and regulations constitute a fixed precondition and therefore fall outside the scope of action. By contrast, a national government considering solutions for the entire country is able to change laws and regulations as needed. In cross-border projects, any necessary harmonisation of laws and regulations between the countries will effectively form part of the project itself. For this reason, the framework generally used within countries is the Five-Layer Framework, while the Six-Layer Framework is almost always used at European Level. As stated, in the Five-Layer Framework, laws and regulations form an external precondition alongside any other preconditions, such as financing.



Figure 2 A graphical representation of the Layer Framework. Left: In six layers, including laws and regulations, for national and international context. Right: In five layers. Because laws and regulations lie outside the scope of action, they form a precondition for use by organisations within a country.

3.2 Why these layers?

Worldwide there are various types of structuring frameworks of this sort. We will briefly explain why we chose this particular framework for healthcare in the Netherlands and Europe. First, the laws and regulations. Many countries have laws specifically dealing with aspects of how information is used in healthcare. Especially for setting models for information exchange and patient access. The care process is the main goal in this framework and requires its own layer. For this reason, the care process and the management of care (organisation policy) are set out separately. In healthcare,

information needs a great deal of attention because the information model is complex. For this reason, the Layer Framework explicitly contains information in its own layer and not within the application layer, as some frameworks do. This is to avoid making information content choices in the wake of application-installation trajectories, and thus possibly being too closely tied to one application and therefore to its lifespan. Finally, the application layer is separate from the IT infrastructure layer. This was done because the healthcare sector has many applications that have been made specifically for healthcare, such as the EHR systems. This multitude of applications requires specific attention. This is important in order to accommodate the information defined in the information layer and to be able to link the large number of applications so that collaboration will be possible.

Furthermore, this representation follows the boundary-setting line. Laws and regulations create boundary conditions for policy makers, while policy makers create boundary conditions for care processes. The care processes require and also provide information. The information is handled by applications. The applications work within a technological infrastructure: networks, storage, databases, etc. Finally, the activities per layer are attributable to one or a few groups of responsible persons and vice-versa. This facilitates the organisation of activities for designing, implementing and managing information solutions.

3.3 Scaling

As stated in the introduction to this section, we use this Layer Framework to develop, implement and manage information solutions within an 'organisational unit'. We will explain this last concept in more detail. In the Netherlands and throughout Europe the experience of the past few years has shown that the concept of organisational unit can be used at many different levels, from the individual patient, especially in their interaction with the healthcare institutions they deal with, to whole countries and in the interaction between those countries for exchanging patient information across borders. The Layer Framework can be used to set out the agenda for issues that need to be solved. For example, setting up the relationship between a patient and a care institution, whereby exchange of electronic information helps the patient in their relationship with that institution. The question of whether a sufficiently clear agreement exists between patient and institution falls under policy. Whether rights and obligations, such as costs and privacy are sufficiently covered. Whether it has been clearly agreed how the professionals within the institution and the patient work together falls under the care process. Whether it is clearly defined which clinical

information is exchanged and how that information has been designed falls under information. The question of which software the professionals in the institution and the patient use (and how these two different software packages communicate with each other) falls under the application layer. At the IT infrastructure layer, the question must be solved as to how the patient and the institution are connected technologically in a safe and reliable manner. Laws and regulations do not form part of this development process and therefore operate here as a precondition. These interactions are outlined in Figure 3.

At the other end of the scale is the European eHealth Digital Service Infrastructure¹. This is where solutions are created for patients who need healthcare in a foreign country. The solution retrieves information from the patient's own country. In this discussion, policy involves national governments that want to participate in the process. The care process deals specifically with what the doctors and the patient do when the patient reports to the foreign emergency department. Laws and regulations therefore form part of the development process because the laws differ between countries. For example, contracts must ensure that the interaction in question is not in conflict with the law in either country.

3.4 Vertical coordination between layers

Of course, subdividing the problem into layers, with different actors and responsible persons for each layer, does not mean that the solution consists of stacking five or six partial solutions. There needs to be vertical coordination between the layers. This coordination is not self-evident, given the completely different profiles of the responsible parties gathered around a table. It is well known that technologists, doctors and administrators do not automatically understand each other. Consequently, bridge builders are required who are able to bring the stakeholders and managers together to reach conclusive agreements. That is why in the Netherlands in 2010 a training course was set up at the Eindhoven University of Technology for clinical informaticians - people who have to do precisely that: build the bridges within the healthcare institution. At national level this is the role that Nictiz plays: bring expertise in a broad area, that forms an interface between policy, healthcare and technology.

In the case of vertical coordination, the aforementioned model is very important from top to bottom. Solutions at technical level must be traceable to policy decisions and not vice versa. This while it is all too often done the other way around, partly due

1 <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission>

to rapid technological developments. “We have a solution, so we’re going to want that solution at policy level as well”. Vertical coordination, however, should also pay attention to more pragmatic conditions from the bottom up, from IT infrastructure to policy. It makes no sense to make policy for solutions that are not technologically possible (that effect has diminished rapidly in recent years). It also usually does not make sense to make policy whose implementation would go over budget. In short, the boundary conditions go from top to bottom in the Layers Framework and the pragmatics go from bottom to top. A second form of bottom-up thinking in the Layer Framework can be technology-driven innovation: recognising the clinical possibilities of newly developed technology. In those cases, the technology first emerges but a development process for an information solution will still have to start with possibilities for the care process and decision-making at the organisational level.

3.5 The concepts of interoperability & intra-operability

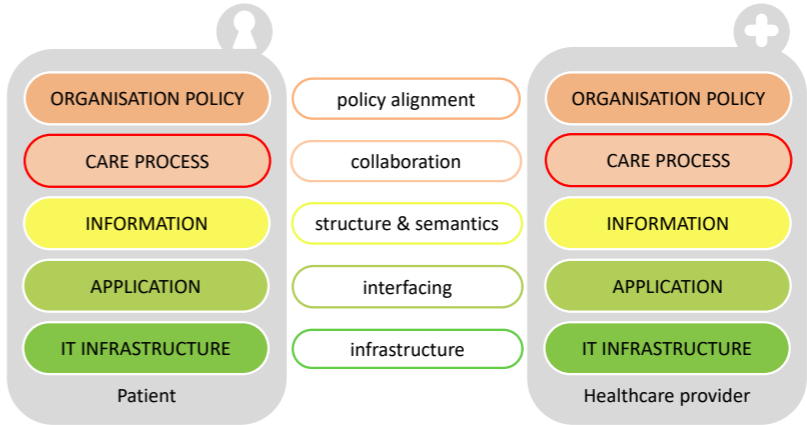


Figure 3 The Layer Framework applied to a simple situation: the relationships between the patient and a care institution.

It was argued above that a layered approach must be used in order to arrive at an effective and stable information-supported organisation. For this, the term intra-operability is used. The use of the term ‘interoperability’ has grown rapidly over the past twenty years, both nationally and internationally. There are dozens of formal and less formal definitions of this concept. For this argument, it suffices to note that two (or more) organisational units are said to be interoperable when the cooperation of both information-supported organisations is also sufficiently information-supported. Figure 3 shows this situation schematically for the interoperability between the

individual patient and a care institution. For cooperation between institutions, interoperability requires them to have similar design, implementation and management strategies. This can only be really successful if each organisation has its intra-operability in order. Unfortunately, the focus in the last twenty years has been strongly biased towards interoperability. Recently, the realisation has grown that we have paid too little attention to the content of the recorded information within institutions. In order to really achieve interoperability, it must be possible for information from the source system to be meaningfully understood and used in the receiving institution. For this, institutions need to harmonise how they set out information.

3.6 Horizontal coordination between the domains

So far, we have mainly dealt with the applications of the Layer Framework within and between organisational units from the perspective of how to develop, implement and manage an information-based organisation or a concrete collaboration. However, as stated in the introduction, the ambitions go far beyond thinking separately for each organisation. Healthcare consists of a large number of independent organisations, spread over domains such as GP care, hospital-based care, pharmacy, nursing and home care. Both the desired continuity of care and the desired active role of the patient, together with the analysis of clinical data across organisational borders, require not only bridges between organisations and institutions, but also coordination across domains. For example: medication data is highly relevant in several or most domains, but the way this data is regarded naturally differs between domains. Nevertheless, unity of understanding must be created across the domain boundaries. Moreover, the many solutions in the healthcare sector consist not only of record keeping applications, but mainly of electronic work environments for the specific organisation, which are therefore strongly domain-specific because the working method is domain-specific. The record function is integrated in this. It is necessary to make agreements at all levels of the Layer Framework, and sometimes also to develop solutions in order to achieve the goals. Of course, it helps if the individual organisations have their solution clearly structured in accordance with the Layer Framework.

Figure 4 once again shows the necessary, both vertical and horizontal, coordination.

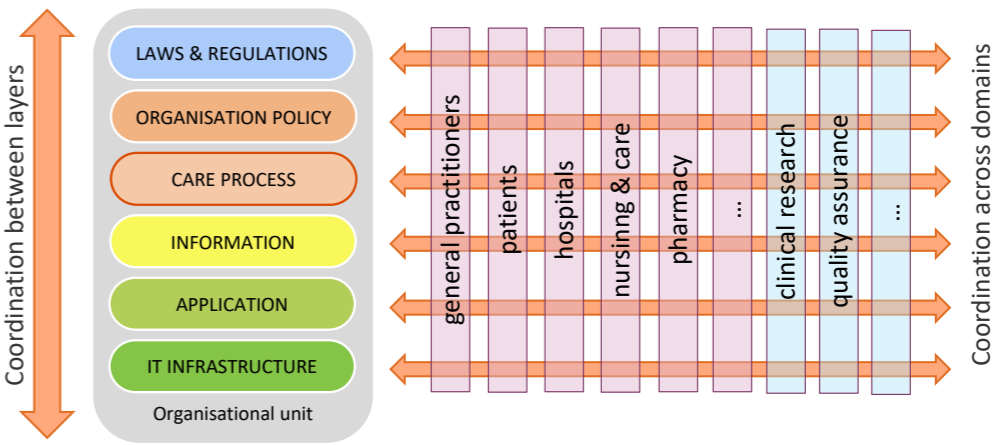


Figure 4 The need for vertical and horizontal coordination

3.7 Information security

Information security has three elements that must be optimised in each solution: availability, integrity and confidentiality. The main theme of this report is the methodology for creating clinically correct and desired solutions. The 'availability' and 'integrity' elements are an integral part of this. For many people, confidentiality feels like an extra burden, an external requirement. That is not the case if confidentiality is built into the design. In addition, confidentiality safeguards must also be analysed and designed using the Layer Framework. For example, confidentiality in a hospital starts with the question of how the professionals deal with safeguarding it for the patient (such as not leaving paper lying around, not leaving monitor screens open, using strong individual passwords). The information sets exchanged should not include any information irrelevant to the purpose. Applications must be well-secured (for logging-in and communicating, for example) and the technology protected against hacking, in accordance with the state of the art, to mention just a few things. The hospital's policy makers also have to commit to the confidentiality issue, in order to prevent attention for this from declining at lower levels in the organisation. Upholding confidentiality requires a culture that needs to be developed and maintained.

4 Required agreements per layer

3.8 The international situation of the Layer framework (ReEIF in Europe)

Attention is also being given at European level to modelling and structuring information-enabling issues. For example, the cross-sector EIF (European Interoperability Framework) has been in place for a number of years². The eEIF (eHealth EIF) has a focus on healthcare³. The EU Antilope project has, as one of its tasks, refined the eEIF to create the ReEIF (Refined eEIF)⁴. We see here, again, that the focus seems to be exclusively on interoperability. Unjustly so, as argued in Section 3.5, it is very important that the way information is recorded is also considered. Nictiz was the driving force on this issue within Antilope. Both the EIF and the eEIF consisted of four layers: Legal, Organisational, Semantical and Technical. The most important refinement in the ReEIF is the splitting of the Organisational Interoperability layer in Policy and Care Process layers (organisation policy and care process deserve separate attention) and the splitting of the Technical layer in Applications (care specific software) and IT Infrastructure (non-care specific technology) layers. Broadening the focus on interoperability in favour of attention for intra-operability was not yet politically feasible at that time.

The results of the Antilope project on this point (ReEIF) were later made into a report for the eHealth Network (eHN, meeting of the health ministries of the member states, at policy level), which was adopted by the eHN at the November 2015 meeting⁵. Since then, the Six-Layer framework described here has been the starting point for discussions at European level and has already been translated into many national languages and applied at many levels of scaling.

Working from this shared perspective raises the effectiveness of actions in sub-areas.

² https://ec.europa.eu/isa2/eif_en

³ <https://ec.europa.eu/digital-single-market/en/news/ehealth-interoperability-framework-study-0>

⁴ https://www.antilope-project.eu/wp-content/uploads/2013/05/D1.1-Refinement_of_Antilope_Use_Cases_v1.2.pdf

⁵ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

4.1 The importance of agreements

Given the complexity of the issue, the autonomy of the many organisations in healthcare and the many suppliers of software and services, horizontal coordination depends very much on making agreements on how to set up information solutions. The main reason is that there are many degrees of freedom in making individual solutions for each institution. In other words, intra-operability can take many forms. Agreements are certainly required if information is also needed outside the institution and such agreements should preferably be nationwide. Where possible and feasible, these agreements should be made internationally, because borders within the EU are becoming more open. Such agreements must be made in all layers of the Layer Framework. On the bottom three layers we call some of these agreements 'standards'. In the world of technology this term has certainly become established. But there are also agreements at the healthcare process level, for example, which are often called protocols or guidelines. In most countries the culture is such that neither a strict top-down approach (government orders) nor a totally free approach ("let a thousand flowers bloom") will work. In most cases it can only work if people are aware that agreements are indispensable. Only when this awareness is present at the top, and the need for these agreements and their scope and purpose is specified from the top down, can consensus be sought at the base. A check then needs to be made to see whether these agreements bring the policy objectives any closer. Only then can it be claimed that a consensus has been achieved and a maintenance process set up. As indicated earlier, this requires people and organisations that can take the process further. In addition, other people and organisations from the various domains and institutions must be prepared to take responsibility and not just prioritise their own interests.

4.2 The care process as the core

The care process is the most important element in our system. That's where the value is created when it comes to health and care provision. But even in this we do not get around the need for agreements about the desired solutions and how to reach them. These are often made at local or regional level between health professionals and between health professionals and patients. Ideally, these local or regional agreements are based on national agreements made between representatives of professional umbrella organisations and with patient representatives. These national agreements can also take the form of protocols and/or guidelines.

4.3 Administrative agreements

The care is not provided by individual professionals alone. They mostly work within organisations. It is also necessary that agreements be made between the administrations, for example in a region where the care continuum is to be promoted. Here too it is strongly recommended that national agreements should be made between the (umbrella) organisations of the institutions. These agreements need to be about the forms of cooperation being pursued, from the form the care should take to its financing and implementation.

4.4 Laws and regulations for setting out rights and obligations

The ultimate types of agreements, of course, are laws and regulations. When there is a widely felt need to establish rights and duties somewhere, and their period of operation is judged to be long-term, legislation can help to provide clarity. For example, a law was adopted in the Netherlands in 2008 that gave care institutions the right to use the Citizen Service Number (BSN in Dutch abbreviation). Until then its use had been limited to the government, and most care institutions are not government services. The law also stipulated that in 2009 the use the BSN for patient coordination between institutions would become obligatory. This is in the interest of the citizen, who benefits greatly from the safety of care derived from unambiguous personal identification. In 2016, an Amendment to the Client Rights in Healthcare Act (Wet cliëntenrechten zorg) was adopted, which gives the citizen the right to obtain their care information in digital form. The same legal model allows the citizen to specify their permission for others to inspect their healthcare information in considerable detail, according to target group and the type of information concerned.

4.5 The information layer as an important link to the care process

The information layer of the Layer Framework forms the link between care and technology. It is the people in the care process (professionals, patients) more than anyone else who know what information is needed at each stage of the process. It is also these human actors who, in many cases, have to provide this information from their own observations and conclusions and from the information providing devices they use. The latter include not just laboratory analysers and imaging equipment, but also the devices used by the patients themselves to measure blood glucose, blood pressure, etc. It is therefore of the utmost importance to hold organised consultations with patients and professionals on how to structure the content. In the United

Kingdom, this process is led by clinicians, via the Professional Record Standards Body (PRSB)⁶. Informaticians then need to structure this knowledge and build it into a systematic scheme. They then have to offer it to software developers for incorporation into systems.

The way we deal with information is undergoing a major change: worldwide we are gradually moving from recording information as free text (reports, conclusions, letters) to more structured information. For example, diagnosis is no longer something a doctor says, but rather the doctor’s selection from an agreed list of diagnoses. This is just a small example of this change, which makes the recording of healthcare information more straightforward and, above all, easier for computers to use. Two developments are important here:

- We define the content of information by making choices from various **coding systems or terminologies**. Internationally, the best-known system is SNOMED CT⁷, which is being increasingly used in Europe and beyond.
- We **structure** the information with a finite list of basic elements that are pre-defined clinical core concepts. Internationally, the term for this is ‘clinical information modelling’. In the Netherlands a consistent set of what is called Health and Care Information Models (HCIM)⁸ is being deployed broadly. Each model contains several data items, each of which is filled in with the terminology.

A national set of agreements regarding content and structure is generally considered to be of great benefit to healthcare. A number of countries are taking this route. The Netherlands is at the forefront of clinical information modelling. It is important to note that these agreements deal not only with the exchange of information, but also and especially with the manner of documenting this information. This points to agreements about intra-operability. We also wish to point out a very special aspect of the agreements in the information layer. You can change many agreements on the other layers later and still retain the same interoperability (for example, introduce other software), but information about a patient which has been documented in a certain way at a certain moment cannot be changed later. Or, to put it another way, information that is not there cannot be exchanged, and information that is incomplete or in the wrong format can never be exchanged in the right way. This underlines the importance of unambiguous documenting and record keeping.

6 <https://theprsb.org/>

7 <http://www.snomed.org/>

8 https://zibs.nl/wiki/HCIM_Mainpage

4.6 Applications and IT infrastructure

Once it is clear how we want to work in the laws and regulations, policy, care process and information content layers, the next question is how that information should be recorded, used and communicated within and between systems. There are great opportunities here for the industry to do this in a user-friendly, safe and future-oriented way. The main reason to make national agreements with software suppliers undoubtedly concerns the communication. If different software systems are to communicate with each other between institutions, agreements about the communication will be needed - the type of unit to be transmitted (document, message), its structure, etc. If all goes well, the content is determined in the information layer, leaving, firstly, the implementation of the information in the systems and, secondly, unambiguous communication to allow the receiving system to record it in a way similar to observations recorder here. There is still a long way to go, partly because EHR suppliers come from a tradition whereby the content is determined in collaboration with the customer (institution). What's more, some EHR suppliers have their own communication mechanism (between their own software in different institutions).

The chance that these non-open mechanisms will become national de facto standards is not great.

Agreements must also be made in the field of care-independent IT infrastructures. For that, it is possible to draw from a much more developed set of basic standards for networks and storage systems. However, choices still have to be made.

5 Governance in the light of the Layer Framework

In each country the above questions and needs for agreements are on the table. There are important differences between national healthcare systems in terms of public/private relations, financing, the influence of umbrella organisations, regional or national government, etc. But these issues and needs present themselves, in one form or another, in all countries and regions. So, regardless of the healthcare system, the question arises of how to govern the agreements so that the aforementioned main objectives, continuity of care and an actively informed role for the patient will be achieved. The management questions mainly involve ensuring that the right agreements are made at all levels and that there is monitoring for compliance in place. This is a complex issue, not only because of the layering explained here, but also in view of the scaling. Solutions and agreements exist at local, regional and national levels. National governance should only involve local and regional solutions if they have aspects that affect the desired national goals. For the rest, maximum freedom must be created to avoid frustrating or delaying initiatives at local and regional level. The local level is crucial, because the actual care (patient, health professional, institution) is always delivered at a certain time at the local level. Enough leeway must be given here to accommodate the professional autonomy of health professionals and the differences between patients.

Observations on governance for each layer, with attention to scaling:

- **Laws and regulations:** these are mainly set out at national level by parliament, but are ideally guided by general care policy and, more specifically, by the information policy for healthcare. In the case of more general laws, the consequences for care need to be worked out.
- **Policy:** at the national level, models are established for the agreements and standards on the other layers. Nationally where it needs to be, but with room for regional and local policy makers where possible. It is essential that this policy is formulated in such a way that others can find guidance for their actions.
- **The care process:** at national level, agreements can be made that provide guidance to professional actions, such as cooperation and the division of tasks, record management and documentation.
- **Information:** here, as we have already argued, we can not get around the need for broad, national agreements. Exchanging information meaningfully across institutional and domain boundaries requires national agreements that are observed locally. To be able to deal with the growing flow of electronic patient data, this is indispensable. In this case, governance action is needed to determine the objectives to be achieved at policy level, the health effects at the level of care,

the feasibility of implementing the frameworks in applications and the actual implementation and deployment of those applications.

For some purposes, such as pharmacological research, rare diseases and cross-border healthcare, it is even necessary to join international systems that extend across national borders.

- **Applications:** if the foregoing has been agreed correctly, the boundary conditions will be clear to the application builders. These, in turn, need a good deal of freedom in the way these applications are ultimately designed. Of course, there is also the competition mechanism. Agreements are not only needed for the information content, but also for the way these applications actually exchange data. Fortunately, there are many standards in this area from the international standardisation bodies, and these both can and should be incorporated into national agreements in this field.
- **IT infrastructure:** the healthcare world is fortunately conforming more and more closely to national and international standards, such as those for data communication, security and storage. The agreements that have to be made for this are not specific to each type of care but do have to be in line with national agreements that apply, for example, in the government domain.

All countries must address these governance issues. The most important recurring problems are:

- It is often not possible to reach a situation where executives actually feel responsible for the implementation on a more technical level. They tend to leave the technical aspects to the technicians. But this does not work for agreements such as those concerning standardisation as it needs to be clear how and why standards contribute to the solution of a larger problem. In other words: standards require executive commitment so that their introduction is linked to a policy objective.
- The desired separation of layers is not always upheld. Exchange mechanisms at application level in particular are often mixed with discussions about the content to be exchanged. This while the content discussion should be broader than just that which affects the exchange of information.
- There is a mistaken belief in many countries that standardisation is achieved by having all healthcare institutions use the same application. That is not the case. In fact, it is precisely in local implementations that the differences emerge. There are numerous examples of implementations of the same software package in several hospitals that cannot be coupled with regard to the content.

- A related idea is that national solutions (national infrastructures) solve the standardisation problems. Too often these infrastructures are built vertically over the layers, neglecting that which takes place outside the pillar in question. In many countries that 'other' is private healthcare, which for patient safety and quality of care should be interoperable with the national pillar. Moreover, foreign countries will have their own pillar, but differently structured. Lastly analysis and quality measurement are often not included in the design of national infrastructures.
- There is often the lack of a single, independent expertise centre that can provide assistance with the desired vertical and horizontal coordination of Figure 4 between all the involved parties. Any such centre should avoid involvement with specific technical activities such as infrastructure management. This centre of expertise could administer agreements systems, such as those in the information domain. In Europe, this type of nationally-operating institution is called a National Competence Centre (NCC). Nictiz is such an NCC. Some of these NCCs find it difficult to exercise this desirable broad expertise function because they do this while also being the managers of one particular technical solution. All these NCCs suffer from the fact that they are expected to offer national solutions while expertise in the field of standards is scarce. In addition, these national solutions are expected to be fully coordinated internationally.

6 Recommendations

Below are five important recommendations for the way forward.

6.1 Broad use of the Layer Framework

The Layer Framework presented here has existed in this form for some years. Experience has shown that this framework is useful for a multitude of activities, from policy formulation and management issues to the analysis of existing solutions, problems, evaluation, etc. It is used not only in the Netherlands, but also, via European connections, in various EU member states and elsewhere and at joint EU level. The acceptance of the ReEIF by the eHealth Network in 2015 certainly helped. The scaling options are enormous, it is being used from local in-house problems up to and including international level and everything in between. The recommendation is to use it widely in the proposed form so that a unified and consistent language arises in the process of searching for solutions.

The framework is taught and used in the Clinical Informatics program at the Eindhoven University of Technology (TU/e) and the use of this framework forms part of the final assessment. It is recommended that this framework should also be taught and used in other educational institutions.

Nictiz facilitates the use of the Layer Framework by publishing reports like the present. Nictiz also provides a toolbox with graphic material that can be used in projects and presentations by anyone.

6.2 Design administration from the perspective of health and care policy

The entire construction as outlined here, of course, only works if the first steps are correctly performed. For a correct incorporation into policy, the recommendation is to design policy in the area of information-enabling according to the broader health and care policy. This applies at all levels, from national to local. Check after realisation whether those goals have actually been achieved. In other words, information-enabling policy cannot be an end in itself, since collecting and using information is not a primary goal of care.

6.3 Increase attention for the information layer

In recent years, insufficient effort has been put into national agreements about how to document in healthcare. With the current move towards using coded and structured information, uniformity of content is essential for providing health professionals, patients, governments and regulators with transparency. Pay particular attention to obtaining the support of health professionals.

6.4 Ensure that technical complexity can be controlled in broad outline

It is too often stated that there is a decoupling between policy and (technical) implementation, supposedly because policymakers know nothing about technology. The recommendation is to ensure that technical complexity is managed by appointing officers such as the Chief Information Officer (CIO), the Chief Medical Information Officer (CMIO) and the Chief Nursing Information Officer (CNIO). They can take responsibility for specific implementation aspects, as derived from the policy. More and more institutions are appointing these types of officials. It would be good if this also happened elsewhere than only in hospitals, and it would also be a good idea to offer the staff specific education and training.

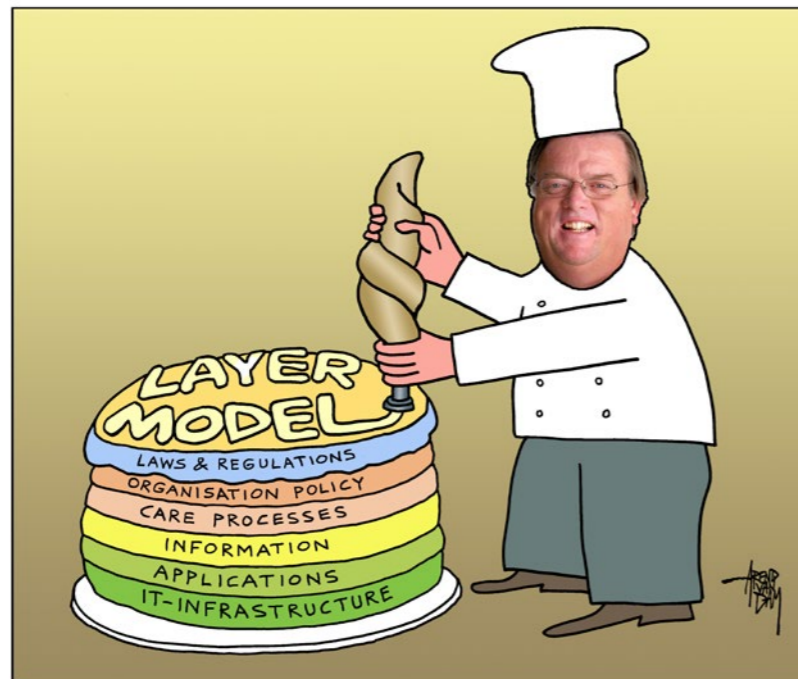
6.5 Design and implement the expertise function for horizontal and vertical coordination

Both within institutions and at a national level there is a need for horizontal and vertical coordination (see Figure 4). This mainly requires an expertise function, both with people and institutionally. On the human side this requires bridge builders, people who bring together the various parties that play a role in the Layer Framework. A professional profile has been written for this at the TU/e, which also offers a post-master course in clinical informatics. The fact that these people generally find jobs easily shows that the training course, set up in 2010, meets a real need.

On the institutional side, this expertise function must also be set up in an institute that can fulfil both coordination functions. The roles can then be disseminating knowledge, bringing people together (if necessary, also from different domains in healthcare), supporting initiatives from the bottom up, converting consensus into policy, etc. Many NCCs fulfil just such an expertise function, and it is important to further develop this function in order to meet a large and growing need for it.

7 Final word

This report examines the ways for arriving at a better information-supported situation in health and care services. That is why this report does not propose specific priorities to exploit those benefits. All the expected benefits from electronic information, as described in Section 2, are relevant for certain stakeholders. For example, we cannot say: "If we inform the patient well, we do not have to set up an advanced working environment for clinicians within large and often complex institutions". On the contrary, it concerns all development areas and also a coherent, complementary series of approaches to these sub-areas. For that reason, in particular, the ideas summarised here also need to be taken as a whole. It is only with this coherent approach that the question "Are we getting better?" comes close to an answer, because that "better" also has many aspects: better health and care for the citizen, more affordable care, more room for innovation. To name just a few things.



Colophon

This report was originally written by Michiel Sprenger on the occasion of his retirement as senior advisor at Nictiz and as a mentor in the Clinical Informatics course at the Eindhoven University of Technology. This original version is in Dutch and is entitled: 'Elektronische Informatie voor Gezondheid en Zorg', published on September 28, 2018. It is available at www.nictiz.nl/interoperabiliteit.

This English version 'Electronic Information for Health and Care Services' was created from that Dutch version, mainly by translating into English, and by broadening the perspective for an international audience.

The author would like to thank the people who have contributed to the concepts by providing comments, improvements and additions: Adri Bleeker, Quintus Bosman, Ward Cottaar, Lies van Gennip, Marianne Gerner, Conchita Hofstede, Gé Klein Wolterink, Marjan Kooter, Hedde van der Lugt, Peter Mooren, Vincent van Pelt, Fred Smeele, Albert-Jan Spruyt, Robert Stegwee and Pim Volkert.

Special thanks go to Manne Andersson from Sweden and Jeremy Thorp from the United Kingdom for their critical review of the English draft.

This report can be found in digital form at www.nictiz.nl/interoperabiliteit. In addition to the report, the figures, which include those used here, are also available for download as a toolbox for those who want to actively use the Layer Framework described here.

A description of a number of terms used in the field of information for healthcare can be found at www.nictiz.nl and, directly, via www.overzichtenbegrippen.nl.

The Hague, June 1st, 2019

Nictiz, centre of expertise for eHealth, www.nictiz.nl.

Training course in Clinical Informatics at the Eindhoven University of Technology (Opleiding Klinische Informatica aan de Technische Universiteit Eindhoven), www.tue.nl/ci.

Editor in chief: Clementine van Stiphout

Design: Studio Eric Dietz

Nictiz

PO Box 19121

2500 CC The Hague The Netherlands

www.nictiz.nl