Collaborating for Digital Health and Care in Europe

eHealth Governance - Country Report: The Netherlands

In collaboration with

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eHealth Governance - Country Report The Netherlands

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1 Introduction

1.1 Scope of the document

This report is one of the 6 reports on the eHealth Governance commissioned by EY Baltic to EHTEL in the context of a contract[1] aiming at proposing a new "Health ICT Governance Framework" to the Ministry of Social Affairs of Estonia (MoSA).

With these reports, EY and MoSA have access to a sample of international good practices on how to govern the deployment of digital health within a country or a region.

	Health system	Governance	EHR architecture
Belgium	Bismarck	Bottom-up/ Top-down	Decentralised
Catalonia	Centrally Managed	Top-down	Centralised
Denmark	Centrally Managed	Top-down	Decentralised
Israel	Bismarck	Bottom-up	Decentralised
Scotland	Centrally Managed	Top-down	Centralised
The Netherlands	Bismarck	Bottom-up	Decentralised

Figure 1: Profile of the countries and regions retained for their good practice in eHealth Governance

These reports have been prepared by EHTEL experts who either have an inside knowledge of the country or region subject to the report or worked in close collaboration with experts having such a knowledge.

They describe, for each country or region,

- The context, i.e. the health and care system and its enabling eHealth system, with its technical building blocks
- The organisation in place for involving stakeholder and
- The main governance processes

A short historical retrospective and a short analysis of successes and what could be done better helps to put these good practices in perspective.

This international experience is intended to be used as input for Deliverable 3 "To-Be model for eHealth system governance" defined in the above-mentioned contract.

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1.2 Methodology

The methodology for the developing these reports has been designed in two steps:

- Distinguishing IT governance from IT management
- Defining what should be included under the term eHealth governance framework.

The line between IT Governance and management has been drawn as follows:

- The governance function is responsible for determining strategic direction.

[1] Contract reference: REFORM/SC2021/003, signed on 10.02.2021 between European Commission and EY.

- The management function takes that strategic direction and translates it into actions to achieving the strategic goals.

To define what needs to be covered under the term eHealth Governance, a few models have been looked at and COBIT 5 has been retained as a relevant one to support health and care in systems in their digital transformation journey[2].

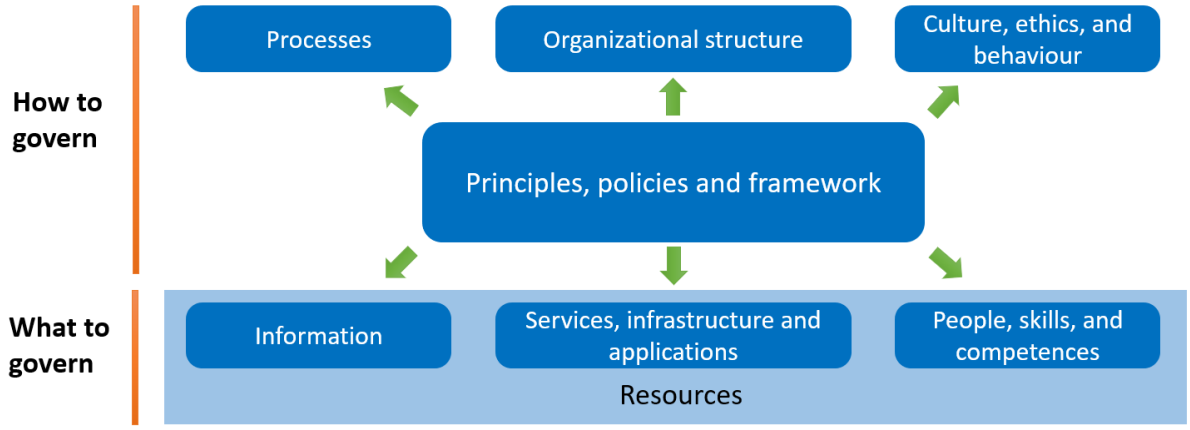

Figure 2: Governance Framework [MARCELO 2018]

2 Report on The Netherlands

2.1 Health and care System description

The Netherlands health system is an insurance system (Bismarckian) where competition plays a key role.

Since the 2006 reform, the Netherlands have replaced the separation between public and private insurance by a universal social health insurance scheme. Managed competition is now the driving mechanism in the healthcare system but its implementation keeps bringing important changes in the system and also directly affect the roles of actors. The health system governance relies thus both on competition - as the main driver of the healthcare system- and cooperation and integration among actors which are necessary to undertake major reforms.
Specialization among hospitals; substitution between secondary and primary care; integration within primary care and between primary care and social care; and seamlessly provided long-term care organized by municipalities are examples of changes that require **harmony and mutual trust**. It may prove challenging to create these conditions in a system **where competition** is the ruling principle

Despite this, the main systemic indicators are quite good: wide access to essential services, acceptable waiting time, limited out-of-pocket payment and overall quality ranked good in comparison with international standards. But the Netherlands still has one of the highest per capita health expenditures in Europe although some efficiency gains have been obtained.[3]

[2] See "Transforming Health Systems Through Good Digital Health Governance", Alvin Marcelo, Donna Medeiros, Kirthi Ramesh, Susann Roth, and Pamela Wyatt (2018)
[3] Health System in Transition : Netherlands Health system review Vol. 18 No. 2 2016

The Health system is mainly regulated by four legal acts which describe the overall workflows and modalities of interactions between actors:

- The **Basic insurance Act** (Zvw) which regulates essential healthcare services provisioning,
- The **Public Health Act** which refers to occupational medicine research and prevention,
- The **Social Care Act** and
- the more recent **Long-Term Care Act**.[4]

The 380 Dutch Municipalities are directly involved in social, youth and long-term care. Involved actors can compete and enter into contractual relationships while official bodies have mainly a quality control or advisory role.

The Ministry of Health's role is thus
to safeguard health care from a distance rather than managing it directly.

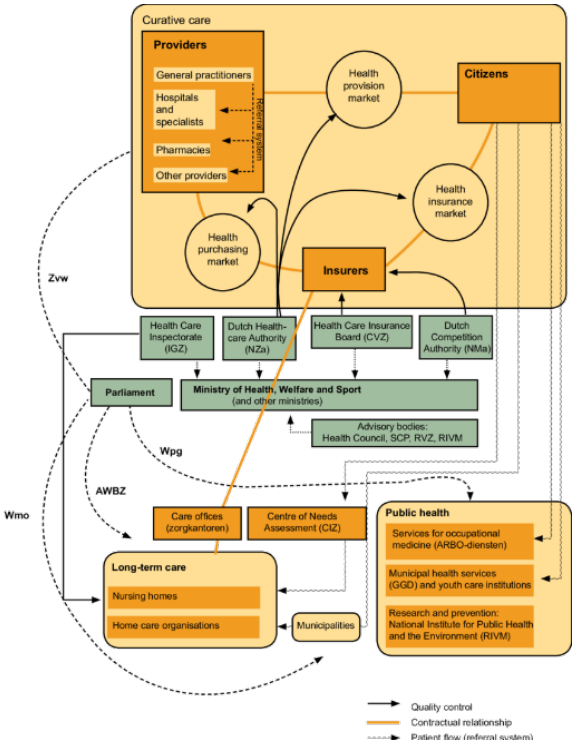

Figure 3: Health Care System of The Netherlands

Arm's-length (independent) agencies are responsible for setting operational priorities:

- At the national level, the **Health Council** advises government on evidence-based medicine, health care, public health, and environmental protection.
- The **Medicines Evaluation Board** oversees the efficacy, safety, and quality of medicines.

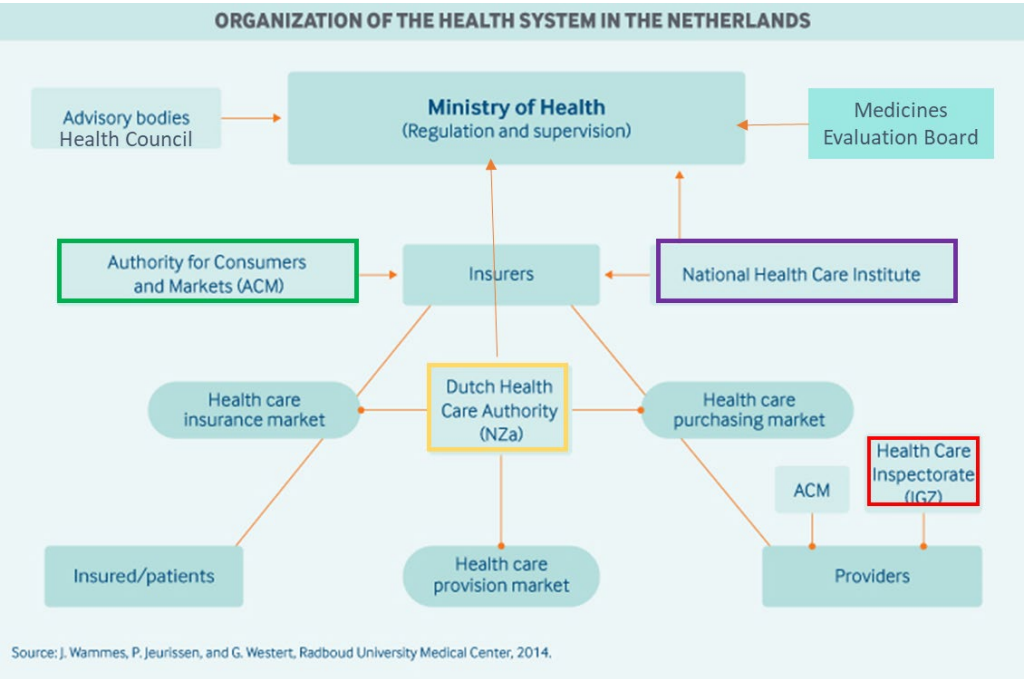

Figure 4: Organisation chart of the healthcare system in The Netherlands

[4] Source: Schäfer et al. 2010:14. Reproduced with permission from WHO Regional Office for Europe © World Health Organization 2010, on behalf of the European Observatory on Health Systems and Policies

- The **National Health Care Institute** assesses new technologies for efficacy and cost-effectiveness, and advises the Ministry of Health on whether to include those technologies in the mandatory benefit package.
- The **Dutch Health Care Authority** (*Nederlandse Zorgautoriteit*) has primary responsibility for ensuring that the health insurance, health care purchasing, and care delivery markets all function appropriately.
- The **Dutch Competition Authority** (*Autoriteit Consument en Markt*) enforces antitrust laws among both insurers and providers.
- The **Health Care Inspectorate** supervises the quality, safety, and accessibility of care. Self-regulation by medical doctors is also an important aspect of the Dutch system.

2.2 eHealth System

2.2.1 National/Regional building blocks (infrastructure and services)

Networks

Historically, **a central infrastructure** for access to decentralized systems called Landelijk Schakelpunt (LSP or AORTA) went live in 2008, run by Nictiz. However, when the health minister introduced a bill to legalize this infrastructure, a very strong Senate opposition led to the rejection of the bill, as this was seen as a major contradiction with the respect of principles of privacy and competition. It was then decided to opt for a decentralized data exchange infrastructure that **regionalizes communication in the system, denying the Ministry any authority over ICT infrastructure developments (2011)** and transferring responsibility of managing the infrastructure to a **private organisation** (Vereniging van Zorgaanbieders voor Zorgcommunicatie-VZVZ).

In parallel to this national infrastructure, networks were also created at regional level, by Regional Collaboration Organisations (RSOs). Some of them are connected to the LSP, some not. The RSOs have the ability to connect healthcare providers, at the level of infrastructure and applications, but also at the level of work processes, organization and management.

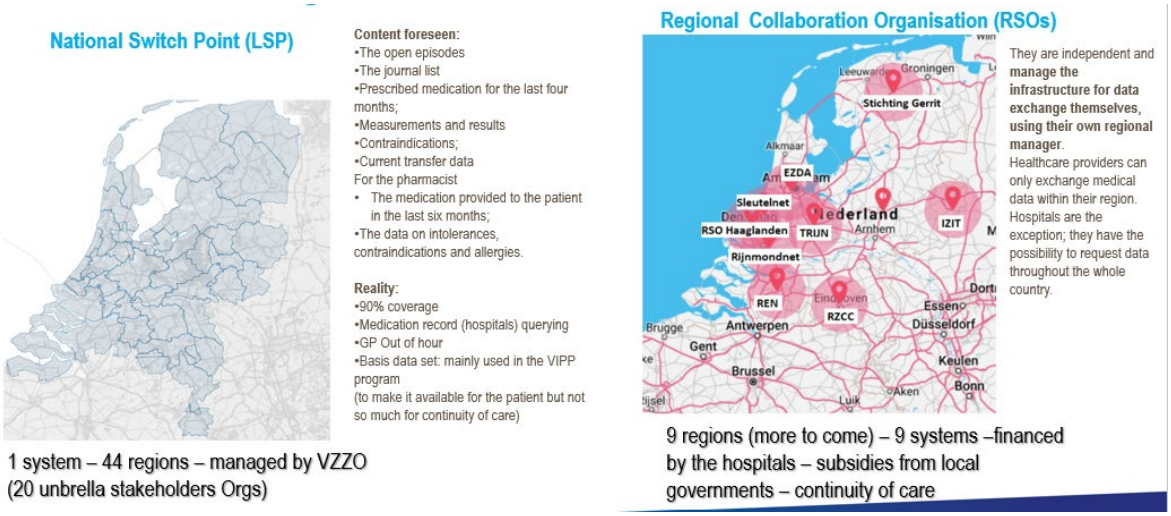

Figure 5: Two type of data sharing infrastructure

Health information systems in The Netherlands are characterised by a **strong resistance to any centralization of data and deployment of central systems**. Hence, **interoperability is here key** and most of the governance efforts are related to this objective. However interoperability between EMRs is still officially not regulated and officially promoted standards are still competing with local or proprietary ones. Nictiz plays however a role in documenting and promoting national standards.

While the **degree of digitalization in the health sector is one of the highest in Europe,** this had not led, up to now, to a consolidated vision and strategy and **different networks co-exist and are not always compatible**.

The former Minister of Health Edith Schippers helped advance the cause of eHealth in the country by ensuring that more than €100 million is invested in promoting patients' digital access to their medical records. Since 2015 indeed, **PHR is one of the central point of attention** but organisations also develop their own strategies, such as independent patient portals. **Access to data by citizens and patient empowerment** are **political priorities.** They led to the development of the **MedMij initiative** which also includes data provided by the citizens.

MedMij

MedMij is an innovative Dutch framework for the secure exchange of health data between the citizen, healthcare providers and health professionals**.**

MedMij has been established as a foundation in 2018: It was proposed in 2015 by the Dutch Patient Federation and first adopted by the National Information Council (NIC) as a program (ended in 2019) before becoming a dedicated Foundation driven by National organizations of patients and healthcare providers and funded by MoH (VWS) and Insurers

MedMij operationalizes the concept of "**personal health environment**" (PGO in Dutch) in the form of a websites and/or app in which one can keep track of information about his own health.
In order to obtain the MedMij certification label (52 labels to date) service providers need to comply with a number of agreements (at the level of network, application, process, legal) and with information standards. Personas have also been created to facilitate the understanding of the system by all parties.

Figure 6: Service providers having obtained the MedMij label

MedMij is governed by a board of 2 Directors and an "owners council" (50% representatives of "users" and 50% representatives of healthcare providers) while the organisations which have obtained the label are allowed to be part of an advisory board.

Other central building blocks

ePrescription is not deployed through a central unique system and is still not yet used to its full potential, in particular in hospital setting. However, a national program "Medication Transfer"[5] (Medicatieoverdracht), a broader implementation program for ePrescription and eDispensation, is currently running under the coordination of Nictiz. A basic set of medication data must be available to any healthcare professional who prescribes, provides or administers through the implementation of three information standards (Medication Process, Lab Values for Medication and Contraindications and Hypersensitivities). This implementation is complex and is progressing slowly because many different healthcare and ICT organizations play a role.

[5] Zorgaanbieder - Samen voor Medicatieoverdracht

In primary care, 8 different **EMR solutions** are currently used by GPs (consolidation still ongoing on, coming from 15 products).

A specific initiative "**data registration at the source**" supports organisations which want to better exploit and reuse their data. It relies on the use of Healthcare Information Building Blocks (ZIBs) when building or designing the EHR and the specification of a basic data set (BgZ). A ZIB Compliance framework has been designed to guarantee consistency.

A national Terminology server has been made available by Nictiz to facilitate semantic interoperability.

Central building blocks are still missing and are only being developed now. One can cite in particular as examples:

- Current identification systems have not yet been set to the legally required security level for digital traffic in healthcare. Logging in with only a username and password remains the rule although using 2FA is being implemented in more and more hospitals.
- The deicion to build a digital cadastre of healthcare professionals has been taken but still needs to be implemented
- Several platforms compete to offer a secure messaging system with no centrally managed address book.
- The explicit consent of the patient is required for the electronic sharing of medical data. This is still now done via different systems - and often even manually. This issue is now considered through the "Mitz" project (2021): a joint service for healthcare providers who want to arrange future-proof permissions for regional or national data exchange independent of the exchange system.

A new bill is in preparation (2023) focusing on mandatory electronic exchange of patient **information** between healthcare provider organisations with a Dutch Digital Maturity assessment (DIMSS) for supporting organisations to get prepared for it.

A website has been recently created to provide an overview of all the eHealth solutions currently used in the Netherlands.

2.2.2 Data sharing and access

Data sharing is only possible via the existing networks through an Opt-In process. Privacy remains a very sensitive issue in the Netherlands and progress in certain segments, such as social care, has been slow for this particular reason. Further restrictions of sharing are applied: only the information necessary for the treatment is made accessible to specific healthcare providers and what the healthcare providers can see depends on their role.

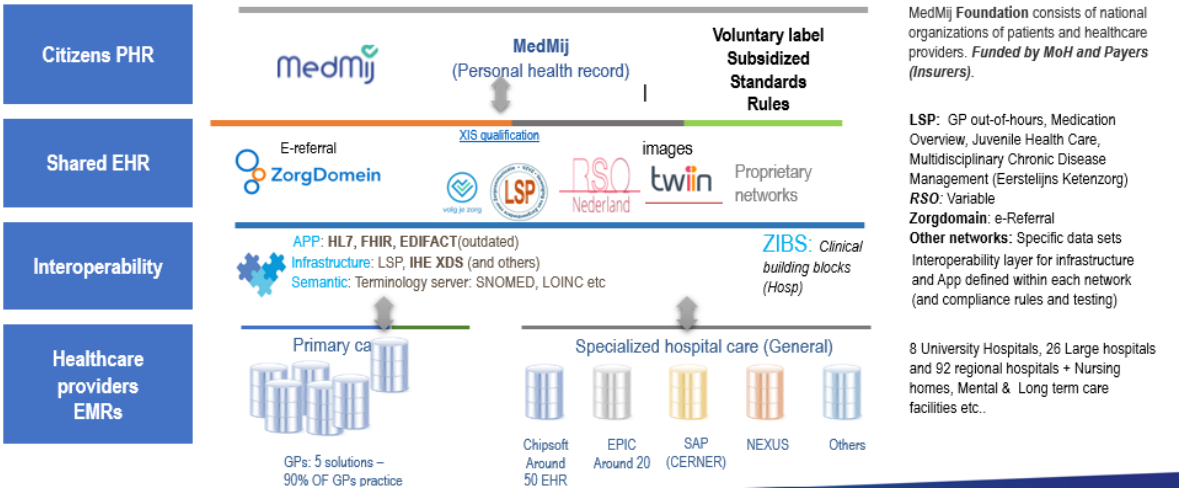

Figure 7: Sharing health data in The Netherlands

The type of data shared is different in the different networks:

- **In the central infrastructure (LSP)**, although the situation is evolving, the main shared data is a basic dataset produced by the GP (General Practitioner) and called "Professional Summary" (PS). It has been defined and is mainly used for out-of-hours services.

  It includes current health problems ("Open Episodes"), last four months contacts including statistics and results from test ("Journal List"), prescribed and dispensed medication, allergies and hypersensitivities to medication and any details seen as important by an acting GP. Pharmacies share the medicines dispensed.

  The only lab results that pass through the LSP are the lab results that are necessary for safe medication management and are part of the new Medication Process specifications that are currently being implemented.
  Data produced by the Juvenile Health Care and Multidisciplinary Chronic Disease Management (Eerstelijns Ketenzorg) are also shared through the LSP.

  Other types of data can also be shared (such of those shared by certain Regional networks) but this is not currently generalized.

  Data related the e-reference of patients (referrals and laboratory requests) are shared through a specific network called "zorgdomein". More than 80,000 healthcare professionals work with ZorgDomein. Including almost all general practitioners and hospitals as well as other practices and healthcare institutions such as mental health institutions and physiotherapists.

- Other data such as **Images** are shared through separate networks such as the network of IHE XDS networks called TWIIN[6].

- The **MedMij initiative** provides a new paradigm for data sharing. MedMij determines the rules (agreements, requirements and standards) for the exchange of data between personal health environments (called "PGO") and (care) organizations. Citizens have however full control of their own health data and decide with whom they want to share them.

[6] As a precursor, the project DVDExit (2020) has realized a platform for the exchange of medical images through Dicom-Mail. All hospitals are connected to this platform.

- A number of other private networks are also used and have their own business model which usually come with a number of applications and data sharing only available to the network clients.

Detailed specifications have been developed by Nictiz to deal with priority use cases such as the medication process, intensive care, birth care, youth care, integrated care (diabetes, COPD, CVRM ..) etc... While HL7 used to be the main standard of reference, FIHR is now used for the development of new specifications (and more specifically in the MedMij context).

2.2.3 People, skills, and competences

The existence of multiple initiatives and the applied bottom-up approach had as consequence to develop a **widely distributed eHealth awareness,** among the main impacted stakeholders. Furthermore, in the absence of legal constraints for standards adoption, particular attention and resources have been devoted to the documentation of the proposed solutions, including e.g. testing environment, compliance framework and supporting tools.

Central bodies have also developed a double approach to stakeholders' engagement: one based on organisations, representing all the segments of the value chain in most of the working initiatives and the other focusing on individual profiles who would be selected for their competencies, ideas and interests. This is for example particularly true for the development/selection of standards which associates experts from the Standardization and business organisations and individual experts.

At central level, most of the **technical expertise** lies within the eHealth competence centre Nictiz. However the development of some important building blocks – such as the Healthcare Professionals Cadastre – fall under the responsibility of another agency (CIBG -BRIC) under the responsibility of the MoH. This agency will also act as eHealth National Contact Point but had up to now limited IT capacity and skills. This explains partially[7] the important historical delay accumulated by the Netherlands for those important building blocks.

The various foundations established to support the networks and the use cases have also been very instrumental in developing the skills needed to document the business requirements in such a way that they can easily be translated into technical requirements.

The importance given to competition has stimulated the diffusion of eHealth skills and expertise but has also contributed to a certain degree of dilution.

The Ministry has also launched an initiative of e-learning targeted at healthcare professionals called "Zorg van Nu". The courses focuses on topics such as : What is healthcare technology? Which smart care solutions are there? How to use them, when and for what purpose? By attending those courses, healthcare providers can gain the accreditation points necessary to be contracted by the insurers.

Each specific initiative has also produced the necessary training materials and support service while eHealth solutions providers have also developed specific training modules and users club. This last category is of course essential as usability and business orchestration plays a critical role in the actual use of eHealth services.

One must also mention the importance of the 4 GPs users groups united under GP IS which are instrumental in developing the skills, experience and change requests.

[7] The development and implementation of the NCPeH is now basically according to plan.

The importance of the roles of CMIO and CNIO in hospitals is also recognized more and more. They are organized in national networks. The MoH also appointed a CMIO.

2.3 eHealth system organisational structure - overview

2.3.1 Stakeholders of the national/regional layer

As mentioned earlier in this report, public authorities do not manage directly eHealth[8] but have been driving the creation of private entities (foundations) which are managing the main currently available services.

Umbrella organisations representing healthcare providers, public health services providers, patients, industry and standardisation bosies are thus directly involved both at national and regional levels.

The list below provides this a first global overview of the stakeholders which are playing a role

- **Ministry of Health, Welfare and Sport (VWS)**: supports financially most of the ongoing initiatives (except LSP) and oversees global governance (Information Council)
- **National Healthcare Institute**: supports eHealth policies linked to data reuse
- **CIBG National Agency**: responsible for the development of the healthcare professionals cadastre and future National Contact Point for eHealth (EU eHDSI). It also issues the UZI-pas: the digital identification and authentication pass for healthcare providers
- **Nictiz**: national eHealth competence centre delivering Standards - Compliance testing-support tools -Guidance and eHealth monitoring.
- Payers : **5 (competing) major payers** cooperating under **Vecozo** and **Vektis** for data flows related to rights and costs claims. Support collectively financially the LSP (via funding of a foundation) and individually selected initiatives.
- **VZVZ**: Union of healthcare Providers for Healthcare Communication which manages the LSP
- **MedMij Foundation**: manages the MedMij initiative and Include National umbrella organizations of patients and healthcare providers
- **Health- RI Foundation**: manages research and innovation initiative which focuses on data reuse. The foundation includes 70 public and private organisations involved in research in the Netherlands.
- **RSO networks**: voluntary network of healthcare providers self-organized at regional level with the support of Municipalities
- **OIZ**: ICT vendors association (membership based) heavily involved in standardization discussions.
- Private networks: **Ezorg**, **KPN zorgcloud** , **Enovation**… provide private cloud infrastructure and associated services (such as e-messaging). Some are connected to the LSP.
- **Cooperative Zorgdomein**: provider referral service from GPs to secondary providers (co-owned by Rabobank)
- **Association of Municipalities** : plays a key role in social and long-term care and are involved in main standardisation initiatives (and in RSO development)
- **Ministry of Interior**: responsible for identification and authentication workflows
- **Dutch Data Protection Authority (Authoriteit Persoonsgegevens)**: responsible for GDPR enforcement

[8] With the exception of Covid-related systems (e.g. Corona Tracking App, Digital Covid Certificate Apps, Hospital IC Capacity Registration)

- **Inspector general for healthcare**: monitors the quality and safety of care and youth care in the Netherlands and in eHealth have created an assessment framework for the 'Deployment of e-health by healthcare providers'
- **Z-CERT Foundation** (Centre for Information Cybersecurity in Healthcare): offers specialized services to healthcare institutions with regards to optimal cyber security protection, and offers support in case an incident

2.3.2 Stakeholders of the health service provider layer

Although EHR providers are key enablers, umbrella organisations representing all the different healthcare (sub)segments are directly represented in most (if not all) of the driving eHealth initiatives both at global and project levels and are actively taking part in the eHealth requirements and decision-making processes.

At the primary care level, most of General Practitioners (GP) use EHRs and have a fair degree of electronic information capacity. The market is mainly shared between 5 EHR solutions represented by 4 user groups united in the GP IS umbrella organisation covering 90% of all GP practices (> 5000). The market is therefore considered sufficiently consolidated though still diversified.

Other primary care professions such as pharmacists, dentists, midwives, nurses and physiotherapists are also widely using EHR systems, although the market consolidation has not yet reached the same level than for the GPs.

As for secondary care, the Netherlands have 8 University Hospitals, 26 Large hospitals and 92 regional hospitals. One may of course also add Nursing homes and the Mental & Long term care facilities.
Several private EHR solutions share the market with one dominant in general hospitals (Chipsoft) with over 50% of the market. Organisations are now very cautious in adopting solutions not proven to be adapted to the Dutch context with – as a consequence – a relatively long probation period for new solutions.

The EHR market for the 26 large integrated mental health care institutions has hardly changed over a decade with two leader solutions (PinkRoccade and to a lesser extent MijnQuarant). However since 2018, the situation is evolving with newcomers getting a foothold and others leaving the scene[9]

In the Long term care facilities (elderly and disabled) market, 3 EHR solutions control 70% of the market with one solution (Nedap) being the undisputed number 1 in elderly care[10]. The market here has been quite stable over time although some companies active in other segments are also developing an adapted strategy to penetrate that market.

2.3.3 Stakeholders of the innovation layer (including businesses)

With its two main clients, the Ministry of Health, Welfare and Sport (VWS) and the Netherlands Organization for Scientific Research (NWO), **ZonMw** is the Dutch organization for health research and care innovation. ZonMw finances health research and encourages the use of the knowledge developed to improve healthcare and health

There are several hubs in the Netherlands that focus on digitalisation and health, with the ambition to stimulate and facilitate innovation involving the business community. Most notable examples of

[9] https://mxi.nl/kennis/479/er-komt-verandering-in-de-zis-epd-markt-in-de-ggz
[10] https://mxi.nl/kennis/389/ecd-inventarisatie-2019

such initiatives are The Netherlands eHealth Living Lab (NeLL) and The Innovation Centre for Artificial Intelligence (ICIA).

ZorgInnovatie is an open platform and community for co-creation of innovations in care and welfare. It is part of Health Holland, the executive organization (Foundation) of the Top Sector Policy Life Sciences & Health. Health-Holland stimulates interdisciplinary R&D in public private partnerships The ZorgInnovatie platform works together with general and regional partners.

As demonstrated by the table below, Dutch universities and research centres are directly involved in a substantial number of innovative eHealth related projects with wearables, home care and telemedicine being the most studied topics.

eHealth solution category	Number of university medical centers with recent publications within solution category[7]	Number of innovation projects in Dutch health innovation database (ranging from concept to implementation phase)[9]
Wearables & Tracking	7/7	69
Home Care	6/7	60
Data, analytics & AI	4/7	54
Telemedicine	6/7	54
Consumer Health Informatics & Guidance	4/7	49
Connected Care & Interoperability	2/7	32
Clinical Decision Support	n/a	27
EHR & HIMS	n/a	20
Rehabilitation	n/a	22
eLearning	2/7	18
Administrative	n/a	14
ePharmacy	n/a	11

Figure 8: Involvement of Universities and research centres in eHealth innovation[11]

The Healthcare institute (ZorgInstituut) has developed an innovation initiative for the use of the blockchain technology with a long term perspective.

The Dutch organisations MIND and the Mental Health platform GGZ, launched the National Mental Health App Guide with the support of ORCHA (UK). This site features only tested and approved mental health apps, with a rigorous Health Technology Assessment at its core (supported financially by MoH (VWS) and specifically VIPP program).

2.4 Approach to main governance aspects:

As reported in section2, while central public bodies keep a major role in general policy orientations and financing, their role is extremely limited in term of direct management of eHealth, both at infrastructure and service levels. Multiple foundations with a private status – each of them with their own internal governance process – have been created. Public bodies are usually represented in those foundations but are not in control of the decision-making processes.

A large number of umbrella organisations representing all the different stakeholders (including industry) and the different segments of the healthcare chain are thus "structurally" engaged in those initiatives and for some of those organisations, in many of them.

[11] https://www.rijksoverheid.nl/onderwerpen/e-health/overheid-stimuleert-e-health

Although the active participation of representative umbrella organisations is a key driver for stakeholders' engagement, they are not always in a position to directly engage their affiliates. They also do not always succeed to build a consensus on the topics to be discussed within their own premises. Hence, a few separate initiatives supporting specific use cases have also been created with a more limited number of organisations in view to have a more effective decision process.

While the governance approach is globally similar in most of these initiatives, the governance at central level has an essential role as it provides the overall foundation for all the other initiatives.

2.4.1 Planning and strategizing

The Dutch health care system is based on the **principle of self-governance**. National obligations are rare. One may say – with some nuances – that this is also largely true for the eHealth system. Integration of EHR systems among providers has been left to the field and political path to digital healthcare has thus been anything but straightforward.

The main central governance body in charge of the global planning and strategizing of eHealth in the Netherlands is the National Health information council (NHIC) which meets 5 times a year and which is directly supported by its core group. Aside from public bodies (Ministry of Health, Municipalities, Community Health Services), the council includes 18 stakeholders umbrella organisations representing all the segments of the healthcare system. There is however no representation of the Industry at that level.

In order to give direction to the development of a sustainable information system in health care, the **Health Information Council** has established four 'outcome goals':

- Medication safety
- Focus on the patient
- Standardized data exchange
- Recording and reusing data once

These goals are a guideline for programs, projects and activities within healthcare.

The Council is chaired by the Secretary General of the Ministry of Health and all the directors of the Ministry are present, including the CIO. This guarantees – inter alia – that the decisions taken are backed up by the funding entities.

Coordination is the main role of the Core Group which meets 10 times a year. Chaired by an independent person, it sets the agenda for the Information Council and filters the questions and requests to be discussed. The Core Group also monitors the implementation of the decisions set by the Information Council. The Core Group consists of the policy-oriented staff of the participating organizations and they can e.g. propose to scale up solutions developed at local / regional level to national one.

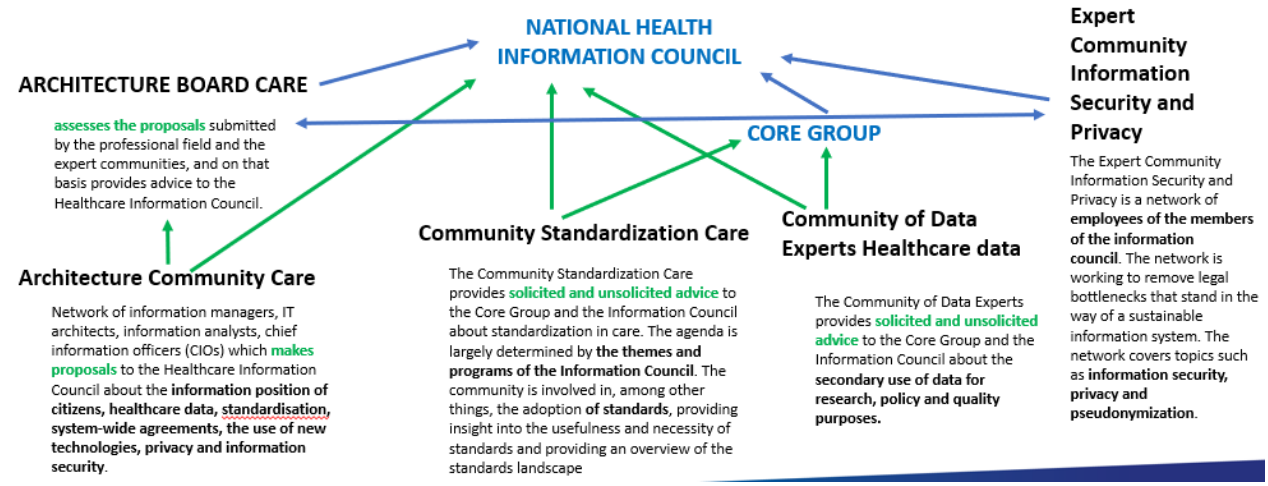

Figure 9: Main national governance structure

The NHIC is supported in its mission by different "technical" groups which aim at achieving both a high level of representativeness (selection of representative and competent organisations) and a high level of competency (selection of individuals, on a voluntary basis).

Once decided and approved by the National Health Information Council, each individual initiative follows its own governance approach.

Aside from the NHIC, the Ministry of Health has developed another channel of communication to identify issues and topics which should receive attention: the "Chief Experience Officer (CEO) Board", chaired by the Policy Directorate of the Ministry has been created to offer a fresh, patient-oriented view to the MoH and may thus influence the eHealth agenda. Participation to the CEO board is voluntary and in **a personal** capacity. The innovative "MedMij" initiative has been channelled through this Board.

Nictiz, as the eHealth competence centre, is in charge of planning the development (selection) of adequate technical and semantic standards to support the selected use case or the development of transversal building blocks (such as for example theterminology sever)

Regional Networks can develop their own strategic plans and may request the support of Nictiz.

The National Healthcare Institute is leading the planning and development of secondary use of health data for research and innovation at central level but an independent decentralised initiative (Health-RI Foundation) exists to support research and innovation.

The 4 main current objectives (medication safety, focus on the patient, standardised information exchange, one-time recording of data) only provide general orientations. Many local/regional or stakeholders networks initiatives covering a wide spectrum of use cases and topics are somewhat also supported with public funding but there is currently no globally coordinated eHealth action Plan which would include all initiatives.

Nictiz has however an important role in anticipating future needs and developing strategies to provide answers to upcoming use cases, being also the main link with European and International initiatives.

2.4.2 Financing of eHealth investments

The **MoH (VWS)** funds structurally **Nictiz** and the main foundations which support priority projects (MedMij, Health-RI...) and the development of main building blocks supporting the infra or infostructures.

The individual connexion to the national infrastructure (LSP) is supported financially by **the Insurers** The regional networks are funded by **healthcare providers** (with possibly some additional public funding).

The MoH (VWS) also funds since 2017 incentivisation schemes called "Acceleration Programs for Information Exchange between Patient & Professionals" (VIPP). VIPP programs have been set-up for various sectors such as hospitals, the mental health sector, general practitioners and maternity care. The MedMij initiative has recently be connected to the programme.

VIPP programs aim to support interoperability enforcement in relationship to specific scenarii and use cases. 409 million € have been engaged since 2017 to support healthcare organisations (and thus indirectly the EHR industry).

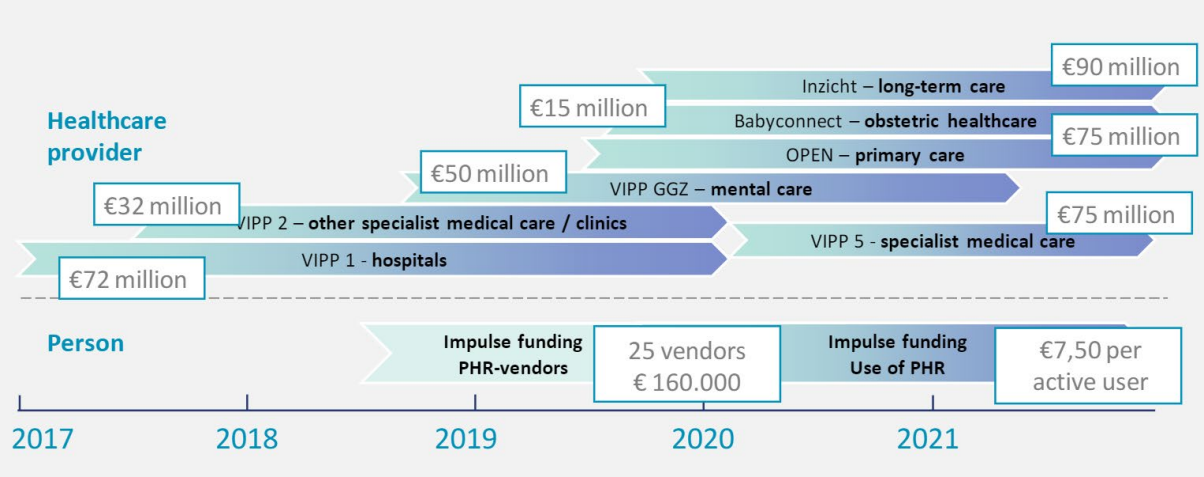

Figure 10: Main incentivisation schemes implemented in The Netherlands

Since the launch of the MedMij initiative 25 PHR vendors are entitled to benefit from a 160.000 € financial support while a new scheme is now directly associated to the use of PHR solutions by rewarding active use of the PHR.

An example of how these incentivisation schemes works is VIPP5, targeted at specialist medical care. VIPP5 VIPP 5 consists of the following three modules, of which modules 1 and 3 are mandatory:

- Module 1: The institution can make digital data available to the patient's PBL in accordance with the MedMij Appointment System.
- Module 2: The institution can digitally exchange information to the patient's PBL in accordance with the MedMij Appointment System and the patient can return information from the PBL to the institution.
- Module 3: The institution can digitally exchange the Healthcare Basic Data Set (BgZ) and relevant correspondence with another institution.

VIPP5 Hospitals, UMCs and independent clinics

- Goal: Patients can securely and digitally access their standardized medical data in a PBL. Hospitals and independent clinics can exchange data with each other.
- Duration: 2020-2022
- Resources: 75 million

Figure 11: VIPP5 program targeted at specialized care and connected to the MedMij initiative

Healthcare providers invest in their eHealth systems from their annual budget but can thus receive financial incentives if they participate in specific programmes (See e.g. above the VIPP programme). The public funding is however often also used to answer other requirements considered as more urgent than the ones defined by the programme. As the main sources of healthcare providers income is the contract with the public system, we can assume that their eHealth investments are indirectly funded to a large extent by the Ministry of Health and the payers.

Healthcare organisations such as University Hospitals (NFU) are also co-funding certain projects/initiatives (such as research infrastructure for health data).

A number of Private Funds are also active and support specific initiatives:

- Gilde Healthcare:
- Lux Research
- PHS fund
- Noaber Foundation
- KPN Ventures.

The direct or indirect support to the industry is mainly justified by the fact that the benefits lie with citizens, health insurers and government, while other stakeholders have to pay. Hence, they consider that they need to be somewhat compensated. Beyond short- or medium-term objectives, it has also been agreed that long term sustainable, structural funding remains necessary in order to expand and make more data available for users. This approach provides IT-vendors with a perspective which guides their investments although recently, hospitals have been complaining publicly that the main EHR-vendors are obstructing interoperability developments by overpricing the necessary adaptions in the systems..

2.4.3 Defining and enforcing an interoperability framework

The **definition of the interoperability framework** is one of the central mission of the NHIC, supported in this task by **4 different types of boards.**

Each of the 4 above listed boards (see Figure 8) brings a contribution to the definition of the interoperability framework.

The Architecture Board Care & Architecture Community care network advises the Healthcare Information Council on complex information issues and IT architecture in healthcare. Its 18 members have recognized technical expertise in their domain and join the Board in a **personal capacity** and out of social interest and responsibility.

The Architecture Board assesses the proposals from the **Architecture Community care** network considering different aspects such as citizens empowerment, healthcare data, standardisation, system-wide agreements, the use of new technologies, privacy and information security. The community care is a network of information managers, IT architects, information analysts, chief information officers (CIOs). They are organized in working groups, i.e. framework of standards, HCP address book and secure data exchange

Chaired by Nictiz, the **Community standardisation care** represent both the standards providers and consumers. It includes 13 bodies/initiatives: the National Healthcare institute, VWS (MoH), HL7NL, IHE NL, Nictiz, IHTSDO,i RIVM, Vektis, Vecozo, VNG Realization (Municipalities), NEN, KNGF, GS1. It focuses on the adoption of standards and provides insight into the usefulness and necessity of standards, aligned with the work agenda of the Information Council. It also actively cooperates with the Forum Standardization, an open advisory committee with experts from various government organisations, the business community and academia.

Chaired by National Institute for Health and Environment (RIVM), **the Community of Data Healthcare data Experts** includes 25 bodies/initiatives, including public bodies, HCPs, research centres and insurers. They focus on secondary use of data (registries harmonization, data quality assurance, data reuse, technology for data reuse etc.)

DISTRIBUTION OF ROLES FOR STANDARDS ENFORCEMENT

While the NIHC and the supporting boards and communities are key for the definition of the requirements and the selection and standards, **Nictiz** is responsible for documenting and maintaining – in close collaboration with the users – the infrastructure supporting conceptual, technical and semantic standards. Nictiz is also responsible to develop the tools which may facilitate alignment between existing open and proprietary standards.
Nictiz provides for example a full overview of all standards used in the Netherlands matched against a number of criteria (including name, description, type, adoption rate…). It plays thus therefore a central role in term of standards enforcement.

To support healthcare providers in implementing the standards, Nictiz also provides a tool to guide organisations through the entire process of adopting an information standard.

Nictiz also offers software suppliers the opportunity to have their software tested for the correct implementation of standards. The assessment is done by the experts of the Nictiz Qualification Centre. The qualifications are used by the software suppliers to demonstrate that their product or

service meets the requirements as set by Nictiz. Nictiz qualifies the implementation of healthcare information standards and network services. The software suppliers that meet the requirements receive **a Nictiz certificate**.

Nictiz had developed the so called "ZIBs" (Clinical building blocks or Healthcare Information Model) which have been introduced via the programme 'registration at the source" for initial data capture at the point of care but unfortunately these models have not always been implemented consistently and the results are therefore limited.

The compliance to legal, regulatory and security criteria for the LSP is ensured by VZVZ. Other networks organize themselves the compliance tests they believe necessary.

The **Electronic Data Exchange in Healthcare Act** planned for 2023 will gradually oblige healthcare providers to exchange data about patients electronically and securely through the adoption of appropriate standards, while the privacy of patients will be safeguarded.

To prepare this transition, a new initiative supported financially by the VWS (MoH) to support interoperability has been created in 2020: "**Norms and Standards Electronic Data Exchange in Healthcare (EGIZ)**". It includes key members of the « Community Standardisation Care Group » and umbrella organisations representing the users and the main networks (such as RSO and vZVZ). **NEN,** the official standards development organisation in the Netherlands, is leading this multi-annual programme which will develop a system of NEN standards and certification schemes together with the healthcare sector.

A tool to assess **digital** maturity system for interoperability (Dutch Interoperability Maturity Model – DIMM) has been developed with HIMSS support and is currently being tested

The MedMij initiative provides a good example on how **the roles are distributed among the different actors**. In MedMij, the roles are divided as follows:

- **The VZVZ Service Centre** and **Nictiz** manage and further develop the appointment system and information standards. They also continuously tests new proof of concepts (PROVES project)
- **Nictiz** decides if a service provider can be accepted after having studied the submission documentation and makes available the documentation and testing environment.
- VZVZ conducts the validation tests.
- The MedMij foundation board formally approves the label granting.

HEALTH-RI is another major standardisation and facilitation initiative. More details on this initiative are provided under section 20.

2.4.4 Developing new eHealth building blocks

New e-Health building blocks are approved by the National Information Council. The list of proposals for new building blocks are continuously updated. The new NEN initiative however will bring a pluri-annual perspective. The Ministry keeps also a certain capacity of initiative in developing appropriate incentivisation model (VIPP) or supporting new initiatives which are always stakeholders inclusive.

A business model is developed for each new approved building block after having conducted an in depth business, technical and functional analysis. New building blocks are developed within the existing budget of the organisation in charge. Budget adaptation needs are then accounted and planned.

Some fundamental building blocks such as E-identification and authentication do require to be a generic solution and have to date not found yet a consensus.

At regional (RSO) and healthcare provider levels, each network/institution develops their own eHealth building blocks although more consistency in the choices operated is expected in upcoming years.

2.4.5 Maintaining and improving eHealth building blocks

Maintenance of system-level eHealth infrastructures is the responsibility of the different organisations or initiatives (foundations) responsible for the existing networks.

Fundamental change requests and adaptations with a transversal impact are discussed in the National Health Information Council (NHIC) and brought forward by the different experts groups.

Healthcare providers (and IT solutions) are requested to adapt their systems according to the adapted requirements established by the different networks they are part of, but there is no compulsory system which guarantee they do this consistently and in a specific timeline.

2.4.6 Monitoring and evaluating eHealth service delivery

Each initiative (LSP, RSOs, Health-RI etc..) and organisation in charge of an e-health component necessary to use an eHealth service develops its own monitoring and evaluation (KPIs) framework.

Nictiz was tasked and paid by by the MoH to report on the main eHealth services related KPIs and to publish them in the eHealth Monitor . Nictiz however stopped this service in 2020 and this important task has bene over by RIVM (National Institute for Health and Environment).

Through the VIPP programme, the MoH also monitors and evaluate the implementation success of the programmes targeted at different segments of the health stakeholders the other eHealth services

Figure 12: Results of VIPP 1 & 2: Hospitals

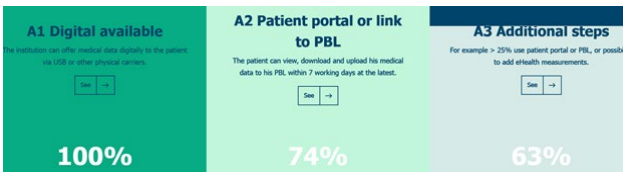

Figure 13: Results of VIPP 1 & 2: Institutions

The other public bodies which have a role in monitoring compliance with fundamental rules and legislation (competition, privacy, security etc..) develop their own method of evaluation.

2.4.7 Stimulating innovation in eHealth

At a high level, the objectives set forward by the Netherlands to stimulate innovation are the following ones:

Area	Description
The right care at the right place *De juiste zorg op de juiste plek*	Efforts towards providing care in a cost-efficient yet effective manner, including a shift from hospital care towards home care. eHealth solution categories linked to this theme are Wearables & Tracking, Telemedicine, Home Care, and Consumer Health Informatics & Guidance.
Patient empowerment	Efforts towards shared decision-making processes and taking control of your own health. eHealth solution categories linked to this theme are Wearables & Tracking, Home Care, Consumer Health Informatics & Guidance, and, to a lesser extent, Telemedicine.
Safely sharing patient medical data	Efforts towards safe, secure and interoperable exchange of data within and between health providers to benefit efficiency and quality of care. eHealth solutions category linked to this theme is Connected Care & Interoperability.
Using Artificial Intelligence and data analytics for prevention	Efforts towards to predict and prevent cases in which expensive specialist treatment is unnecessary. The eHealth solutions category linked to this theme is: Data, analytics & AI.

Figure 14: High level objectives related to innovation

As already mentioned in section 2.3.3, a number of actors and initiatives support innovation in the eHealth domain. In this section, we will particularly focus on a strategic initiative which involves a complex governance process, Health-RI (Research Infrastructure).

Health-RI aims at building an integrated health data research infrastructure accessible for researchers, citizens and care providers. Health-RI wants to facilitate and foster the optimal use of knowledge, tools, facilities, health data and samples to enable a learning healthcare system and accelerate sustainable and affordable personalized medicine and health. The focus is here more on data mapping and normalisation. The organisation actually operationalizes the VWS (MoH) and Netherlands Organization for Scientific Research (NWO) objectives related to the design research and innovation programmes.

Health-RI is organized as a private foundation funded by:

- ZonMw (Public Benefit Organisation (ANBI)which is part of the NWO network of foundations that manage government funding for research in general.; It manages almost all government funding for health research
- NFU: The federation of University Medical Centres

As demonstrated by the figure here below, Health-RI has been co-created with the active involvement of 70 stakeholders over an initiation period of 4 years.

Figure 15: Co-creation process of Health-RI

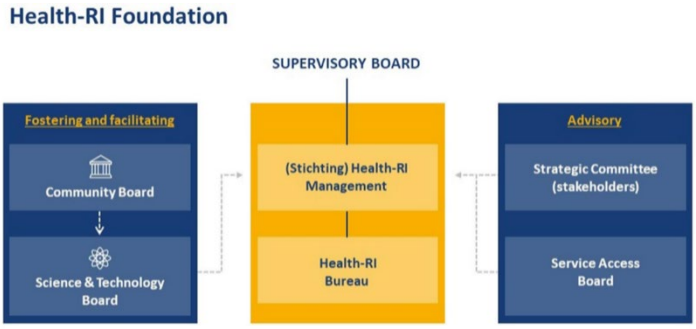

Figure 16: Health RI Governance – Supervision Board

The governance of Health-RI differentiates between executive (supervision board), fostering and facilitation (communities) and advisory roles

The communities have an important role in Health-RI. The communities of people either share similar interests, face common challenges or pursue the same goals.

A core function of Health-RI is to foster and facilitate these communities. They are either **thematic** communities (e.g. imaging, multi-omics, biobanking) or **local data infrastructure** communities.
Each community is represented at a **strategic level** by a representative in the Science & Technology Board (STB) and a **tactical level** in the Community Board (CB) .

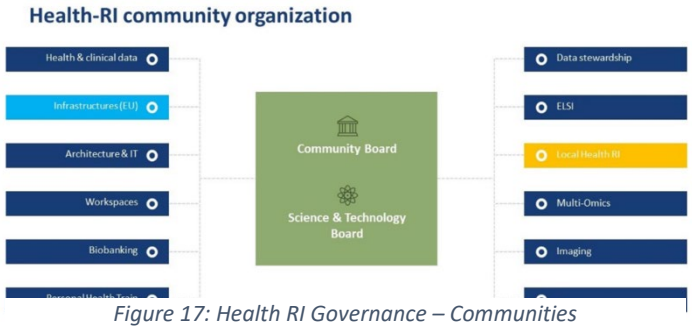

Figure 17: Health RI Governance – Communities

Organisations can decide the role they want to play in those communities:

- Strategic alliance: the organisation is funded by Health-RI and participates in the community
- Special Interest Group (SIG): Health-RI provides secretarial support, facilitates meetings and provides a platform to share information
- Temporary working groups: Health-RI also provides support but for a shorter period of time.

To date, Health-RI has started 14 projects focusing on:

- Analytics and software
- Education & Training
- FAIR Data stewardship
- Health Data samples

One also needs to mention the contribution of Nictiz to essential building blocks supporting innovation, such as the national Terminology server.

Aside from Health-RI, one needs also to mention another promising initiative: the National AI-coalition (Algorithms that work for everyone) which is also active in the Healthcare sector. It works as membership organisation with more than 170 private and public members active in the AI segment. A working group, operating in separate teams, focuses on t he following themes: ecosystem and matchmaking, need for data in health infrastructure and appointments system, COVID overview, citizen and patient participation, information and education of care providers and citizens, financial support and case overview.

Finally, the Netherlands have also invested resources to document and make publicly available all the projects supporting innovation.

Let's mention in particular:

- The Landelijke Kennisbank eHealth(National Knowledge Bank eHealth) which is currently being developed with the ambition to provide a comprehensive overview of eHealth initiatives recently being undertaken in the Netherlands and also incorporates user feedback. It documents for example existing test labs and living labs and make transparent which innovations each test lab is working on, so that pilots can be distributed and unnecessary duplication of testing is prevented. It can also be instrumental in organizing joint purchasing processes for innovations and/or resources (economy of scale).
- The zorginnovatie digital platform of the public agency for the Life Sciences & Health sector (Health~Holland)to share and search health innovations.

2.5 Some historical retrospective - how the current state has been achieved / if doable?

- 70s – Hospital Information Systems developed and introduced
  Developed by parallel collaboratives of hospitals and IT vendors
- 80s – GP Information Systems developed and introduced
  Using a common GP information model, required to be eligible for subsidy
- 90s – Interoperability and regional networks introduced
  1992: HL7 Netherlands established
- 2000s – ePrescribing introduced as a professional standard and basis of the centralized infrastructure (LSP) developed
- 2002 – The Netherlands eHealth competence centre Nictiz is established
- 2005 –A motion asks the government to take the responsibility of creating a national infrastructure for data exchange.

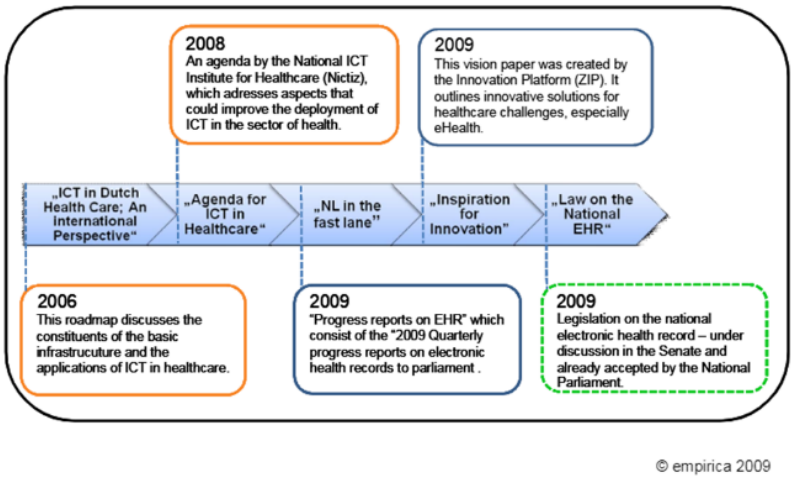

Figure 18: Retrospective - post

- 2008: Epic goes live with the first Dutch general hospital; they will follow with Radboud UMC in 2013
- **2010s** – Main wave of Hospital Information System shake-out and EHR renewal
    - Also: large scale EHR adoption in mental health and long-term care
- **In 2011**, legislation to install a **national EHR system** (the bill, popularly known as the 'EPR Act', provided that all care providers were obliged to connect to the National Switch Point) **failed in Congress** but a law on the requirements for data exchange in the health system is passed.
- In 2011, hospitals, pharmacies, after-hours GP cooperatives, and organizations representing GPs set up the **Union of Providers for Health Care Communication (VZVZ:** *Vereniging van Zorgaanbieders voor Zorgcommunicatie*), responsible for the exchange of data across various platforms and settings via the National Switch Point (LSP).
- In 2015**: MedMij** is proposed by the Federation of Patients Association
- In 2016, The first **RSOs** are established
- In 2017, an **Acceleration Program for Information Exchange** (VIPP) supports financially Healthcare Providers (and Industry) with however mixed results.
- In 2017: the **Health-RI business plan** is approved
- In 2018: The **MedMij foundation** is created
- In 2021: A new bill is being prepared (for 2023)

2.6 Successes and what could be done better?

2.6.1 Main successes

- ✓ Very active involvement of all stakeholders and lot of expertise (and experience) available in all (including prospective) domains
- ✓ European champion to support Patient Empowerment (MedMij initiative)
- ✓ Wide use and experience in Public-private partnerships
- ✓ Excellent documentation of knowledge areas and standards documentation (and support tools) to support Interoperability with a clear users perspective.
- ✓ Evolving Incentivization packages with a progressive increase focus on actual use
- ✓ Scalable infrastructures (but too many)
- ✓ A specific (separated) data for research infrastructure

2.6.2 Possible areas of improvement:

The decentralised nature of the Health IT landscape makes it very difficult to get consensus on the services to be developed and who is authorised to run them. As a consequence,

- The link between **policy – governance** and **practice** remains weak: data governance is an area where large gains can still be made;
- Some **critical building blocks** are still missing or fully operational (HCP address book, patient consent central service, identification/authentication service…);
- Patient data is now shared on a **voluntary basis** but only at the regional level and only for continuity of care. Umbrella organisations have only partial influence on their members. An active and widespread stakeholder's engagement strategy is thus not sufficient by itself to produce results;
- One can observe a considerable **gap** between the **range** of eHealth solutions on offer and the extent to which they are **actually used**;
- **Too many parallel initiatives** – each with their own proper governance – are very much time and energy consuming with also a risk of lack of visibility and only partial alignment and also a barrier to innovation;
- **Privacy and security** remain a major concern and limits progress in certain domains (e.g. social care);

- Due to difficulty of coordination between initiatives**, business and technical orchestration** is still partial.
-

The Netherlands still lack a stable framework or a national eHealth strategy with a more unified and somewhat simplified governance. The current **political move with the proposed 2023 bill** is a first response to the voluntary nature of all eHealth development. As a consequence, the Health Information Council is currently discussing which parts of the **infrastructure could/should be mandated** and not left to the open market.