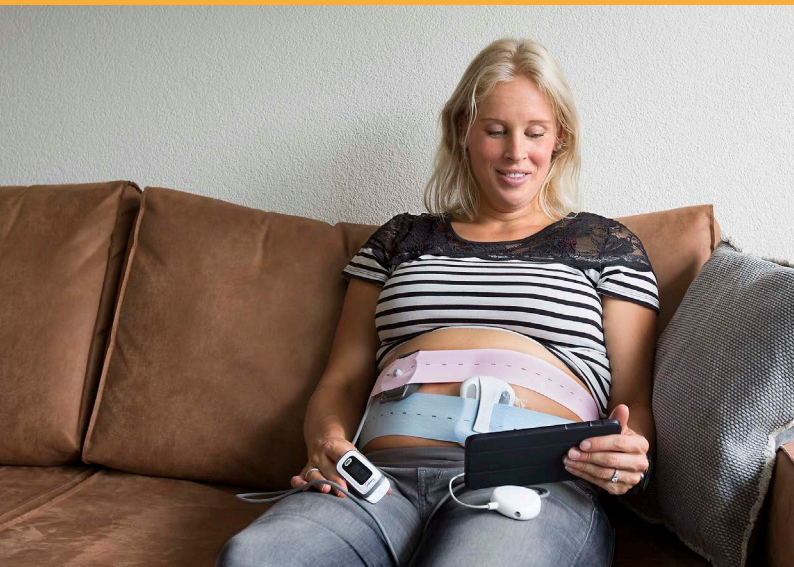
Health and Youth Care Inspectorate
Ministry of Health, Welfare and Sport

IGJ assessment framework

Deployment of e-health by healthcare providers



The assessment framework in this booklet is the starting point for supervision by the Dutch Health and Youth Care Inspectorate (Dutch initials: IGJ) of e-health among healthcare providers.

This supervision focuses on the existence of the right preconditions for the use of e-health by healthcare providers.

The IGJ's inspectors thus look specifically at whether healthcare providers are furnishing the right conditions for the use of e-health.

A more detailed version of this assessment framework, including further background information on the underlying sources, can be found on the IGJ website.

What is an assessment framework?

An assessment framework consists of a number of standards and associated assessment criteria. These are based on legislation and regulations, as well as on 'field standards' that are drawn up by professional organisations of caregivers.

An assessment framework groups the various standards into a number of subjects or themes. Inspectors assess these subjects during an inspection visit.

Since September 2018, the Health and Youth Care Inspectorate has been using this assessment framework to monitor the deployment of e-health by healthcare providers.

What is e-health?

E-health is also known as digital healthcare.

E-health is not just about e-health solutions focused on patients.

It is also about the healthcare-information systems of healthcare providers themselves.

By e-health, the IGJ means the deployment of modern information and communication technologies (ICT) to support or improve healthcare.

Examples include:

- Electronic patient records
- Electronic health information exchange
- Web portals for clients/patients
- Personal health records
- An electronic prescription system
- A medicine dispenser
- Online requests for repeat prescriptions
- E-appointments and e-consultations
- Mobile apps with information about care paths
- Teleconsultations between general practitioners and medical specialists
- Online treatment platforms in the mental-health sector
- The automation of home monitoring in nursing and care: cameras, sensors, and listening systems
- Healthcare robots for physical exercise
- Use of virtual reality headsets in the mental-health sector for anxiety disorders

Why is the IGJ looking at e-health?

The basic principle is that the use of e-health should be a positive development, as long as it is deployed under the right conditions. After all, e-health offers opportunities to support and improve care. It can help in organising healthcare differently, for instance. Patients have to go less frequently to a healthcare facility, people get better insights into their health information, and communication with, and among, caregivers can be more efficient.

At the same time, e-health is bringing about major changes. That can also lead to new risks, and it is important that the quality and safety of the care not be compromised as a result.

The IGJ's inspectors thus look specifically at whether healthcare providers are providing the right conditions for the use of e-health.

What is the IGJ looking out for when it comes to e-health?

The e-health assessment framework comprises five subjects or themes. For each of these, we look at the preconditions that are important for the provision of good and safe healthcare when e-health technology is deployed.

1

Good governance and responsible innovation

E-health can have far-reaching consequences for the organisation of healthcare, so it is important that tasks, responsibilities and decision-making are clearly agreed on.

2

Introduction and use of e-health products and services

E-health products and services are often complex. Many different stakeholders are involved in its deployment.
That is why a good process is needed to implement it, and why attention must be paid to needs and wishes, as well as to risks, training, testing and maintenance.

3

Participation by patients

Many e-health applications are intended to provide better service to patients. The patient must be able and willing to make use of the new services, and that must also come in for some attention. Good information, support and aftercare for patients are therefore important.

4

Collaborating within the network and electronically recording and exchanging data

E-health enables other forms of collaboration among caregivers themselves, for example in the case of transfers, but also between healthcare providers and patients.
This requires clear agreements among healthcare providers themselves, but also between healthcare providers and their ICT suppliers.

5

Information security and continuity

The growing dependence on technology means that organisations must be prepared for the risks involved. Problems in information security or power failures could, for example, directly affect the continuity of care. Healthcare organisations must be prepared for this.

1 Good governance and responsible innovation

E-health can have far-reaching consequences for the way in which healthcare is organised.
Also organisations are becoming increasingly dependent on various forms of ICT.
If the organisation wants to be in control, management's attention is also required.
The responsible use of e-health requires attention at various levels within the organisation.
A clear policy and transparent decision-making help in this respect.
Good organisation and clear responsibilities in the field of e-health are also important.

An assessment framework consists of a number of standards and related assessment criteria. Below you will find the standards and assessment criteria associated with the theme 'Good governance and responsible innovation'.

1.1. The healthcare provider has set out the objectives for e-health in a policy. The healthcare provider has coordinated that policy with the parties involved. The healthcare provider regularly evaluates the policy.
   1.1.1. The healthcare provider has an established policy for e-health.
   1.1.2. It sets out the goals for the deployment of e-health.
   1.1.3. Management at the healthcare provider have made sure that the policy is drawn up in consultation with interested parties, such as employees, client representatives, and partners.
   1.1.4. Management have approved or adopted the policy.

1.2. The healthcare provider ensures that the organisation is well structured, so that the introduction, use and management of e-health result in good care.
   1.2.1. The healthcare provider assigns ultimate responsibility for e-health to management.
   1.2.2. The healthcare provider allocates tasks, responsibilities, and authority in the field of e-health, within the organisation.
   1.2.3. The healthcare provider sets requirements for the training and experience of the people who have tasks in e-health. This can be seen, for example, in job descriptions, in the text of vacancy notices, and in training programmes.

1.3. The healthcare provider has agreed on how to make choices about e-health initiatives. It is clear who is involved and in what way. This applies to both changes and new initiatives.

1.3.1. The healthcare provider has agreed on a process for making choices about e-health initiatives.

1.3.2. It is clear how and when the healthcare provider involves different groups in decisions, such as departments in the organisation, caregivers, clients, partners, and suppliers.

1.3.3. It is clear what expertise is needed in the decision-making process, for example when it comes to the care content provided, legal matters, and/or as regards quality, IT architecture, and information security.

1.4. The healthcare provider is familiar with the main risks associated with the ICT/e-health environment, now and in the future. The healthcare provider has taken measures to control these risks. In this connection, factors such as patient safety, continuity of care, and information security have been taken into account.

1.4.1. The healthcare provider regularly sets out the risks associated with the current, and possibly the future, ICT/e-health environment.

1.4.2. The healthcare provider has taken various factors

into account, such as continuity of care, information, and patient safety, including the safety of medications.

1.4.3. If the healthcare provider has identified significant risks, they have taken steps to manage them.

1.5. Management at the healthcare provider is in control of developments around e-health. This applies to progress, quality and costs.

1.5.1. Management have an investment budget for e-health, and set priorities for renewal and procurement.

1.5.2. Management receives regular information on the progress of e-health initiatives, as well as on qualitative and financial results.

1.5.3. The healthcare provider has a good picture of the costs involved in maintaining current systems at the required level of performance.

1.5.4. For any pilots, the healthcare provider knows whether there are enough resources, after a given pilot is completed, for it to continue.

2 Introduction and use of e-health products and services

If a healthcare facility decides to implement new digital systems and services, an extensive process ensues. This ranges from the formulation of user requirements to the implementation and management of systems. E-health products and services are often complex.Many different stakeholders, who have various expectations and areas of expertise, areinvolved in deploying them. A good mapping out of needs and wishes helps ensure that the chosen solution is satisfactory. Attention must also be paid to the risks that can be expected to arise when innovations are introduced, and that are weighed against the expected benefits for the target group, as well as to the expertise and training of those in involved.

An assessment framework consists of a number of standards and related assessment criteria. Below you will find the standards and assessment criteria associated with the theme 'The introduction and use of e-health products and services'.

2.1. The healthcare provider has agreed on a process for the purchase and implementation of an e-health service or product. It is clear who is involved and in what way.
    2.1.1. The healthcare provider has agreed on a process for the purchase and implementation of an e-health service or product.
    2.1.2. It is clear who should be involved at what stage in the process of procurement and implementation.
    2.1.3. The healthcare provider can demonstrate that they follow in practice the process that has been agreed.
    2.1.4. The healthcare provider evaluates the agreed process and adjusts it in the light of previous experience.
2.2. The healthcare provider makes a schedule of requirements (SoR) for the purchase and implementation of an e-health product or service. In this report, the healthcare provider pays attention to functional and non-functional requirements.
    2.2.1. The healthcare provider draws up an SoR for the purchase and implementation of an e-health product or service.
    2.2.2. The SoR contains both functional and

non-functional requirements. The latter include availability, response times, compliance with existing regulations, and architecture, for instance.

2.2.3. In drawing up the SoR, the healthcare provider involves the employees who are experts in its various aspects.

2.3. The healthcare provider makes a risk analysis for the purchase and implementation of an e-health product or service.

2.3.1. The healthcare provider has criteria for determining whether a risk analysis is required for the purchase, introduction or modification of a particular e-health product or service.

2.3.2. If this makes sense according to the criteria, the healthcare provider will carry out a prospective risk assessment (PRA) for the procurement and introduction of e-health products or services. The healthcare provider does an impact analysis for the implementation of changes.

2.3.3. In carrying out a PRA or an impact analysis, the healthcare provider involves employees who are experts in the various risk factors.

2.3.4. The healthcare provider takes measures in a demonstrated way to manage the risks that are found.

2.4. The healthcare provider provides users with instructions before an e-health product or service is rolled out.

2.4.1. The healthcare provider ensures that users of an e-health product or service receive training in advance, even after significant changes.

2.4.2. The healthcare provider also trains new users after the original introduction of an e-health product or service.

2.4.2. The healthcare provider adapts the training material if there is reason to do so, and offers retraining or additional training.

2.5. Before the introduction of an e-health product or service, whether amended or not, the healthcare provider tests everything to ensure it works well, safely, and according to expectations.

2.5.1. The healthcare provider does the necessary tests before putting an e-health product or service into use.

2.5.2. The healthcare provider has clear acceptance criteria.

2.5.3. The healthcare provider adjusts the test requirements if there is reason to do so – for example, if new, previously untested functions

have been added.

2.6. The healthcare provider ensures that e-health products and services are adequately maintained.

2.6.1. The healthcare provider has made arrangements for maintenance, both within and outside the organisation if needs be.

2.6.2. These include the expected level of service, the agreed activities, and the costs.

2.6.3. The healthcare provider sets up an organisational structure that fits in with the maintenance agreements.

2.6.4. The healthcare provider ensures that the agreements on maintenance are being complied with.

3 Participation of patients

Many e-health applications are designed to provide better service to patients. The healthcare provider can offer care anytime, anywhere, or can furnish better information. The patient must be able and willing to make use of the new services. Otherwise there is a risk that, in the end, the form of care offered will not fit in with the patient's day-to-day environment.
This can lead to problems with acceptance or even the incorrect use of e-health.
It is therefore important to pay attention to the way in which patients are involved in the innovation process.
In addition, the healthcare provider should consider both the provision of the right information to the patient about the services offered, as well as support and aftercare.

An assessment framework consists of a number of standards and related assessment criteria.
Below you will find the standards and assessment criteria associated with the theme 'Participation of patients'.

3.1. The healthcare provider involves patient representatives in choices about e-health.

3.1.1. The healthcare provider involves the client advisory board in drawing up e-health policy.

3.1.2. The healthcare provider involves patients and their representatives in the choices that are important to them in e-health programmes or projects.

3.2. Both before and after an e-health product or service is rolled out, the healthcare provider checks whether it is suitable for clients. In doing so, they take into account the healthcare needs of the clients and the features of the e-health service.

3.2.1. The healthcare provider examines how an e-health product or service meets the healthcare needs of the existing patient group, and what requirements this places on the physical and/or cognitive capabilities of patients.

3.2.2. For non-trivial products or services, the healthcare provider does an intake before a patient starts using them.

3.2.3. The healthcare provider evaluates the experiences of patients with an e-health product or service.

3.3. The healthcare provider ensures that patients have the information they need to decide whether an e-health

product or service meets their healthcare needs
Patients are thus also aware of any risks or drawbacks, and can make an informed and conscious choice.

3.3.1. The healthcare provider offers clear information about the e-health service or product in question. Attention is paid in this regard to the following:
- what skills the patient should have;
- what motivation they should have;
- what costs they should incur;
- how the process works and how the equipment should be used;
- what risks or drawbacks there may be for the patient.

3.3.2. The healthcare provider ensures that the patient can make a well-informed and conscious choice about whether to use the e-health service or product. The healthcare provider ensures that the patient knows what the available alternatives are.

3.3.3. The healthcare provider evaluates the provision of information and makes any adjustments, if necessary.

3.4. The healthcare provider offers a clear point of contact for clients who are using an e-health product or service.

This point of contact provides support and the client can address any complaints that he or she may have.

3.4.1. The healthcare provider offers a point of contact for clients who are using an e-health product or service.

3.4.2. If necessary, the client can get support should they have any questions or complaints.

4 Collaboration in the network and electronic recording and exchange of data

E-health plays a role in facilitating other forms of collaboration on the one hand among caregivers, such as in the case of transfers, and on the other, between caregivers and patients. This includes clear agreements among healthcare providers themselves, but also between healthcare providers and their ICT suppliers.
In most organisations, medical data is recorded electronically.
The exchange of information between cooperating parties may be supported by the exchange of electronic data.
That calls for a good mapping of information needs.
In addition, there are preconditions, including statutory ones, in the areas of privacy and information security.

An assessment framework consists of a number of standards and related assessment criteria.
Below you will find the standards and assessment criteria associated with the theme 'Participation of patients'.

4.1. If the healthcare provider cooperates with other care providers, they are aware of what data their caregivers need. The healthcare provider knows what electronic collaboration services are required for this, and ensures that they are in place.

4.1.1. The care provider is aware of the health information needs of those of its caregivers who take part in collaborative processes, such as transmural care paths, integrated care for patients with chronic illnesses or elderly patients, and/or shared care plans. This applies in particular to information needs in those moments when transfers are being made. The fact that the requirement for data is known is evident from the following, for instance: a policy for electronic data exchange and the use of available platforms and/or standards that are available for this purpose. An overview or architectural chart setting out the requirements and possibilities for the exchange of electronic data.

4.1.2. The healthcare provider has seen to the set-up of the electronic data services required for important data flows.

This is shown by specific examples.

4.1.3. It can be done, for example, through participation in joint choices by a regional cooperative organisation, for instance, of one or another platform for information exchange.

4.1.4. The healthcare provider evaluates whether the caregivers involved in the aforementioned collaborative processes are getting enough information in a timely fashion.

4.2. The healthcare provider sets out in writing agreements on policy and procedures with each of the parties with whom data is exchanged electronically.

4.2.1. The healthcare provider sets out in writing agreements on policy and procedures for the electronic exchange of data with other parties.

4.2.2. The healthcare provider ascertains that a patient has expressly and explicitly given permission before they make that patient's data available to third parties via an electronic exchange system.

4.2.3. The healthcare provider evaluates the existing agreements on a regular basis.

4.3. The healthcare provider arranges the transfer of medication information together with the joint caregivers in the region. The healthcare provider makes it possible to exchange information of the standard medication-transfer set.

4.3.1. The healthcare provider has clear agreements with other healthcare providers in the region about medication information transfers in the regional context.

4.3.2. The healthcare provider sees to it that medication is prescribed electronically.

4.3.3. The healthcare provider sees to the electronic transfer of overviews of medication and, if applicable, ensures that these are passed on to the prescriber in their own organisation.

4.3.4. The healthcare provider evaluates the implementation of the collaboration agreements regarding medication.

5 Information security and continuity

Healthcare facilities are becoming increasingly dependent on ICT, and threats such as those involving ransomware are on the rise.
Information security must therefore be up to par. Disruptions as a result of information-security problems or unexpected events such as power failures can have a direct impact on the continuity of care.
The inspectorate expects healthcare providers to demonstrate that they are working on an information-security management system that complies with legal standards, and that there is a continuity plan in place that is also tested regularly.

An assessment framework consists of a number of standards and related assessment criteria.
Below you will find the standards and assessment criteria associated with the theme 'Collaboration within the network, and the electronic recording and exchange of data'.

5.1. Management have seen to the setting up, implementation, maintenance and continual improvement of a management system for information security.

5.1.1. Management have documented and adopted the information-security policy.

5.1.2. Management have established and assigned roles and responsibilities in the organisation for information security.

5.1.3. Management has seen to an objective and impartial audit, and documented the results.

5.1.4. Management have arranged for measures to be taken in response to any anomalies that have been turned up.

5.2. The organisation has established, documented, implemented and tested a continuity strategy.

5.2.1. The healthcare provider has a documented continuity plan that explains how to handle major disruptions in public utilities, and the effects of such disruptions on ICT.

5.2.2. The healthcare provider has introduced the continuity plan. This is evidenced by measures that have been taken to mitigate the effects on ICT of major disruptions to public utilities.

5.2.3. The healthcare provider carries out tests to ensure the proper functioning of the continuity plans.

5.2.4. If an incident has occurred in which the utilities have been disrupted, then based on it, the healthcare provider has evaluated the operation of the continuity plan.

What sources have served as the basis for the assessment framework?

The sources in this assessment framework are based on legislation and regulations, as well as on 'field standards' that have been drawn up by professional organisations of caregivers,and that are listed on the next page.

These field standards, as well legislation and regulations, are constantly evolving.
We regularly evaluate assessment frameworks and adjust them if needs be.

Why is the assessment framework publicly available?

By making this assessment framework for e-health available to the public, the inspectorate wants to contribute to the following:

- transparency in its working methods;
- fostering awareness of good healthcare;
- encouraging healthcare providers to make improvements;
- informing healthcare providers, patients, clients, citizens and health insurers about the points of emphasis in monitoring.

List of laws, regulations and field standards

Here is the list of laws and standards.
Other laws and standards may also apply in specific situations.

- Act on Quality, Complaints and Disputes in Healthcare
- Implementing Decree on that Act
- Act on Supplementary Provisions regarding the Processing of Personal Data in the Healthcare Sector
- Governance Code for Healthcare
- Framework for the Monitoring of Good Governance
- Framework for the Quality of Nursing-Home Care
- Guidance on the Division of Responsibilities for Collaboration in Healthcare
- Performance Indicators for Quality Assurance in Medical Systems

- Guide to the Transfer of Data on Medication within the Healthcare Sector
- Guidelines for Electronic Prescriptions
- Covenant on Medical Technologies
- Guidance on New Interventions in Medical Practice
- Guide to the Automation of Home Monitoring
- NEN 7510 Medical Information Technology: Information Security in the Healthcare Sector
- NEN 7512 The Basis for Trust regarding the Exchange of Information
- NEN 8009 A Safety-Management System for Hospitals and Facilities that Provide Hospital Care
- NEN 8028 Medical-Information Systems: Requirements for the Quality of Telemedicine
- NEN-EN-ISO 22301 Societal Security: Business-Continuity Management Systems

More information about e-health can be found through the following sources:

Discover smart solutions in healthcare:
Zorg van Nu [Healthcare Today]
www.zorgvannu.nl (in Dutch)

Knowledge Bank for Innovation:
Zorg voor Innoveren [Making Innovation Happen]
www.zorgvoorinnoveren.nl

Projects and research in innovation:
www.zonmw.nl

Further information on the monitoring of e-health and the assessment framework looked at here can be found on the IGJ website:
www.igj.nl/onderwerpen/ehealth [in Dutch]