ICT in Business - Leiden University

Master Thesis:

Finding the role of disease-specific, standardised Electronic Health Records in a Hospital's Information Architecture, closing the Policy-Practice Gap; A Case-Study approach.

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Version : 1.1

Date : 21/06/12

Synopsis

This work is divided into three levels of abstraction: In the 'Domain Analysis' societal issues are explained that cause the need for interoperability improvements in hospital care. The 'Theoretical Background' section explains the means at hand to realize interoperability between Electronic Health Records. Finally, in the 'Case Study' an example is given of an operational EHR system featuring most of the interoperability means discussed in the previous chapters.By the year 2040, almost 1 out of 4 Dutch inhabitants is reaching the retirement age. The age on which people are in the need of health care the most of their entire life. The number of physicians is not expected to be increased with a proportional equal amount by that time, leading to capacity problems. Therefore drastic measures that make the Dutch health care system more efficient and feasible seem unavoidable. Policy-level solutions have been sought by fostering competition between hospitals by means of specialisation and privatisation. Increased liberalisation results in medical institutions finding themselves trapped between a national demand for higher production on one side and a quality-demanding health care inspectorate on the other. The patient-centred care-chain ideology that policymakers tend to give paramount importance, relies on the thorough belief that digitized transmural information-exchange will boost health care efficiency. Roadmaps that set forth the implementation of information standardisation are widely available but cause little relief since the effects of investment in standardised medical information systems are not instantly clear. According to policymakers, standardisation of information will lead directly to improved interoperability. The use of (open)standardised data- and information models has been promoted since the introduction of Dutch health care liberalisation in 2005. Technical difficulties, great complexity and the absence of a long-term view on the added value of EHR standardisation makes IT-suppliers and hospital CIO's prefer to use conventional technologies. Systems that supply the hospital's physicians with an IT-solution that covers the requirements of their own specialisation only. In this study, the present situation within the hospital's information architecture is analysed and triangulated with a case-study on the Electronic Health Record created by the AEXIST firm. Offering an opportunity to study what would happen in a situation where supplier-independent medical information standardisation is implemented in a hospital organisation.

Conclusions

The study revealed that transmural- semantic interoperability can be achieved using the means available as indicated by policymakers. AEXIST did so by using freely available open source components as the base of their systems. Using the NICTIZ core-EHR dataset that was based on Huff's Continuity of Care Record in combination with Gartner's 'diorama' philosophy, AEXIST EHR systems are tackling the semantic interoperability problem in the fields of core- and disease-specific-EHR systems. Implementing EHR systems Platform-as-a-Service(PAAS) can disrupt the EHR market empowering a hospital's IT department. The AEXIST Service Oriented Architecture approach has great potential as a blueprint for hospital IT-architecture but leaves questions about SOA Orchestration or Choreography unanswered. A second open ending is the incompatibility of medical terminology standards caused by the differences in ontological abstraction. On a higher level, EHR standardisation comes difficult due to the lack of distributing Detailed Clinical Models centrally.

Acknowledgements

Writing this document required me to overcome many obstacles. Having met fierce resistance occasionally, I would not have found the road to completion without the unconditional support and faith of all the people who helped me. Both with substantive-, methodological-, educational- and psychological support.

I want to thank management scientist Bauke Steenhuisen for sharing his insights with me on liberalizing public organisations. My Leiden University coaches Professor Dr. Ir. Fons J. Verbeek and Professor Dr. Hans LeFever I want to thank for understanding my broad interests and for being patient. In particular managing director Ir. Remko Hoekstra of AEXIST B.V. deserves many thanks, since the cooperation of his organisation revealed a significant insight into EHR standardisation and the use of open source technology in hospital organisations. Furthermore I want to thank Erwin van Betten for helping me to review the document.

I dedicate this work to Mirjam Klein whose endless patience enabled its accomplishment. Hoping to have influenced her professional opinion towards medical computer science in a positive manner since she represents a new generation of physicians.

Peter Hendriks

Leiden, June 12th 2012

N.B.

Even though health care is globally regarded a scientific discipline, it's practical application differs between nations. The Netherlands are no exception. Terminology used in this sector is mostly specific to the Dutch Hospital domain. With the glossary at the end of this document, I tried to clarify most of the understandings and provided a Dutch translation in order to minimise bias and to maximise the scientific relevance of this work.

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1 Motivation

Besides clarifying the direct motivation of the research topic in general, this section informs the reader about the background of the subject. Emphasis is put on summarizing why healthcare automation can offer such powerful solutions leading to cost-savings, quality improvement and even new medical insights.

1.1 Medical Information Technology

Healthcare and technology affect us all. We are used to solving specific problems with suitable technical solutions varying from pacemakers to traffic lights. The benefits of interconnected technologies are increasingly evident resulting in flourishing Information Technology markets. Interconnecting healthcare information systems nationally proved to be a challenge in The Netherlands. Narrowing down the scope to the hospital information domain provides a simplified but still complex view on the problems at hand.

1.1.1 Interoperability Mismatch

Before purchasing new information systems, organisations tend to do a cost-benefits analysis to which hospitals are no exception. When the highly specialised medical divisions the hospital is known for are asked to supply the requirements for a new information system, main focus is put on the particular medical specialism and less on interoperability of information between medical practitioners. This is reinforced by the system of medical partnerships forming highly autonomous sub-organisations within the hospital. These partnerships have their own budgets and are just as interested in saving cost as the hospital's board of directors is. Interoperability between medical information systems is therefore given lower priority, since the short-term benefits of investments in standardisation aren't instantly clear.

1.1.2 Technical Challenge

Besides these financial discouragements, the technical difficulties that come with medical information interoperability are big and involve the challenge of aligning medical data-models in an IT market that allows system vendors to choose how data is ordered and stored autonomously. Vast amounts of resources are invested in research on the improvement of information interoperability. Yet the potential of the disease centred Electronic Health Record is not fully exploited.

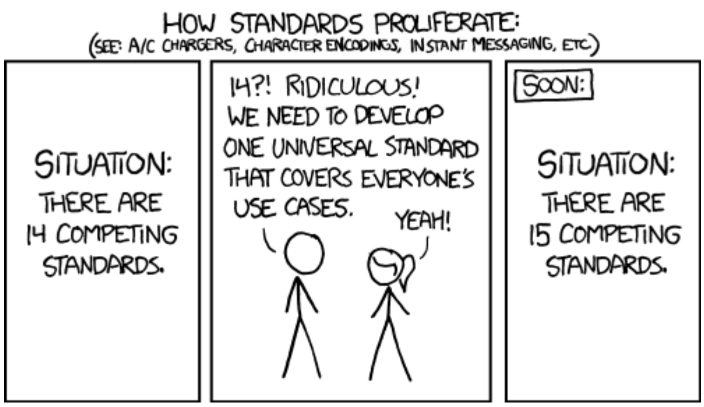


Figure 1: Source: xkcd.com

1.2 General Context

According to European Union policy makers and health care strategists, approximately 29% of the Dutch population will be aged 65 or above [Dutch Hospital Data 2008][1] by the year 2050. The number of available clinicians is not expected to have been increased with a proportional equal amount by that time, leading to considerable higher cost for hospital health care which is currently largely funded with public money. Drastic measures that make the Dutch health care system more efficient and feasible seem unavoidable. Policy-level solutions have been sought by fostering competition between hospitals, by means of specialisation and liberalisation. Unfortunately due to strict government intervention, medical institutions are trapped between the market on one side, and authorities on the other. The vast complexity of the sector is instantly evident when simply regarding the amount time required to train a medical specialist. In Western-Europe, training a General Practitioner takes about ten years [Bion, Ramsay et al. 1998][2]. Considering the fact that health care in The Netherlands aspires accessibility for the entire population, the cost of health care are a direct financial burden to the national community. Keeping such a complex system available publicly, means that an equilibrium has to exist between costs and benefits. With more people reaching the retirement age, the capacity of Dutch hospital health care will be insufficient soon.

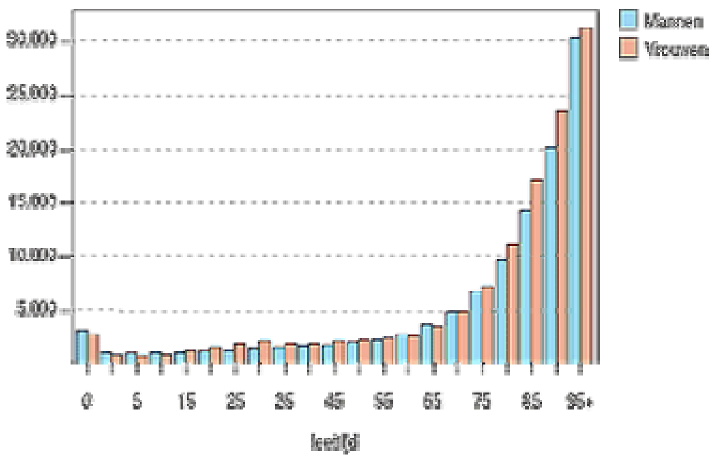


Figure 2: Cost of health care ordered by age and gender, yearly average cost per resident in Euro. [Polder e.a. 2000]

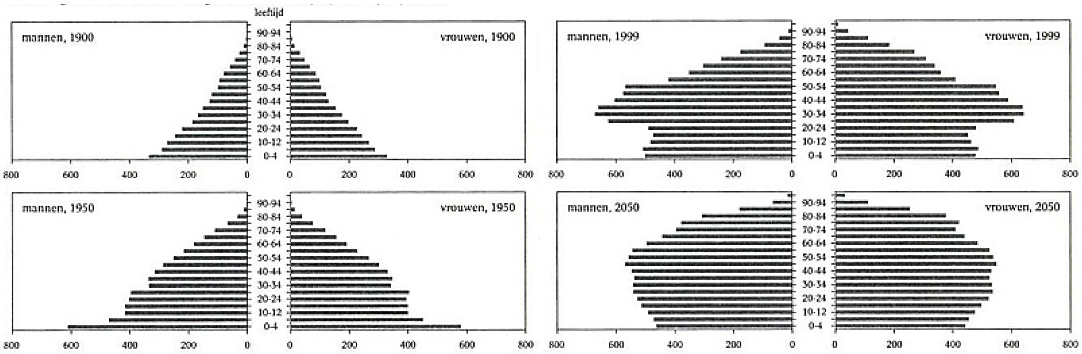


Figure 3: Dutch population (x1000) ordered by gender and age, 1st of January. [Prins & Verhoef 2000]

Training more (expensive) medical staff has been regarded a solution. This could eventually tip the cost-benefits balance in a way that will cause health care to be available only to the higher incomes. In order to maintain the availability of the current system, steps need to be taken to improve on efficiency, quality and to reduce cost [Wesert, van den Berg et al. 2010][3].

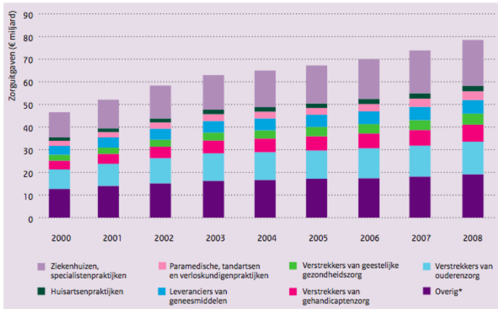


Figure 4: Increasing expenses in Dutch health care [RIVM, 2010]

1.2.1 Hospital Liberalisation

Improving the efficiency of modern semi-public organisations [Mouwen, 2006][4] can be done by means of fostering differentiation and specialisation strategies boosting the organisation's competitive advantage and improving the quality of it's products and services. The partial privatisation of Dutch hospitals enabled specialisation on a national level. According to a 2011 published item [Dutch Health Administration 2008][5] of the ministry of VWS[I], by the end of 2012 approximately 70% of hospital treatments should be valued, based on free-pricing. Within the already highly specialised hospital environment, experiments involving the increased 'separation of functions' that proved to be successful in other countries, do not seem to provide the desired results:

An effective solution, as evaluated by Horrocs et. al in 2002, is the use of Nurse Practitioners. These are specifically trained healthcare professionals(nurses) who takeover several tasks that normally require a physician. The Horrocs et. al research reveals that patient-confidence is equal in 95% out of the 23 cases where physicians were replaced by nurse practitioners.

Using nurse practitioners cuts cost dramatically but critics state that the physician's cognitive helicopter view is essential to the patients' well-being. Another problem of this approach is that so far, only results on the patient's confidence have been measured. Thoroughly evaluating this approach requires specific medical knowledge and years of research in a domain where nurse practitioners are already playing an active role. In North America, nurse practitioners have been deployed for several decades. Yet the Dutch(European) healthcare system has such fundamental(cultural, commercial) differences that other options are to be considered, leaving the 'conventional' physicians in charge.

I VWS: *'Volksgezondheid Welzijn en Sport'*, Dutch Ministry of Public Health

Internationally acclaimed organisation theorist Michael E. Porter asked himself the question: *"Why is competition failing in health care?"* [Redefining Health Care, 2006][6] He concludes:

"(...) the sheer complexity of the health care system is mind-boggling. The practice of medicine is complicated and arcane and medical practitioners are notoriously skeptical of non-physicians' ability to contribute. 'health care is different' or 'you just don't understand' are phrases one hears over and over again in the field".

In his publication, Porter highlights the resistance met when trying to bring 'Business Mindedness' to the attention of all sorts of medical practitioners. Stating:

"There is quite a low status attached to 'management' in the medical field, and business is almost a dirty word (...)"

and

"(...) in health care, many practitioners consider the whole idea of competition to be suspect. Physicians are taught that competition is wasteful, that it promotes self-interested behaviour, and that it undermines patient care."

Porter's findings are largely based on observations of the health system of North America which, in contrast to most of the health systems in Western-Europe and The Netherlands in particular , has been organised in a more commercial and individualistic manner. Leaving little to one's imagination about the attitude of Dutch medical specialists towards business and management in the hospital domain. More on this topic can be found in the 'Domain Analysis' section of this document.

1.2.2 Hospital Automation

Since information systems were interconnected in the early 1960's, the power of omnipresent information has become evident in almost any domain. Hospital health care is no exception. Increased availability of medical information means better transmural health care by empowering patients, encouraging e-health innovation and by providing better treatments exchanging new scientific insights globally [van Dijk, NVMA, 2005][7]. Within the Dutch Hospital Information Technology landscape, in both the university- and community hospitals, a broad variety of different information systems are applied. Based on different starting points, serving different goals [NZA, 2008][8].

In contrast to other public domains that already underwent a cost-cutting transformation using Information Technology, hospital health care has to catch up. Using technology for exchanging information is limited to the medical specialist's domain: Currently, General Practitioners have specific systems for administering patient-records, radiologists have systems for the storage of X-ray files and pharmacists look up medication digitally. Each having their own separate connection with insurance companies, patient associations and scientific researchers. In a NIPO report [TNS NIPO, 2004][9], conclusions are drawn that medical errors caused by erroneous information transfers in the Dutch medical sector occur relatively frequent compared to nations with a higher level of integrated health care automation.

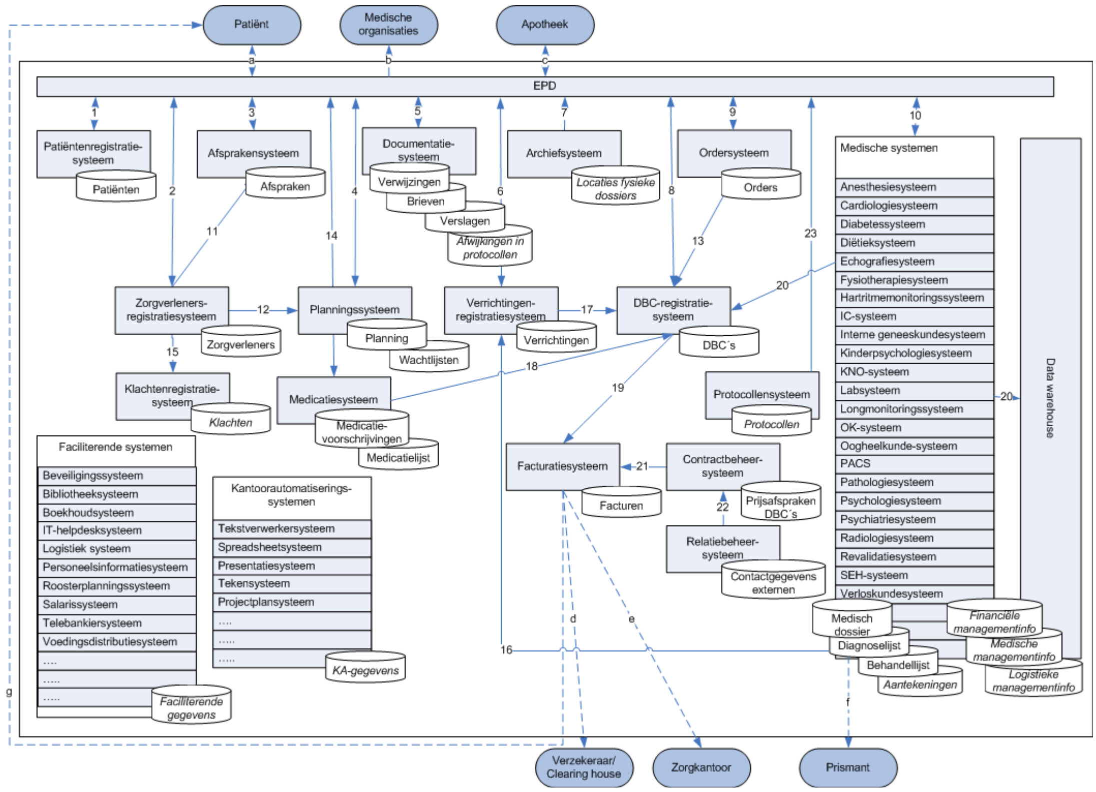


Figure 5: Overview of Information Systems within a Dutch hospital. [Zaans Medisch Centrum 2008]

1.3 Problem Description

1.3.1 Semantic Information Management

The common aim of modern hospitals worldwide is to provide 'patient-centred' care. According to a study [Stewart, 2001][10] from the Ohio based Centre for Studies in Family Medicine, this definition involves regarding patients the main entity in the process of care provision. In the Netherlands, steps are taken to comply with this approach. Empowering patients by giving them choices between different hospitals. Medical information is generally based on this patient-centred topology [Doblhoff, 2002][11] in which data is organised and identified considering the subject of care to be the key entity. The Dutch health care inspectorate [VWS, 2011] states on patient-centred care:

> *"Patients should be central in the care process: Both their diagnosis, treatment and aftercare. It would be good if patients also have a more central role in information exchange. The measurable quality of care increases if the care is organized around the patient(...)"*

Patient-centred care

Traditionally, patient-information is stored in a physical medical file that is created when the patient registers at a hospital for the first time. For each treatment, examination or other form of internal care provision, a report is added to the file that is structured according to regulations described in the *'Wet op de geneeskundige behandelingsovereenkomst(WGBO)' law*. Medical specialists are able to consult the file and use it to decide upon future treatments. According to the '*Wet Bescherming Persoonsgegevens(WBP)*', patients are allowed to request a copy of their own file [AMC website, 2011][12].

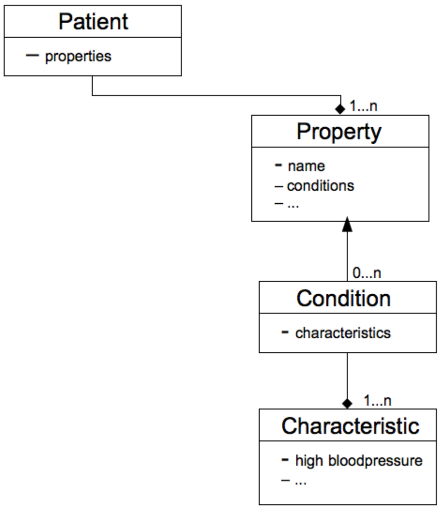
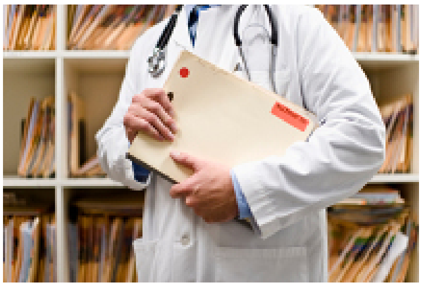


Figure 6: health care information class-diagram topology in which the subject of care is the pivotal entity.

In order to reduce complexity and to improve the quality of care, the medical domain is divided into different specialisms each focussing on different aspects of health care. The individual medical specialisms commonly cover a number of particular pathologies. Considering health care-information in it's disease-specific patient-centred context is therefore essential for providing the best treatment possible. Therefore traditionally, the choice is made to collect patient information in a disease-contextual manner.

Storing information in a physical file has specific disadvantages with regard to the quality of hospital health care [NICTIZ 2010]:



- *The information is bound to the disease-specific context. Extracting information in a context other than the medical one is difficult. Making scientific research and quality control complex.*
- *Not all information is available: The file contains mostly summaries in the form of referral- or resignation letters created by medical specialists.*
- *Exchanging subject of care information requires the entire physical folder to be moved.*
- *Information is stored in a non-standardised and incomparable manner since written documents differ in structure and context.*

The benefits of Information technology [Staggers, Thompson et al. 2001][13] appeared in the medical domain in the late 1970's in the form of financial support systems. Using technology to unveil the power of information disclosure was tried a few decades later. Conceptual attempts have been made to provide patients with an Electronic Personal Health Record [Gartner Group 2001] that would be available nation-wide containing all relevant medical information in a patient-centred manner available from birth to death. Thorough examination of the Personal Health Record however clarified the technical and ethical complexity when implemented nationally. The smaller-scale hospital information landscape however appeared more coherent, standardised and better suited for exchanging information digitally. In this perspective, the advantages of the digital availability of medical information seem to be infinite [Hoekstra, 2011]:

- *Information can be shared more quickly*
- *Information is not per-se contextually-bound*
- *Information storage is not limited to summaries*
- *Better availability of medical information to scientists directly improves health care*
- *Information can be used for better decision support*
- *Financial administration of medical treatments is more accurate*
- *Workflow is driven by stored information*
- *Availability of common medical information saves time in processes that involve information gathering.*
- *. . .*

In 2009 Susan Cram, founder of the ValueDance [ValueDance, 2011][14] consulting firm publicly advised IT-investors to consider investments in organisations producing Electronic Health Records. In her publication *Making the Most of Electronic Health Records* [Cramm, 2009][15] the relationships found between financial incentives and rational medical benefits are explained. The table below summarises these results and emphasises the internationally accepted benefits of EHR systems:

Incentive	**Rationale**	**To increase breadth of adoption...**	**To increase depth of adoption...**
Improved profitability	Doctors receive only 11 percent of the EHR benefits	Share benefits more equitably by requiring private insurance companies to increase reimbursement rates as well	Reimbursement rates should increase only for those doctors who enter information necessary to drive supply chain efficiencies
Cheaper technology	Over half of doctors without EHR cite difficulty in finding solutions that fit the needs of smaller practices	Facilitate agreement on required EHR functionality for smaller practices	Ensure that reduced functionality does not impede capture of critical data
Better subject of care marketing and retention	Most medical consumers are not aware the safety and cost savings benefits of EHR	Educate medical consumers that they should ask their providers about their use of EHR	Educate consumers that they should expect doctors to interact with computers during their exam
Faster, better information	Norway, for instance, has 90 percent adoption, but limited data sharing given incompatible data definitions	Require technology vendors to incorporate common data standards within a prescribed timeframe	Provide quality of care insights to doctors that voluntarily share data about their treatments and outcomes

1.3.2 Policy-Practice GAP

Exchanging detailed medical information between medical specialists will improve the quality of hospital health care since more accurate information is available. It will also reduce cost [Burns, DeGraaff et al. 2010] since time-consuming processes like anamnesis can be based on existing information rather than patients having to answer the same questions with different specialists. In order to improve information-exchange in the medical sector, both national- and international policymakers have undertaken action. They strive to increase innovation and cost-efficiency on one side, encouraging different IT-Firms to provide health care solutions, while encouraging inter-system information exchange using standardisation on the other side

The 'free-market' encouragement policy in which IT-Firms are encouraged to provide hospital health care solutions since 2005 has already proven [Hasaart, Pomp et al. 2006][16] to be effective. Virtually all Dutch hospitals have adopted a wide range of specialised health care information systems. Though the effectiveness of individual health care information systems is clear, exchanging medical information amongst them proofs to be a challenge.

A 2011 published report [VWS website, 2011][17] of the Dutch health care inspectorate, (which is part of the ministry of VWS) addresses the problems that occur when attempting to exchange information intramurally, regardless of the application of IT. "*(...) records are not up to date, incomplete and do not always contain the information that is relevant for medical specialists*". Although more and more institutions are using electronic patient records, information exchange between clinicians(and their systems), remains a major bottleneck. Moreover, the information stored on a subject of care appears to be highly fragmented, even within the boundaries of a single medical institution.

Major recommendations of the health care inspectorate are[II]:

- *"New guidelines and protocols should establish how information transfer processes are to be structured and managed. The Inspectorate requests the Dutch Council for Quality of health care to include this as a firm requirement in its 'Regulations for Guidelines' document."*

- *"Health care institutions should implement a formal policy for the responsible transfer of information between professionals, both within and beyond the institution itself, doing so no later than 2013. This policy must also ensure that patients are able to gain access to their own records on request. Health insurers can encourage and facilitate this process."*

- *"There must be norms and standards which apply throughout the health care system, establishing the type of information that is to be kept, how it is to be stored, the terminology to be used, and how the information is to be made available to those who require it.* ***The Inspectorate recommends that the Minister of Health should appoint a commission to examine the relevant aspects. It will fall to the Inspectorate to ensure full compliance with the resultant norms and standards."***

II According to the summary at the end of the 2011 report

The third recommendation of the inspectorate is particularly interesting because in 2002, the NICTIZ expertise centre was established by the Dutch ministry of VWS to encourage the use of Information and Communication Technologies in health care. It's website[III] states about the goals of the organisation:

1. *"Sharing knowledge on health care innovation in ICT and help to shape policies for ICT in health care at national and international level."*

2. *"Recommending and guiding on the standardisation of medical information and IT, from design to implementation."*

3. *"Provide a secure and reliable ICT infrastructure for health care by managing the infrastructure AORTA so that any authorised provider can access relevant subject of care information at any time of day, anywhere in the Netherlands."*

III Nictiz organisation: www.nictiz.nl

This seems to imply the following remarkable situation: A centralised expertise centre for Dutch health care-IT exists and yet the health care inspectorate indicates that a separate commission should be formed to decide upon norms and standards and to audit their implementation. Clearly a mismatch exists between prescribed policy and practice when it comes to the use of Information Technology in the medical domain involving standardisation and problems that occur with hospital health care liberalisation:

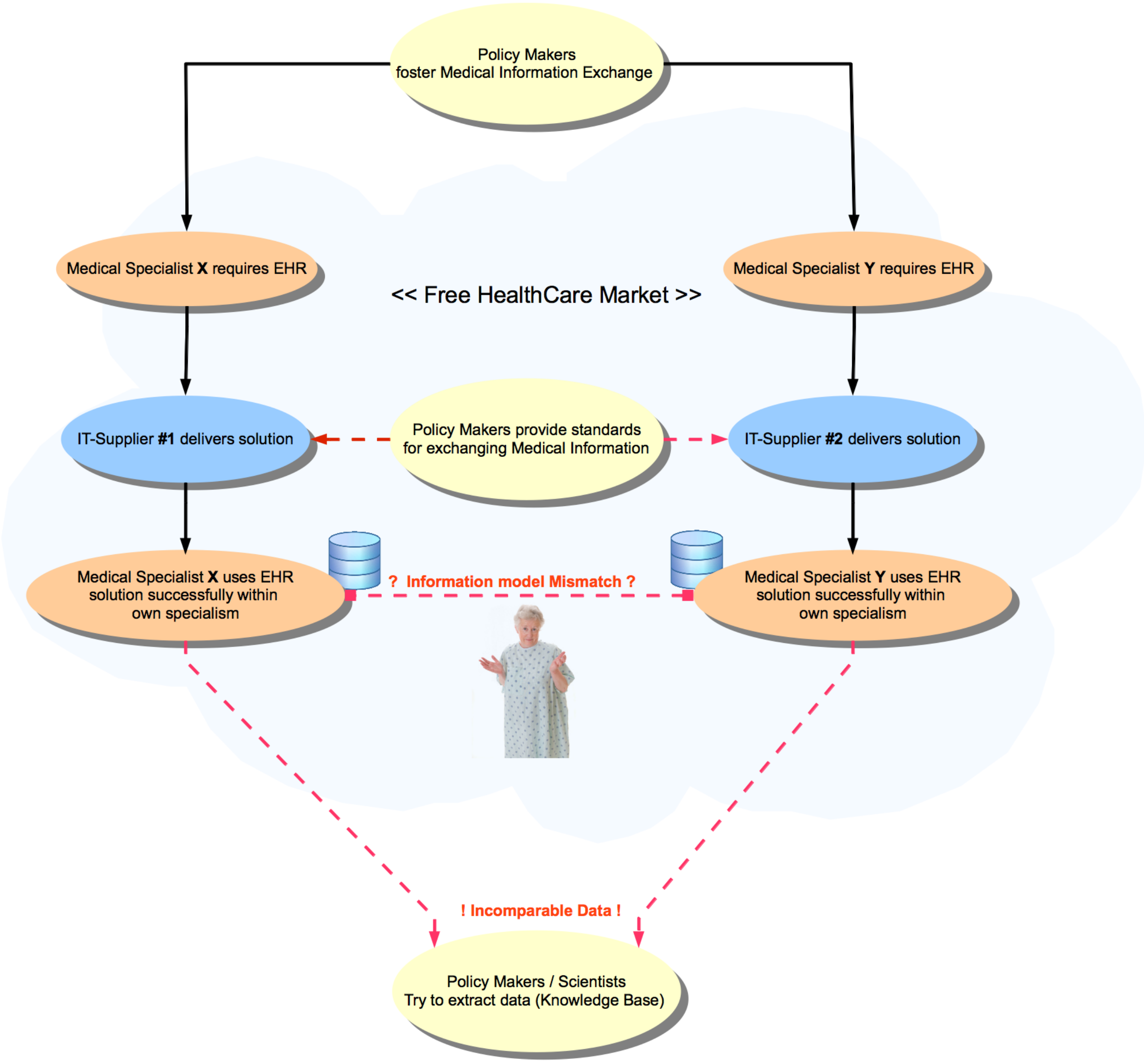


Figure 7: The Policy-Practise GAP within the hospital information domain.

Before purchasing new information systems, organisations tend to do a cost-benefits analysis, hospitals are no exception. When the highly specialised medical divisions the hospital is known for are asked to supply the requirements for a new information system, main focus will be put on the particular medical specialism and less on interoperability of information between medical practitioners. This is reinforced by medical partnerships forming highly autonomous sub-organisations within the hospital. These partnerships have their own budgets and are just as interested in saving cost as the hospital's board of directors. Interoperability between medical information systems is therefore given lower priority, since the short-term benefits of investments in data-model alignment and standardisation aren't instantly clear.

1.4 Research Goal

The brief contextual analysis described in previous sections of this document reveals only a relatively small list of problems that have to be looked into more closely in order to encourage transmural information exchange within the hospital health care system. On various interdisciplinary levels, strategic alignment [Truijens, 2002] problems occur. For this research project however, objectives are to identify problems that occur with the creation and implementation of Electronic Health Records within a Dutch hospital environment and to examine whether it's presumed power can be fully utilised when requirements of (inter)national policymakers, the national health care inspectorate and medical professionals are met. In order to refine this still voluminous objective, the research goal is reinforced using research questions that, when answered, should provide new insights into this relatively unexplored topic.

1.4.1 Main Question

This research-project involves the execution of descriptive research into the role of disease-specific HL7v3 enabled Electronic Health Records within hospitals in The Netherlands. With an extensive domain-analysis backed up by literature and cross-referenced with a unique case-study, answers are to be found to the following main question:

What can be the role of a disease-specific Electronic Health Record featuring HL7v3, SNOMED-CT and W3C standardisation within the Information Architecture of Dutch hospitals?

1.4.2 Subquestions

In order to find answers to the main question, it is broken down into sub-questions the first of which cover the policy-level motivation of researching interoperability of information in the medical sector:

- Why is it so hard to standardise medical information?
- What is the concern of the hospital's clinicians regarding improving medical information exchange?
- What are the effects of health care liberalisation regarding the interoperability of medical information?
- What is the definition of Electronic Health Record?
- What is the goals of EHR implementation?
- What is meant by interoperability?
- What does a generic medical record keeping process look like?
- What instruments are available to achieve interoperability?
- How does Information Architecture affect semantic interoperability

For answering subquestions regarding the AEXIST case-study, the structure of the four TOGAF architectural perspectives is used. Though, for this study the four perspectives indicated as 'Architecture Type' are being discussed using the SOA-Reference Architecture model instead. For it is more applicable to the AEXIST systems.

Architecture Type	Description
Business Architecture	The business strategy, governance, organization, and key business processes.
Data Architecture[2]	The structure of an organization's logical and physical data assets and data management resources.
Application Architecture	A blueprint for the individual application systems to be deployed, their interactions, and their relationships to the core business processes of the organization.
Technology Architecture	The logical software and hardware capabilities that are required to support the deployment of business, data, and application services. This includes IT infrastructure, middleware, networks, communications, processing, and standards.

Table 1: Architectural perspectives supported by TOGAF 9. [The Open Group 2010]

Business

- What does a generic medical record keeping process look like?
- What do these processes look like?
- Why is medical information handled in a disease contextual manner?
- What is the common definition of the term 'Electronic Health Record'?

Information

- What information is needed during the processes described above?
- How is information transferred from one specialist to another?
- What is the significance of the disease contextual meaning of this information?
- What is meant by interoperability of information?
- How can categorised information best be kept in its state and still fully support interoperability?
- Why is this information required and what is the minimal data-set supporting this information?
- What is a core-EHR and how is it developed?
- How can a core-EHR be used in a disease specific context?
- How are requests made from a disease-specific EHR to another EHR?

Application

- How does a disease-specific EHR fit in a hospital's application architecture?
- Which interactions exist between the core-EHR and the disease-specific EHR?
- Which interactions exist between a disease-specific EHR and other hospital information systems?
- Which interactions exist between a core-EHR and other hospital information systems?

Technology

- What is the role of Service Oriented Architecture (SOA) [Chen ,2006][18] in disease-specific EHR?
- What is the role of Service Oriented Architecture in core-EHR?
- Can a 'information-push' or a 'information-pull' model best be used by the exchange of information between EHR systems?
- What is the interaction of EHR systems with other hospital information systems considering information push or pull models?

1.5 Research Scope

Studying medical information management into great detail, requires choices and assumptions to be made. Therefore, in this research the following assumptions are made:

1.5.1 Assumptions

Hospital Domain

Though health care can be seen as a national or even global affair, this study is only limited to the domain of information systems within Dutch hospitals. This is done because the domain itself is already subject of great complexity. The assumption is also made that the IT-Architecture used within a Dutch hospital can be seen as a model for the national health care IT-Landscape involving General Practises, Medical Centres, Psychiatrists, Physiotherapists and other medical practitioners.

Medical Record Keeping

The Hospital's IT landscape displays a vast variety of specialised systems. Lab-test systems and x-ray machines are only a few of such systems. Because of their specific nature, these systems are usually already standardised to a certain degree and are involved with data processing and data gathering only. In this project, only systems that incorporate medical record keeping are addressed.

Medical Culture

The current Dutch health care system is paradoxical. Market mechanisms are introduced and managers are appointed while doctors themselves prefer to stay away from commercialisation and business-mindedness. For this research we therefore assume that the current medical culture is here to stay and that changes will not occur on short term.

HL7v3 / SNOMED-CT / ICD10

Open medical information standards are ubiquitous. Different interest groups have developed many different standards, all derived from a particular philosophy. In this specific research, the assumption is made that the HL7v3, SNOMED-CT, and ICD10 are the standards of choice when it comes to the Dutch health care industry. This is backed up by articles from the European Commission, from the NICTIZ institution and from the NEN organisation. References to these publications will be made later in this document.

AEXIST Case-study

In this document, comparisons are made between literature and Electronic Health Record Systems as developed by the AEXIST organisation. The risk of a biased frame of reference is considerable, therefore an effort will be made to draw truthful unbiased conclusions. In general however, this is the common risk of the case-study methodology.

Disease-specific Electronic Health Records

This research is about disease specific electronic health-records, not about EPR-like systems.

2 Research Approach

This chapter sets out to partition a very broad topic into tangible sections. The research-domain covers a wide range of various disciplines involving Information Management, Hospital Healthcare, Application Development and more, inducing an overwhelming avalanche of seemingly incoherent information. Increased credibility for the approach chosen to transform this mush of information into a well-structured set of arguments that lead to reliable results should be the outcome.

2.1 Overview

Finding answers to the main research-question, an unconventional set of methodologies is chosen. Using online scientific search engines, no 'out-of-the-box' methodologies could be found that could help with answering the main research question making use of the available resources.

2.1.1 Descriptive Research

Generally, the overall research-type can be defined as 'descriptive research' since new knowledge is not acquired by means of empirical experiments. In the article '*Focus on Research Methods: Whatever Happened to Qualitative Description?*' [Sandelowski, 2000][19] the importance of the often undervalued qualitative research method of descriptive research is amplified. Interestingly the article addresses the main comment on this type of research involving the lack of comparability and long-term sustainability of scientific insights gathered using this method.

Sandelowski's recommendation on using the descriptive technique as an overall-method while filling the gaps using other more suitable methodologies is taken on-board in this project. Eventual conclusions are to be drawn using three types of analysis each narrowing the scope of the research. The reason for starting from such a wide perspective is that the topic is not limited to a single case, organisation or group of stakeholders. In order to find the role of standardised EHR systems within a hospital's environment, the value of these systems must be understood from the perspective of all of the different stakeholders each regarding the topic from a different frame of reference.

This might sound somewhat exaggerated but when considering the developments of the past decade involving the cost of creating a national infrastructure for exchanging medical information [Stigchel, Boon et al. 2011][20], the necessity of a thorough situation analysis becomes apparent [Volkskrant, 2008][21]:

> *On the 1st of November 2008, eight million Dutch households received a letter from then present minister Klink of public health informing them about the development of a nationally available public health record providing information to care practitioners, insurance companies and pharmacies. The letter underexposed the fact that technically, patient-information would* ***not*** *be stored in a centralised database but that it would be exchanged between the Healthcare Information Systems of medical institutions only when an authorised physician made a valid request to see it's content. Though the 'Elektronisch Patienten Dossier' terminology was used to simplify the understanding of healthcare-information interoperability by standardisation, by the end of the year the letter was misunderstood by more than 330.000 citizens including leading political individuals. They sent in the leaflet that came with to the flyer stating that they did not want to become part of this new national technological development.*
>
> *By the 5th of April 2011, the effects of misconceptions about a nation-wide EHR programme became fully clear when members of the senate of The Netherlands rejected the proposal. By the 8th of November it also became apparent that exploiting the national EHR programme commercially was not sufficiently supported by the medical sector. Total cost of the project so far have been estimated on approximately 4,3 million Euro.*

The situation-sketch above emphasises the importance of valid and complete information used for decision-making in (semi-)public sectors.

Public opinion is formed largely by press and politicians. The financial burden caused by the failed national exploitation of the AORTA infrastructure conceals the amount of knowledge acquired during the design- and testing-processes. The fact that this knowledge is forming a pivotal element in fostering medical information interoperability, remains underexposed. Complete and valid information is what leads to credible long-term insights on a topic that has a nation-wide impact. This is the main argument for the descriptive character of the research project.

Figure 8: Nation-wide EHR flyer as published by the Dutch ministry of VWS in 2008

2.2 Domain Analysis

Developments in the IT-sector are known for their rapidity. Over fifty years after the first application of the transistor, Moore's law still applies. Offering new technological possibilities in an incomprehensible pace while time passes. This poses the challenge of researching the topic in detail while trying to create long-term scientifically sound insights, introducing the risk of making unwanted generalisations. For this reason, proven methodologies are used some of which date back to the 1980's. Since they are not used strictly, in this study their structure is used to bring rigidity to otherwise somewhat uncomprehending descriptive research.

What	How
Domain Analysis on Hospital Care:	Mc. Kinsey 7s model, offering a description of Dutch hospital care and the systems involved. SOA Reference Architecture Model
Literature Studies on Electronic Health Records:	Available written resources clarifying the choices made providing an insight in the available tools for interoperability and giving a uniform view of the concept called Electronic Health Record.
Case Study of the AEXIST firm:	The Open Group SOA Reference Architecture

Using present developments like the national EHR project or the 2011 report of the health care inspectorate (about improving information exchange in the sector) as a starting point proves the actuality of the subject. Making this study into a scientifically sound project however, requires the acquired knowledge to be still valid in the future when situations have changed. This explains the necessity of doing a brief analysis on the researchable domain: The hospital organisation and it's information management. This brief analysis sets out to clarify how present hospitals are organised and which different actors are involved in using information technology.

In an attempt to add long-term value to the insights gathered in this project, a distinction is made between the current(IST) situation in the hospital care domain, still being subject to various changes, and the less-volatile definitions that were used to decide upon standards used in Electronic health care Records(SOLL situation).

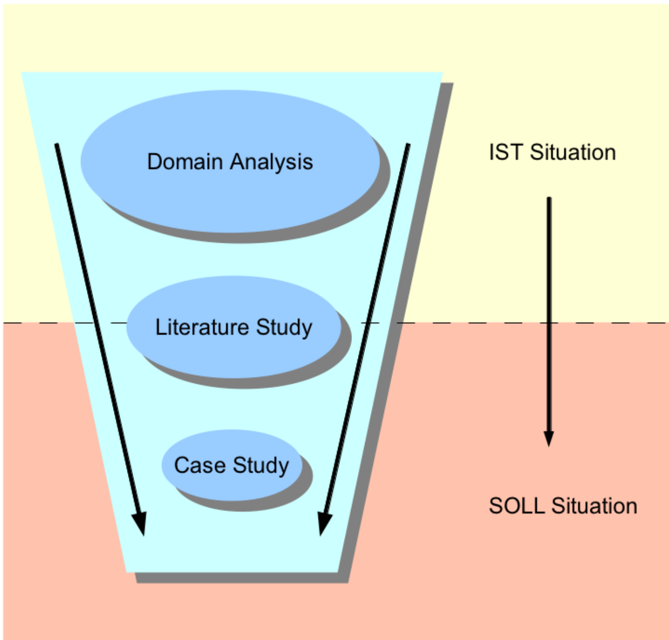


Figure 9: Research Funnel: Making the topic more specific

2.2.1 McKinsey 7S Model

The domain analysis is mostly based on information gathered from textual sources. Making the analysis into a structured statement that covers all important factors and yet keeping it small enough to provide an overview is the challenge involved. When trying to understand how an organisation works, mapping the interconnectedness of different elements of the organisation can provide a profound insight into it's operation. The McKinsey consulting firm has over thirty years of experience in the field of organisation analysis. In the early 1980's Tom Peters and Robert Waterman, two consultants working at the firm created the 7S model in order to evaluate the internal alignment of organisational aspects. According to its creators, the model can help with the following:

- General description of the organisation
- Improve the company's performance
- Examine the probable effects of future organisational changes
- Align departments and processes within the organisation
- Determine how to implement a proposed strategy the best way

Because this research project is about transmural information exchange within the hospital domain, this model was chosen. It is used to describe the current (IST) situation from the perspective of a hospital organisation.

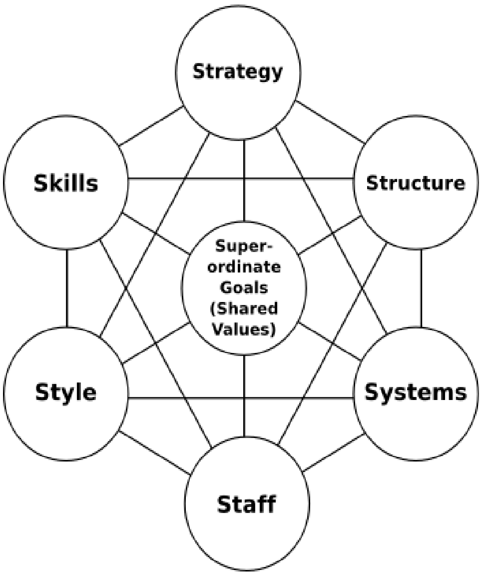


Figure 10: 7S Organisational description model by Robert H. Waterman, Jr. and Tom Peters

2.3 Literature Study

In research, literature studies are done for several reasons. The most obvious of which is finding the status of current research on the topic and defining the position of a research project within the area of interest. Another reason for studying topical literature is removing ambiguity and providing credibility for choices made.

In this research project, the method serves both purposes by defining concepts and by justifying assumptions and choices. Not only involving scientific papers but also including information models that were created by organisations like NICTIZ and Parelsnoer. Policies and understandings are reviewed, helping to narrow the research-scope into the case-study of the AEXIST EHR to which results from the literature study can be triangulated when answering the research questions at the end of the study.

2.4 Case-Study

As described in the '*Motivation*' section of this document, chances of finding a fully standardised Electronic Health Record in a Dutch hospital environment are rare, for reasons still to be emphasised by both the Domain Analysis and the Literature Study.

2.4.1 AEXIST EHR approach

The Den Haag based AEXIST B.V. specialises in the production and implementation of disease-specific electronic Health Records within a hospital setting. Studying the disease-centred and fully standardised approach of this firm, reveals a cross-section of the challenges involved with EHR implementation. Below, motivations for using this company as a case-study are listed. The main source of this information is Mr. Hoekstra, the firm's CEO.

- When designing an Electronic Health Record, choices have to be made regarding the contextual route to be followed. The medical specialist's work field typically covers a multitude of disorders. Yet it is the contextual coherence of information about specific diseases that the specialist will use to decide upon treatment. This is why a disease-centred approach will help
- The AEXIST EHR approach reflects the implementation of European Policy on standardising Electronic Health Records. According to the 2009 'Research and Deployment Roadmap for Europe' [Stroetman, Kalra et al. 2009] document, repositories containing Detailed Clinical Models should be available to EHR manufacturers in 2013. This approach is currently already being used by the AEXIST organisation. Finding another case of inter-comparable EHR's living up to this level of standardisation was not feasible within the timeframe of this research.
- Since more and more EHR suppliers, policy makers and hospital managers are realising the value of semantic interoperability within the medical domain, the demand for knowledge about Core EHRs will grow, proving the value of unambiguous ontology usage in the sector economically, socially and medically [Rapport: Kerndossier in Nederland, NICTIZ 2011].
- The 'parelsnoer' project is a cooperation between eight university-hospitals assembling clinical data for the improvement of medical treatment. The AEXIST EHR systems are designed to export data into the Parelsnoer databases. The (inter-operable) exported data can be used as a reference for the creation of a Core EHR
- Currently, the scope of the study is limited to four EHR systems, implemented in the Radboud hospital in Nijmegen. Though being a single case only, the four systems offer a unique representation of what a hospital's ICT architecture might look like when it is composed only out of similarly standardised EHR systems. This research contributes to the global scientific knowledge of using standardised ontologies for semantic interoperability in health care information systems.
- In practice, Dutch hospitals do not have systems that are fully HL7v3 compatible. The increased application of the HL7v3 medical standard in combination with SNOMED-CT however makes this research more relevant.

2.4.2 Architecture Analysis: TOGAF 9

To find the role of medical EHR's within a hospital domain, the organisational architecture is mapped. The definition of organisational architecture is defined by the ISO/IEC 42010 in 2007 as:

> *'The fundamental organisation of a system, embodied in its components, their relationships to each other and the environment, and the principles governing its design and evolution.'*

As described in the 'synopsis' section of this document, a major motivation for this study is the availability of the AEXIST case-study in which a landscape of four functional HL7v3 SNOMED-CT based EHR systems exist. In order to dive deeper into the role of such systems within hospital information-architecture, the SOA-Reference Architecture model [The Open Group, 2011][22] is used as a guideline. The SOA-RA is based on The Open Group's Architecture Domains Model(ADM). A TOGAF based model was chosen because of it's frequent use throughout the Information-Technology industry and due to its application by the NICTIZ organisation which uses it for the description of IT-Architectures in Dutch health care environments. The third reason for choosing the SOA-RA model as a guideline is the fact that it is an Open Standard. Though registration is required on The Open Group's website, each individual is allowed to download and implement the methodologies offered. This way, all interest-holders are equally able to access the methodologies.

Alternatives

Particularly in a situation where industry standards are used to objectively evaluate a certain situation, the risk of getting biased results due to groupthink can be present unnoticeably.

In 1997, the 3GLM [Buchauer, Ammenwerth et al. 1997][23] methodology as described by Buchauer et al. was presented to be the first method enabling the comprehensive description of a hospital's information architecture. Using a three-level graph-based model to deal with three different levels of abstraction, the method was regarded highly innovative. As can be seen in the example image below, the three-level architecture description offers a clear view of the available systems each having their place in a different level of abstraction. A major drawback of this approach can be found in its unambiguity. Making a rigid distinction between the three perspectives removes the ability of adding or removing a layer, apart from the fact that the method is not an open standard and that it is therefore less mature than it's more common counterparts.

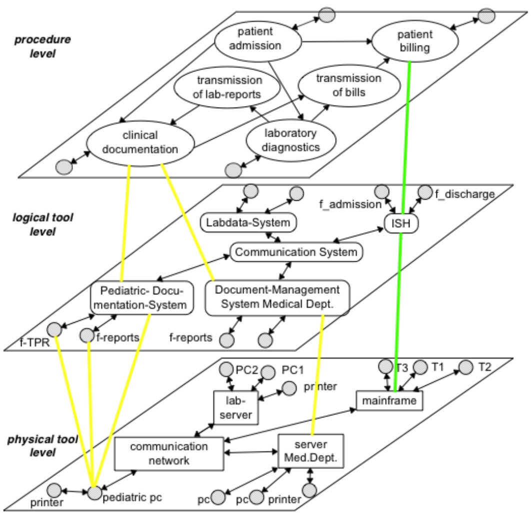


Figure 11: 3GLM example architecture description

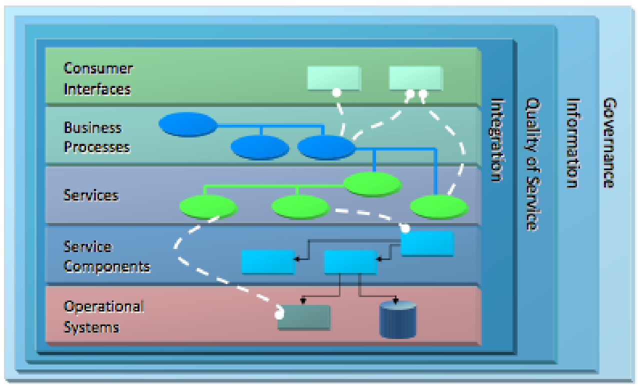


Figure 12: The Open Group SOA Reference Architecture [The Open Group 2010]

3 Domain Analysis: *Hospital Care*

Complex problems occurring in a specific situation can sometimes best be understood by looking beyond the obvious. Finding out how a hospital organisation works is essential to fully understanding the value of medical information interoperability.

By using the Mc Kinsey 7S model as a reference, the hospital care system is briefly described. The model is traditionally used for the internal analysis of a single organisation. For this study it is applied to clarify the definition of the word 'Hospital' from the context of this research project. The boundaries of the internal organisation are often crossed in order to create a profound but brief sketch of the situation. This section is required for understanding the concepts introduced in the 'Theoretical Background' chapter providing answers to the subquestions:

- *What does Information Management in Dutch hospitals look like?*
- *Who are the major stakeholders that benefit from the exchange of medical information?*
- *What is expected from the Electronic Health Record?*
- *Why is it so hard to standardize and exchange medical information?*
- *What are the effects of healthcare liberalization regarding interoperability of medical information?*

3.1 Style

The definition of the word 'Hospital' differs between nations. According to a Elsevier Science publication about the history of anaesthesia [Askitopoulou, H., Konsolak, 2002][24], the generalised hospital organisation is described as an institution fit for the treatment of various diseases that do not necessarily have a mutual connection. The authors draw a distinction between *General Hospitals, District Hospitals, Specialised Hospitals, Teaching Hospitals and Clinics*. This description suits the Dutch understanding in which according to the Dutch Association of Hospitals(NVZ)[IV] a difference can been seen between: *General Hospitals, Teaching Hospitals and Specialised Hospitals.*

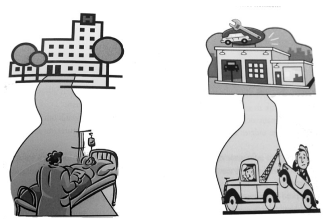


Figure 13: A hospital is not a 'workshop for people'. Source: Schat, Cillessen et al. 2010

3.2 Skills

General(n=85)-, and Teaching(n=8) hospitals are the most common [NVZ website, 2011][25] in The Netherlands according to the branch organisation. General Hospitals can be found in minor cities and agglomerations. Providing mostly secondary care, the hospital organisation incorporates many specialisms. In General Hospitals, these specialisms are somewhat equally divided, the Teaching Hospitals often have one or more areas in which they excel. The combination of physicians and scientists studying a particular subject causes this excellence. It

IV Nederlandse Vereniging van Ziekenhuizen NVZ: www.nvz.nl also makes the Teaching Hospital difficult to control from a managerial point of view since interests are intertwined sometimes even contradictory.

3.3 Staff

The specialised and autonomous character of medical professions renders the hospital a remarkable organisation. According to Putters [Putters, 2001][26], it's workforce can be divided roughly into care provisioners, and supportive staff. In a commercial organisation this would not be different. The public hospital though, is subject to an unusual configuration: Medical specialists tend to play a pivotal role in its operation since they have nearly managerial autonomy. Instructing lower medical staff, choosing treatments and being largely responsible for the performance of their department. When regarding international findings on the organisational structure of the Hospital, this appears not to be an exception.

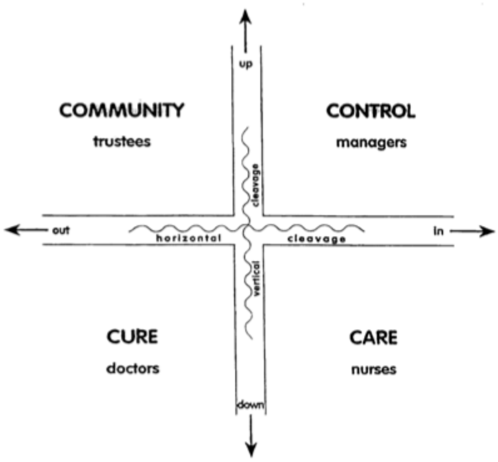


Figure 14: Source: Glouberman & Mintzberg 2001

United States researchers [Glouberman, Mintzberg, 2001][27] describe the typical relationship between management and medical specialists in a hospital organisation. These researchers however, studied mainly commercially driven systems in which health care is not a public domain. The North-American hospital is characterised to be a *professional bureaucracy* [Mintzberg, 1979][28] which is typically decentralised and run by its staff. Putters states that this classification also applies for hospitals in The Netherlands and even asserts the position of medical specialists in this organisation to be 'intrapreneurial'. Targeting their autonomy on a professional-, organisational- and financial level.

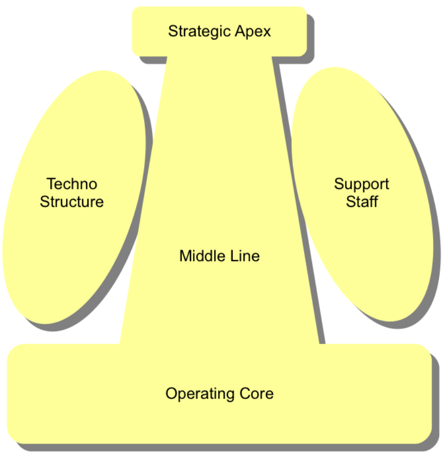


Figure 15: The 'ideal' organisational [Mintzberg 1979].

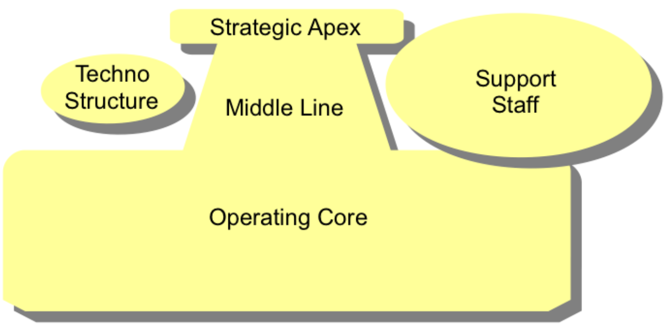


Figure 16: The 'Professional Bureaucracy' [Mintzberg 1979]

When looking at the organisational charts of different hospitals, the Medical Staff ('Medische Staf') is usually found on a level of administrative hierarchy equally to the board of directors. This emphasises the empowerment of medical specialists in Dutch hospitals.

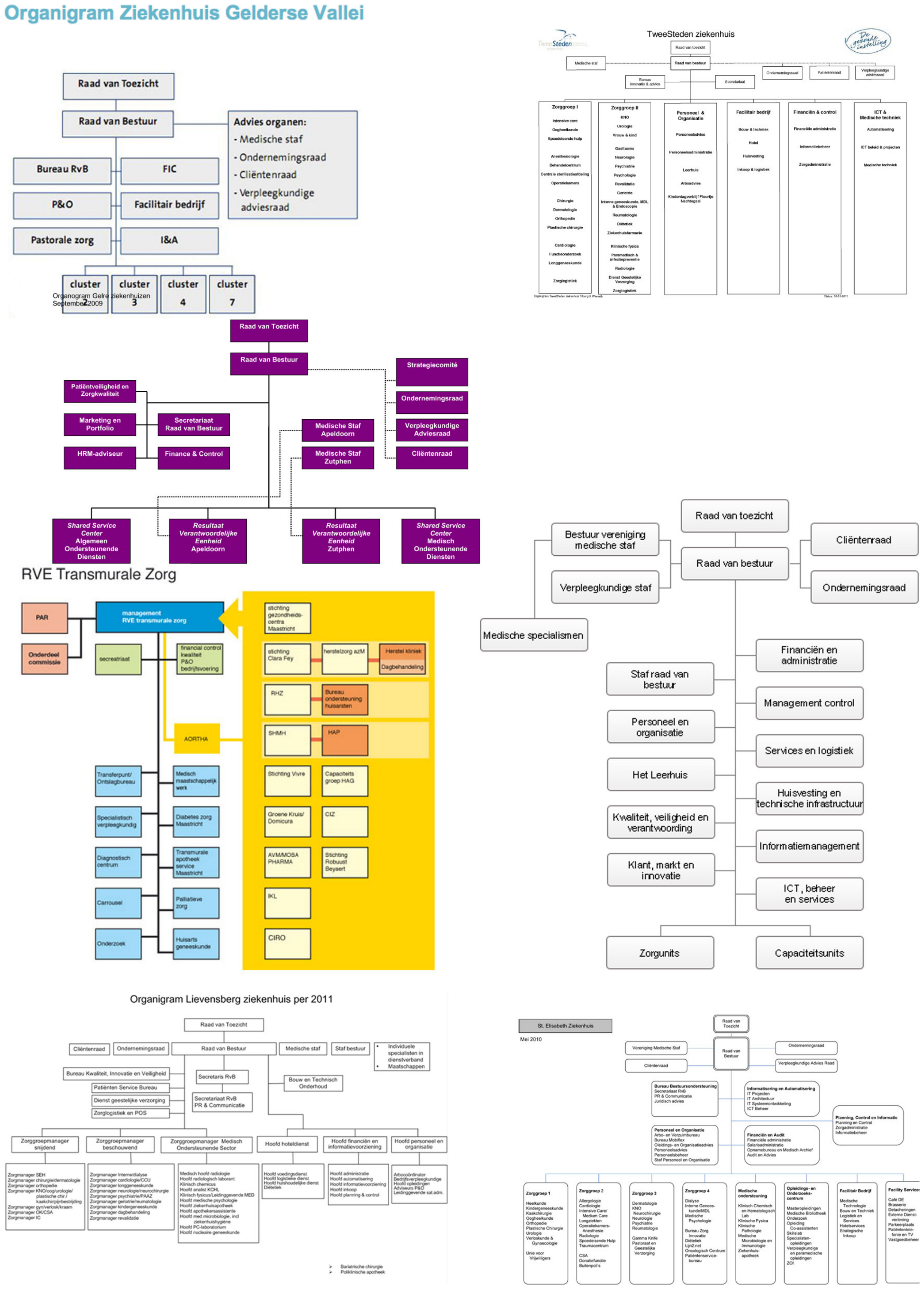


Figure 17: Organisational charts of Dutch hospitals found on their websites in November 2011

Delft University researchers [Dicke, Steenhuisen et al. 2011][29] state in a recent study about liberalisation in Dutch public sectors that 2001 appointed minister of health Els Borst was the initiator of demand-driven care in which patients were given more control by enforcing their legal status, improving provision of information and by facilitating better independent care-counselling. Borst also attempted to improve the transparency of medical institutions by assembling quality indicators. This resulted in a gradual rearrangement of the balance of power between health insurance, patients and hospitals. It simultaneously changed the immutable position of medical specialists who found themselves obliged to provide performance indicators. Dicke et al. describe the fierce protests by medical personnel and patients in 2005 when legislative proposals about increased health care liberalisation were discussed in Dutch parliament. The frequently heard argument stating that 'health care is not a market' did not prevent the law from being passed in January 2006.

3.4 Structure: From value-chain to care-chain

When considering organisation theorist Michael E. Porter's '*Value Chain*', describing how value is added to products and services in organisations and branches, two elementary systems can be distinguished:

- The first one, being the stream of productive activities, describes the internal operations within the firm leading to products or services.
- The second system reveals the economical process of supply and demand by describing the stream of activities across firms.

This setup [Porter, 1985][30] presumes the generalised firm to have suppliers delivering commodities or intermediates and purchasers receiving the product or service when (partially)finished. Unlike other service-oriented organisations, the hospital appears to be difficult to describe when it comes to understanding how value is added.

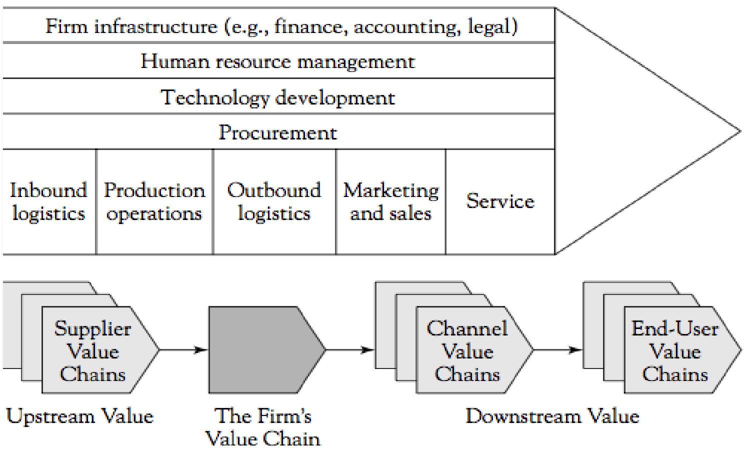


Figure 18: Porter's Value Chain showing two types of organisational systems.

Source: Michael E. Porter. Competitive Advantage: Creating and Sustaining Superior Performance. Copyright © 1985, 1999. Adapted with the permission of the FREE Press, a division of Simon & Schuster, Inc.

Wharton School researchers [Lawton, Burns et al. 2001][31] Lawton, Burns et al. tried to find an answer to the question: "*Do value chains exist in the U.S. health care industry?*". Emphasising Porter's theory claiming that value chain analysis can lead to supply chain improvement and to more efficient organisations. Burns et al. try to identify the extension to which hospitals deal with supply chain management. They used a definition of 'supply chain' [Everard, Lynn 2000][32] stating: *"The ultimate goal for any product moving through the chain is to reduce cost and add value at the same time."* The Wharton School researchers identified some major drawbacks in the creation of value chains within U.S. Hospitals:

"There are several explanations for the health care industry's short- comings as a value chain. First, unlike other industries, products are often ordered by workers on the front line of health care delivery, such as physicians, nurses, and so on. Purchasing is thus not an organisational competence, let alone a core competence, but rather the domain of non-businesspeople. Products are ordered in a way that maximises their availability when needed, rather than minimises the costs of holding inventory. Moreover, the end user ordering products is not typically the buyer (that is, paying for the product). Product demand is thus based heavily on the clinical preference of physicians rooted in their medical training, not on any formal cost-benefit analysis or budgetary constraint."

When evaluating the representation of the value chain of Dutch Hospitals in the figure below, it becomes apparent that in a hospital only processes involving the critical path(direct care) are regarded to be productive activities.

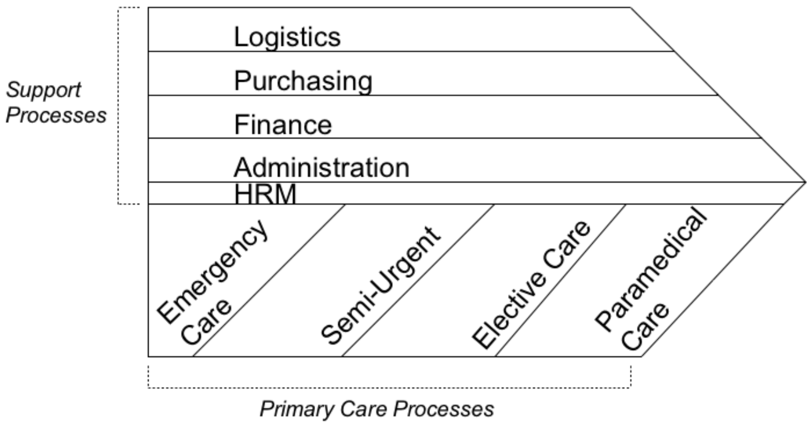


Figure 19: Hospital value chain Source: www.zorgatlas.nl November 2011

In the book "*Redefining health care*" [Porter, Olmsted et al. 2006][33], Porter refers to his earlier theory on value chains by emphasising the roles of general practitioners, nursing homes, insurance companies, patient organisations and other players involved with the healing process. According to Porters view on patient-centred care, the boundaries between different types of care providers fade so that a complete care program gets a price tag instead of individual treatments. The subject of care goes through a chain of care from hospital to rehabilitation introducing the concept '*care-chain*'[V].

V Porter's understanding of Care-Chain is called "Care Delivery Value Chain" or CDVC

3.5 Strategy

Dike, Steenhuisen et al. describe in their narrative analysis of Dutch health care liberalisation how three main actors can be distinguished in the system. These three actors involve hospitals (health care institutions), patients and insurance companies. Dutch citizens are obliged to be insured for medical expenses, ensuring that care providers will treat all inhabitants when in a life-threatening situation. Increasing health care liberalisation empowers insurance companies by enabling them to settle arrangements with specialised health care institutions providing higher quality of care for a lower price. Theoretically, patients are able to choose any hospital suiting their preferences making them into '*savvy health care consumers*' instead of patients. In practice, reduced insurance rates leave the task of choosing a hospital up to the insurance firms. Yet this approach renders insurance companies part of the care-chain.

In social and political debates, the question is asked if patients can be turned into 'savvy consumers' since the cost of healthcare increases exponentially with people aged 65 and above. This part of the population is generally not regarded to be able to find the optimal hospital using modern media like the Internet.

The resulting equilibrium between the three parties is regulated by several governing institutions, each assessing different aspects of the system. Seemingly, these organisations are autonomous. They are however controlled by the government.

Nederlandse Zorg Autoriteit

The "*Nederlandse Zorg Autoriteit*"(Dutch health care Authority) is an institution responsible for the supervision of all health care providers and health insurers in the curative and long-term care market [NZA website, 2011] [34]. The NZA creates regulations, budgets and tariffs for health care institutions that are subject to liberalisation. The organisation provides recommendations to the ministry of health on the composition of new policies though it's main purpose is to make sure that the implementation of market-mechanisms in Dutch health care does not have negative effects on its society focussing on quality, affordability and accessibility [Langejan, 2011][35].

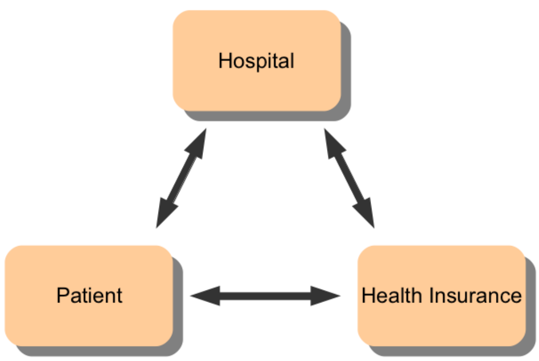


Figure 20: The main actors in the hospital care system [Dicke, Steenhuisen et al. 2011]

Inspectie voor de Gezondheidszorg

The "*Inspectie voor de Gezondheidszorg*"(health care Inspectorate) monitors the quality of Dutch curative care by forcing medical institutions to deliver reports containing quality indicators over each year [Dutch health care inspectorate website, 2011][36]. Areas of special interest that need to be reported on differ every year depending on the type of organisation and on new medical insights obtained using the '*Evidence Based Medicine*' (EBM) [Timmermans, Mauck 2005][37] approach in which the findings of large-scale medical trials are used to decide upon the improvement of medical treatments. Providing a stronger scientific foundation for medical guidelines.

3.5.1 Quality Indicators

Centraal Begeleidings Orgaan

The CBO institution, which is part of the Dutch TNO organisation, regulates peer-reviewing amongst clinicians. It was formerly known as the 'Association of Medical Specialists'. It is therefore directly involved with the development and implementation of new health care protocols and quality indicators. It publishes new models supporting higher standards of care. The 'Model Stuursysteem Decubituszorg' [Kwaliteitsinstituut voor de Gezondheidszorg, 2003][38] (quality indicators on decubitus or bedsore) is an example in which quality indicators are described in detail. It consists of three stages the first of which contains a list of elements that need to be registered:

1. *The percentage of patients on which a structural risk assessment is performed (RIp process indicator).*
2. *The percentage of patients to whom, despite structured inventory, develop decubitus (Riu outcome indicator).*
3. *The percentage of patients taking appropriate preventive measures (PRP process indicator).*
4. *The percentage of patients who, despite structured risk assessment and preventive measures, develop decubitus (outcome indicator PRU).*
5. *The percentage of patients with pressure sores properly identified and diagnosed (DP1 process indicator).*
6. *The percentage of patients with the right degree of decubitus are identified and diagnosed (DP2 process indicator).*
7. *The percentage of lesions that develop to a higher degree (Du outcome indicator).*
8. *The injury rate that the degree of pressure sores receives appropriate treatment (Bp process indicator).*
9. *The rate of decubitus despite appropriate treatment, more than one average (in the institution / country) healing time (outcome indicator Bu).*

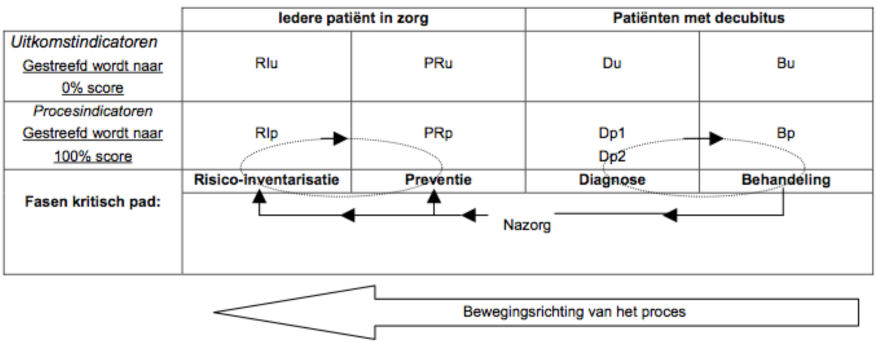


Figure 21: Model of quality indicators on decubitus. [cbo.nl 2011]

The second stage of the model is a list of information that needs to be available in order to make valid calculations on the quality indicators:

1. *The number of patients with some form of structured risk assessment is done;*
2. *The number of patients with some form of structured risk assessment is done and in which its related preventive measures taken;*
3. *The number of new decubitus since the previous survey;*
4. *The total number of injuries;*
5. *The number of decubitus occurrences known to the doctors*
6. *The number of decubitus occurrences known after doing an additional round of diagnosis;*
7. *The degree of any injury that the doctors and nurses know;*
8. *The degree of any injury that is known after doing another round of diagnosis;*
9. *The number of injuries that has been developed to a higher level (that is deteriorated);*
10. *The number of injuries resulting in decubitus*
11. *The number of injuries that have longer than average healing time.*

$$\text{RIp} = \frac{\text{het aantal patiënten waarbij enige vorm van gestructureerde risico-inventarisatie is gedaan}}{\text{het totaal aantal patiënten}}$$

$$\text{RIu} = \frac{\text{het aantal nieuwe decubitusletsels ten opzichte van de vorige meting}}{\text{het aantal patiënten waarbij enige vorm van gestructureerde risico-inventarisatie is gedaan}}$$

$$\text{PRp} = \frac{\text{het aantal patiënten waarbij enige vorm van gestructureerde risico-inventarisatie is gedaan en waarbij tevens daarop geënte preventieve maatregelen zijn genomen}}{\text{het aantal patiënten waarbij enige vorm van gestructureerde risico-inventarisatie is gedaan}}$$

$$\text{PRu} = \frac{\text{het aantal nieuwe decubitusletsels ten opzichte van de vorige meting}}{\text{het aantal patiënten waarbij enige vorm van gestructureerde risico-inventarisatie is gedaan en waarbij tevens daarop geënte preventieve maatregelen zijn genomen}}$$

$$\text{Dp1} = \frac{\text{het aantal decubitusletsels dat bij de artsen en verpleging bekend is}}{\text{het aantal decubitusletsels dat bekend is na het doen van een extra diagnoseronde}}$$

$$\text{Dp2} = \frac{\text{de graad van elk letsel dat bij de artsen en verpleging bekend is}}{\text{de graad van elk letsel dat bekend is na het doen van een extra diagnoseronde}}$$

Figure 22: Decubitus score, calculation model. [cbo.nl 2011]

The third stage is a computational model, enabling the scores to be calculated for the specific health care institution.

Within the boundaries of hospital organisation, opinions on the information required on different operational levels are continuously being improved. The NICTIZ organisation works together with associations of medical specialists (CBO) to create inter-disciplinary datasets supporting quality indication on various levels.

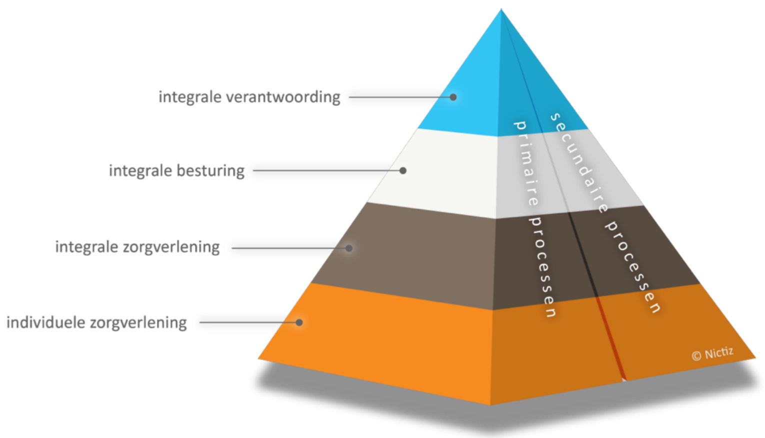


Figure 23: An example of an attempt to standardise datasets: The IZI triangle as described by the NICTIZ organisation. [NICTIZ 2011]

3.5.2 Information Availability

Financial Information

Information about medical institutions proves itself useful to authorities and scientists, it's availability is also significant to patients and insurance firms. Until 1983, medical treatments were performed invariably, independent on the cost [Leeuwen, Bruinsslot 2004][39] involved. Predictions on future cost increases lead to the introduction of the '*Functional Budgeting'* system, interconnecting medical treatments directly to fundings, enabling insurers to form policies on the quality of medical procedures. In January 2005, the *'DiagnoseBehandelCombinatie'* (Diagnose Treatment Combination) was introduced materialising the functional budgeting approach by providing a tool for administering treatments financially. The DBC system enables patients to choose an insurance portfolio covering the '*care products*' of their choice. Due to the vast amount of different codes (*representing medical operations*) used in DBC, independent organisations are required to evaluate if the codes chosen by care providers are correct and if they can be reimbursed by insurance firms. When a medical treatment is completed, the DBC system allows care providers up to a year to declare the cost of this treatment. The complexity of choosing the right codes combined with these long declaration times makes the system inefficient. The successor of DBC is already being promoted and is called DOT[VI]. It represents the effort to improve the financial transparency of medical treatments by forcing the care provisioner to move along a process in which treatments are divided in more simple operations. The DOT system will allow care-products to have a fixed price.

Transparency of Information on medical competition

Difficulties involved with evaluating care quality in a hospital can be found in the fact that better quality can mean the difference between life and death of a patient. Dike et al. state that this is known by the inspectorate and by physicians but also point out that due to publication of comparable quality-information, some hospitals will be marked to be 'worst in the country' on a specific treatment. Understandably, this is why information on quality indicators is disclosed gradually until the official publication planned in 2015 according to chief inspector Schellekens of the health care inspectorate.

"*Zichtbare Zorg*"(visible care) is an initiative of the health care inspectorate which itself is controlled by the ministry of health. The foundation's main task is to ensure the reliability and the quality of information about medical institutions in order to improve comparability [Zichtbare Zorg website, 2011][40] of these organisations.

3.6 Systems

Currently, hospital managers, medical policymakers, scientists and medical specialists are supported by a broad variety of information systems, eventually for the achievement of a single goal; providing better care to patients. Amongst these systems, a rough distinction can be made between ERP-oriented- and medical information systems [Lodder, Zwetsloot-Schonk et al. 2008][41].

VI D.O.T. : 'DBC's Op weg naar Transparantie' http://www.nza.nl/zorgonderwerpen/dossiers/dbc-dossier/

ERP-oriented Information Systems

ERP-oriented systems are designed focussing on patient's registration within a hospital and with the accountability of a specific treatment towards insurance companies(DBC) in mind [Hoekstra, 2011]. Basically facilitating a Hospital's elementary system of supply and demand. The ERP-oriented information systems are in many cases the IT-backbone of a Hospital's information architecture. In order to facilitate billing, most other systems are connected to this one system. In Dutch hospitals, this system is frequently referred to as *'Ziekenhuis Informatie Systeem' (Hospital Information System)* or ZIS. Because interoperability between other hospital information (ZIS) systems involves mostly basic patient- and billing information, this has not been regarded an issue for this type of systems. Typically the ZIS provides additional functionalities for support processes like: Order management, Planning, Patient registration, DBC registration, Billing and Purchasing [Eekeren, Ginneken et al. 2010][42]. Though the ZIS is sometimes mistakenly called Electronic Health Record (EHR or EPD in Dutch), EHR systems support the critical path, providing different functionalities that are specifically medically-oriented.

Electronic Health Records

Medical information systems within a hospital often originate from the requirements of medical specialists[VII]. Experienced doctors' direct involvement in the development of medical information systems, is a common practise since the specialisms for which the domain is known are so complex and knowledge-intensive.

Medical information systems are usually meant for the administration of single specific diseases or specialisms. The logic in this approach can be found in the aim of these systems to replace the original cardboard folders containing the patient's physical Health Records. Therefore these systems are referred to using terminology known as Electronic Health Record (EHR or EPD in Dutch). EHR systems can be found throughout the entire hospital domain ranging from the operating room to internal medicine and the physiotherapy unit.

Since their construction is based on the requirements of medical specialists, data storage is done within each individual system following the workflows and information models required for the particular specialism. Transferring patients from one medical specialist to the other is often done manually using a paper reference-letter. Because of this, medical specialist rely only on patient-information provided by referral-letters while systems are available that might offer more accurate, very specific patient-information. The sheer complexity of the different specialisms results in EHR systems that are not built with interoperability in mind.

Medical Messaging

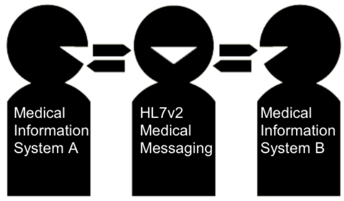


Figure 24: Using the HL7v2 messaging standard requires data transformation of two information systems from and to the messaging standard.

Supporting the DBC convention for financial administration, most [Mensink, Birrer 2010] contemporary EHR's are able to send messages to the ZIS-system containing information about billing and treatment completion. These messages are composed using the HL7(Health Level 7) version 2 standard for exchanging medical information. This standard for information exchange has a limited dataset and requires the EHR system to transform stored data in such a manner that it suits the HL7v2 messaging standard. When the message is received by the ZIS(*or any other medical information system*), it has to be decomposed and transformed according to the data-model of the receiving application.

VII Using the NICTIZ Domain Reference Model v0.1 as a guideline, specialists are regarded to be: clinicians, Paramedics and Nurses

3.6.1 Data-model Misalignment

As stated in the 'motivation' section of this document, present EHR systems use conventional techniques that have proven to be successful in the field of computer science. One of which is the *'relational model for database management'* invented by computer scientist Edgar Frank Codd.

The relational data-model is the foundation of most current database systems in which information is deconstructed, categorised and stored in tables. Interrelated records are identified with a 'key' parameter. Relational databases have proven to be able to handle large amounts of data incredibly fast while requiring relatively little computing power. The relational model has however some severe drawbacks [Strauch, 2011][43].

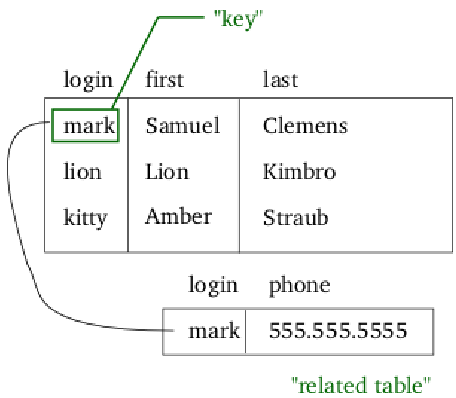


Figure 25: The Relational data-model as developed by Codd uses a 'key' to link related records

When for example items of the dataset to be stored are constantly changing, system engineers have the tendency to add extra required columns to the table and leave old columns unchanged since altering them might affect other tables that are dependant on the old column. This can result in a scenario with cluttered databases of which the used columns are unknown.

The previous example clarifies that direct interoperability of medical data can only take place when a shared data-model is present. Typically this is hard to realise in a liberalised and privatised health care IT-sector. Moreover regarding the specific dataset required for the administration of different medical specialisms. NICTIZ employee and former chemist Gerrit Boers about the relational data-model:

> *'In the IT sector it is common practice but when you think of it:*
>
> *It would be foolish to disassemble your car and put all it's components into separate boxes every time you come home and drive it into the garage. Only to assemble it again the next day, when it is needed for another trip.*
>
> *So why **are** we doing this with our data in relational databases?'*

Besides continuous changes of medical information models, another problem that occurs with relational databases is the storage of 'unstructured information'. With care practitioners having nearly ten minutes of administration time per patient, registering all required information consistently proves to be a daunting task.
Especially clinicians working on the 'emergency care' division commonly have very little time for patient administration in which has to be decided on the type of information to be registered. Whereas having more detailed information about the patient(allergies, medication,blood type etc.) might save critical minutes when consulted during preparations of the surgery for a subject of care that is still at emergency care [Cornet, Keizer 2009][44].

3.6.2 Code-system Incompatibility

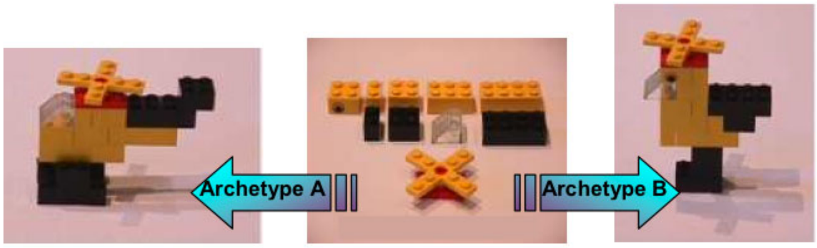


Figure 26: LEGO illustrating the use of Archetypes as building blocks. Source: H. Lodder, B.Zwetsloot 2008.

In order to facilitate direct interoperability between Electronic Health Records, complex code systems based on open standards are provided. These code systems consist of reference information models and templates created with archetypes enabling computerised storage and comparison. Even for medical information systems that use the same code systems however, interoperability poses a problem involving semantics. The following example emphasises the problems when using medical terminology standards like SNOMED-CT:

The treatment of various diseases involves periodic monitoring of the patient's blood-pressure. When these values are registered using the medical terminology standard SNOMED-CT, the general code used for systolic blood pressure measurement is:
163020007

Whereas for the treatment of diseases like diabetes mellitus, it is required to store the state in which the measurement took place. e.g. Standing, Sitting or Lying. All of these states must be distinguishable, therefore individual codes are assigned.The code for systolic blood pressure measurement while lying down is: ***407556006***

Due to these technical difficulties and great complexity that come with data-model alignment, this approach has only seen limited implementation in the hospital landscape [Koppenaal, Bemelman et al. 2007][45].

3.7 Shared Values and Trends

Eventually, the common goal of all actors involved in the hospital care system is continuous improvement of health care quality for patients. Nevertheless will the role of some of these actors be reconsidered due to imminent changes taking place in the sector. Changes resulting in more power flowing towards patients are unavoidable. Initiating the need of more and better information on available clinical treatments. The Atos consulting firm applied the van der Heijden 'Scenario Planning' methodology to find out about the future of hospital health care in The Netherlands in a scope ranging to 2020. The analysis [Atos Consulting, 2010][46] was based on seven trends that were noted by independent experts from the industry. These trends summarise beautifully what is happening in the sector:

1. **Government:** Influence is decreasing. Critics claim that the introduction of liberalisation has failed in health care. According to Dike, Steenhuisen et al. disavowal and functional fixedness are normal phenomena regarding profound social changes. Stating that privatisation and liberalisation of the sector will continue in an evolutionary manner in which trial and error is the methodology of choice, they conclude that we are only half-way the process of change. The first benefits of increased innovation due to the changes in health care can already be noticed in terms of local initiatives.

Four hospitals alongside the A12 highway, running through one of the most densely populated areas of The Netherlands, have started to work together to increase the quality of care. [Rinke, van der Parre 2011] They do so by exploiting specialisation and by making joint purchases. Aligning five intensive-care units on operational and information technical levels enabled the organisations to share a single PET-CT-scanner cutting cost dramatically.

Initiators of the 'MijnZorgNet' enterprise Prof. Kremer (gynecologist) and Prof. Bloem (neurologist) are both employed in the St. Radboud hospital in Nijmegen. Providing a platform for online care-communities, the MijnZorgNet project sets out to find and interconnect patients and all sorts of care providers regardless of the institutions involved. Using current web2.0 technology, the patient-centred approach is enforced since establishing a community does not require more than a group of patients.

2. **Finance:** Hospitals are increasingly being funded using private resources, though legislative measures assure risks are not borne by these organisations alone.
3. **Insurance:** Health Insurance firms are gaining increased influence on care providers. A question asked by many market players is: *What are the reasons for insurance companies to choose a hospital to do business with?*
4. **Patients:** Are gaining an increased influence on care services.
5. **Performance Indication:** Hospitals are being judged more on price and quality ratios.
6. **Primary Care:** General Practitioners are gaining influence and are given more control in the patient's care process.
7. **International Orientation:** Patients are no longer focussed on local care only. Looking over the borders for the best care is becoming a trend.

3.8 Intermediate Conclusions

Having analysed the hospital as an organisation and having clarified the current(IST) situation in the domain, answers can be given to the first set of subquestions:

What are the effects of health care liberalisation regarding the interoperability of medical information?

Increasing liberalisation is changing the points of interests within the healthcare market. It enforces care practitioners to focus on the quality of their discipline by requiring indicators annually. Meanwhile, individualism is facilitated by the effects of a free market. Entrepreneurial individualism ensures that care providers are less interested in investing in intramural information exchange. While it is this information interoperability that could provide better quality to practices and that could give the hospital a competitive edge.

Why is it so hard to standardise medical information?

Being highly trained professionals, clinicians are spending decades of their lives on mastering a specific medical discipline. Though having many rules and protocols, decisions that have to be made in every day's practise require a cognitive understanding of combined sciences like biology, psychology, physiology, chemistry and social science. It is up to doctors to decide what information is required in order to be able to make a sound decision.

Making an information- or data-model that involves multiple medical specialisms therefore requires not only profound knowledge of the specific fields, but also requires knowledge on how to translate contextual information from one specialism to another. Given the speed with which scientific insights are moving forward, such information models also have to be able to support rapid structural changes. Relational data-models, as used in current relational databases, are not flexible enough to work with such large but ever changing information models. The complexity of medical data poses a technical challenge when attempting to exchange it digitally.

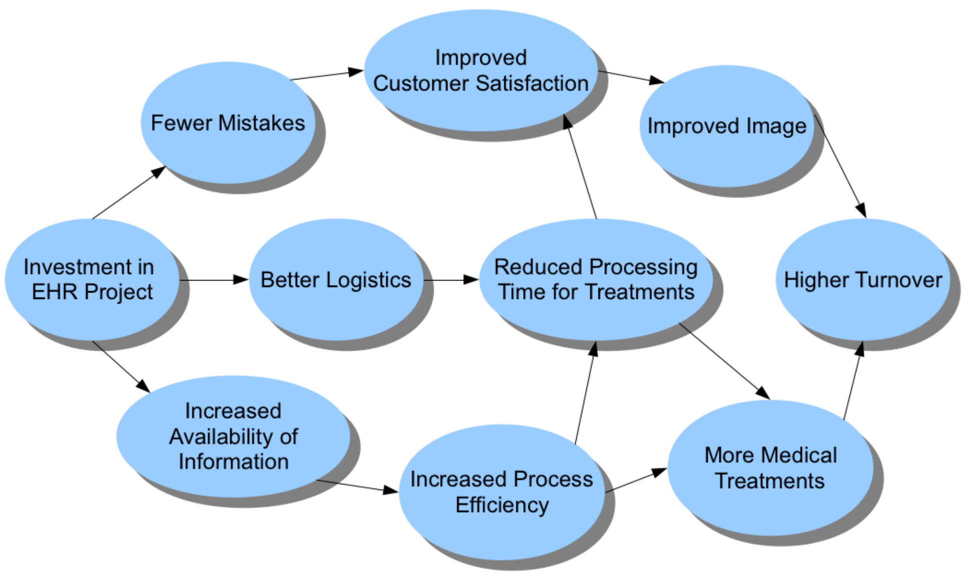


Figure 27: EHR value cycle. [Eekeren, Ginneken et al. 2010]

What is the concern of the hospital's physicians regarding the improvement of medical information interoperability?

Increases in comparable structured medical information will enable scientists to base new findings on data collected from all sorts of real-world information systems reducing the need for large trials that are usually taking place in a controlled environment. Medical mistakes due to wrong or little information will occur less frequently and eventually the quality of care will increase, inducing improved quality of life for patients. Appearing to be the ultimate goal of modern health care [Westert, van den Berg et al. 2010][47].

The statistical approach of the '*law of large numbers*' which is founding the chain of evidence for most medical knowledge, does not apply to technological innovations in clinical care. Situations differ between hospitals and since IT appears not to contribute to the critical path[VIII] directly, its interoperability is rendered low priority by medical staff.

Overall trends in architecture can be noted regarding the separation of concerns on information management. The traditional '*Ziekenhuis Informatie Systeem*'(ZIS) system is being separated into different systems. ERP systems, responsible for purchasing, financial administration and Medical Information Systems(EHR) storing the patient's medical information digitally.

VIII Clinical pathway of the subject of care when carried over between different specialists.

4 Theoretical Background: *The Electronic Health Record*

Claiming that hospital care provision involves great complexity will not encounter great opposition. Doing the same for information technology will not result in much resistance either.

In this chapter, the major concepts involved with Electronic Health Records will be emphasised and wherever possible invigorated using publications. The views of policymakers on the topic is addressed clarifying the incentives of the Aexist EHR approach.

This chapter aims at finding intermediate answers to the questions:

- *What is the definition of the term 'Electronic Health Record'?*
- *How does this definition relate to the Dutch EHR market?*
- *What is meant by interoperability?*
- *What instruments are available for achieving interoperability?*
- *What does a generic medical record keeping process look like?*
- *How does Information Architecture affect semantic interoperability?*

4.1 EHR Definition

The very word brings up associations with the commonly known physical health-record assembled in a cardboard folder being implemented in an electronic way. Administering medical information electronically has been done successfully since the 1990's. The term 'Electronic Health Record' can be interpreted in several manners. A description has been given by various experts each having their own particular view on the subject using different definitions. Therefore, finding a suitable definition can be hard. Academic-, governmental- and consultancy-institutions have created a broad variety of understandings on the topic including [HL7 corp. 2004][48]:

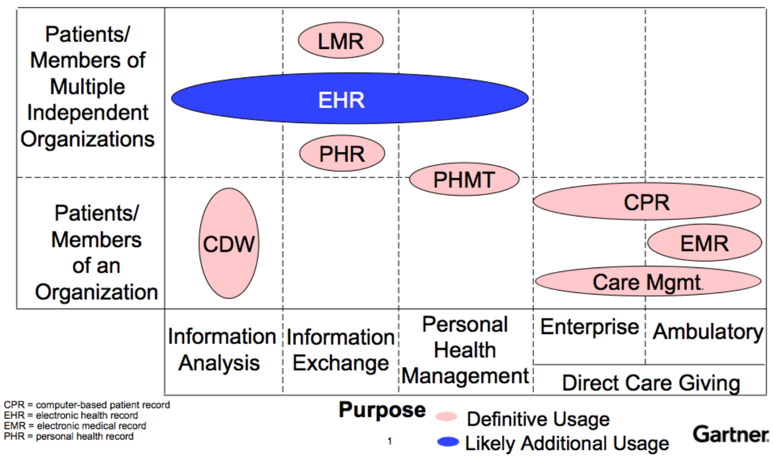


Figure 28: [Handler, Hieb 2007 The Updated Gartner CPR Generation Criteria]

- *Electronic Medical Record (EMR)*
- *Electronic Patient Record (EPR)*
- *Computerised Patient Record or Computer-based Patient Record (CPR)*
- *Electronic Health Care Record (EHCR)*
- *Virtual EHR (VEHR)*
- *Personal Health Record (PHR)*
- *Digital Medical Record (DMR)*

These concepts seem to be the results of over time developments in the field of medicine and information technology. Handler and Hieb use the generic term '*Digital Record Systems*' to describe a series of medical information systems responsible for the storage of clinical data directly supporting the care process.

4.1.1 Gartner's 5 generations

The globally recognised publications of the Gartner Consultancy Group often use a definition that first appeared in a 2001 article [Gartner Group, 2001][49]. In this article, EHR-systems are described to be a more generic type of clinical system, supporting workflow and financial administration. Current understandings on the Electronic Health Record are clarified best by using the article's definition of Computer-based Patient Records'(CPR) being:

> *"(...)Containing patient-centric, electronically maintained information about an individual's health status and care, focusing on tasks and events directly related to patient care and optimised for use by clinicians(...)"*

The reason for the Gartner definition being used often is the roadmap in which five generations of systems are described, ordered by level of sophistication. The five generations model enables the international conceptualisation of the developments on EHR systems in a relatively unambiguous manner. It is not a coincidence that the well known CMMI [Chrissis, Konrad et al. 2005][50] model for process improvement also consists of five steps towards improvement. The CMMI hands-on, best-practise approach was used as a guideline for Gartner's five generations description:

1. **First generation: *'The Collector'***
   Simple systems collecting data from various specialised medical information systems.
   e.g. electrocardiographs or lab results. First generation EHR systems offer functionalities for viewing information only, modifications can not be made. For this reason, the capabilities of such systems are compared with that of a children's '*diorama*' which is also meant for viewing only. Characteristic of a '*Collector*' EHR is the patient-orientedness of accessible data.

2. **Second generation: *'The Documentor'***
   Can be regarded to be a first generation system with the added functionality of medical record keeping. In the 'Documentor' a disease-contextual approach is also chosen. In the definition of Gartner, this system also incorporates basic order management- and planning functionalities.

3. **Third generation: '*The Helper'***
   Extending the benefits of the first two generations, this system offers decision support and has extended order management. Transmural care is supported by attaching workflow features that can indicate which actions involving other systems are required. e.*g. the system responsible for the prescription of medicine.* This system should also provide standardised data that can be used in the Evidence Based Medicine cycle.

4. **Fourth generation: '*The Colleague*'**

   Whereas the previous generations were largely provided with information coming from specialised medical systems*(e.g. lab results),* the fourth generation of EHR systems should provide practitioners with decision support based on information from the patient's care-chain. In order to be able to do so, the system should seamlessly interact with data gathered from other medical systems. This system often knows more details on specific patients than the docter does. It can recommend on-, or discourage the practitioner's decisions becoming a profound source of information.

5. **Fifth generation: *'The Mentor'***

   The last generation of EHR systems is able to recommend acting physicians on their particular specialism. It becomes part of the Evidence Based Medicine cycle by providing standardised subject of care data for scientific research and by using new insights in its *'business logic'*

   e.g. if new insights for the treatment of diabetes are available in which patients cannot take more than 200 units of insulin, the system will prevent a doctor from entering 201 in the patient's care plan.

   Especially the risk on dangerous combinations of medicine being prescribed is reduced.

Currently, second and third generation EHR systems are being implemented. Capabilities of other generations cannot yet be utilised [Heitmann, Jonkersz et al. 2009][51]. When a fifth generation system is implemented, similarities with the CMMI model become apparent.

4.1.2 ISO 20514

Though Gartner's conceptualised description of the CPR is universal, in this study we stick to the term Electronic Health Record(EHR). We use the definition of the International Organisation for Standardisation(ISO) because it incorporates the requirements and philosophies used by both European- and National policymakers and those of other standardisation organisations. This definition relies on the statement that systems involved with medical record keeping can be divided into shareable- and Non-shareable systems, both being instances of the Basic-Generic EHR.

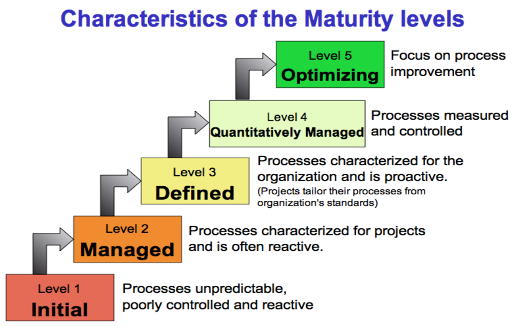


Figure 30: The 5 levels of the CMMI model comply with Gartner's 5 EHR generations

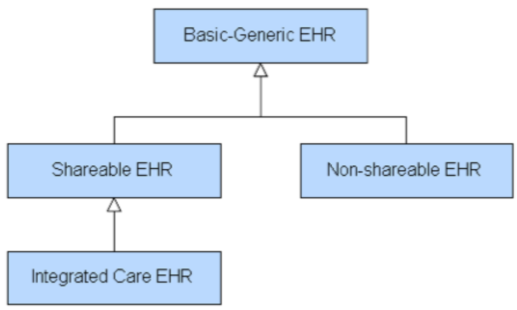


Figure 29: ISO20514 on the definition of EHR systems: "The approach taken in this Technical Report is to make a clear distinction between the content of the EHR and its form or structure."

Basic-Generic EHR

Is not unambiguously defined in the ISO20514 document in order to keep the understanding as comprehensive as possible. It sets out to describe all systems involved with electronic medical record keeping, stating:

"The basic–generic definition for the EHR is a repository of information regarding the health status of a subject of care, in computer processable form.
It has been noted that in regard to the term "Electronic Health Record", the word "Computerised" or "Digital" may be preferable to "Electronic" since the record itself is usually stored in digital form on a magnetic disc or other medium such as magnetic tape, 'smart card', or CD-ROM, none of which are strictly electronic, except that the hardware that processes them (and therefore the record) uses electronic circuits. However, this is a rather pedantic view and the term "Electronic Health Record" and its abbreviation "EHR" are now so well established internationally that a further name change would cause unnecessary confusion."

and

"(...)the definition is essentially a concatenation of the CEN definitions of a "healthcare record" ("a repository of information regarding the health of a subject of care") and the EHR ("a healthcare record in computer readable format") (see ENV 13606-1:2000), with one important change. The phrase "computer readable" in the CEN definition has been changed to "computer processable" which encapsulates readability but extends this to include the notion that information in the EHR must be amenable to programmatic manipulation and therefore to automatic processing."

shareable & Non-shareable EHR

The ISO20514 document addresses the differences between shareable and non-shareable systems as follows:

"The difference between a non-shareable EHR and a shareable EHR is analogous to the difference between a stand-alone desktop PC and a networked PC where the latter adds enormous benefits in terms of locating, retrieving and exchanging information using the internet, an intranet, email, workgroup collaboration tools, etc."

The ISO organisation emphasises that the very purpose of administering patient-information digitally is to improve medical interoperability. The generalisation below also reveals that the current unwanted Dutch situation, in which EHR monopolists are deciding upon the data- or information models used, can be regarded to be globally applicable:

"At present, almost all EHRs are based on proprietary information models within EHR systems, with little or no interoperability between EHR systems and little or no ability to share EHR information beyond the immediate boundary of a single health organization In fact, it is often impossible to share EHR information between different disciplines within a single organisation (e.g. between doctors and nurses) or between different applications within a single clinical information system (e.g. a non-integrated decision support or care planning application is unable to access the EHR which is bound to the "EHR application"). Non-shareable EHRs are nearly always tightly bound to both the EHR system software and also to a particular database product. This is the case with the large majority of EHRs implemented in all areas of health at present."

Clarifying the term 'Non-shareable EHR' to be an information system that might be capable of sharing information digitally, the statement above indicates that 'non-shareable' can be explained as: *Build around a non-standardised data structure- or model.*

Shareable EHR and ICEHR

Using the 20514 ISO definition, the sharing of EHR information can take place at three levels:

- **Level1:** Information is shared between different medical practitioners that are working from different disciplines but use the same application.
- **Level2:** Information is exchanged in the form of data within the actual EHR system. e.g. from a software application to a database.
- **Level3:** This is when medical information can be transferred across different supplier-independent EHR systems that cover various medical disciplines. The 20514 definition indicates that interoperability will be mainly achieved by using a standardised set of items that can be applicable to the majority of medical disciplines. Systems that live up to this standard are called Integrated Care EHR(ICEHR)[IX].

Level3 EHR systems can in turn be subdivided into Core EHR and Extended EHR. The core system mainly consists of a standardised multi applicable dataset which is specifically defined in the ISO/TS 18308 document. The Extended EHR covers the so called "*Health Information Landscape"* as defined by Beale in 2001. It differs between health organisations but sample data items of this Extended EHR are given: *patient administration, scheduling, billing, decision support, access control and policy management, demographics, order management, guidelines, terminology, population health recording, querying, and analysis.*

The understanding 'hospital EHR systems ' as it is being used in The Netherlands is based heavily on the insights of both the ISO-organisation and the Gartner Group as can be seen in the figure below:

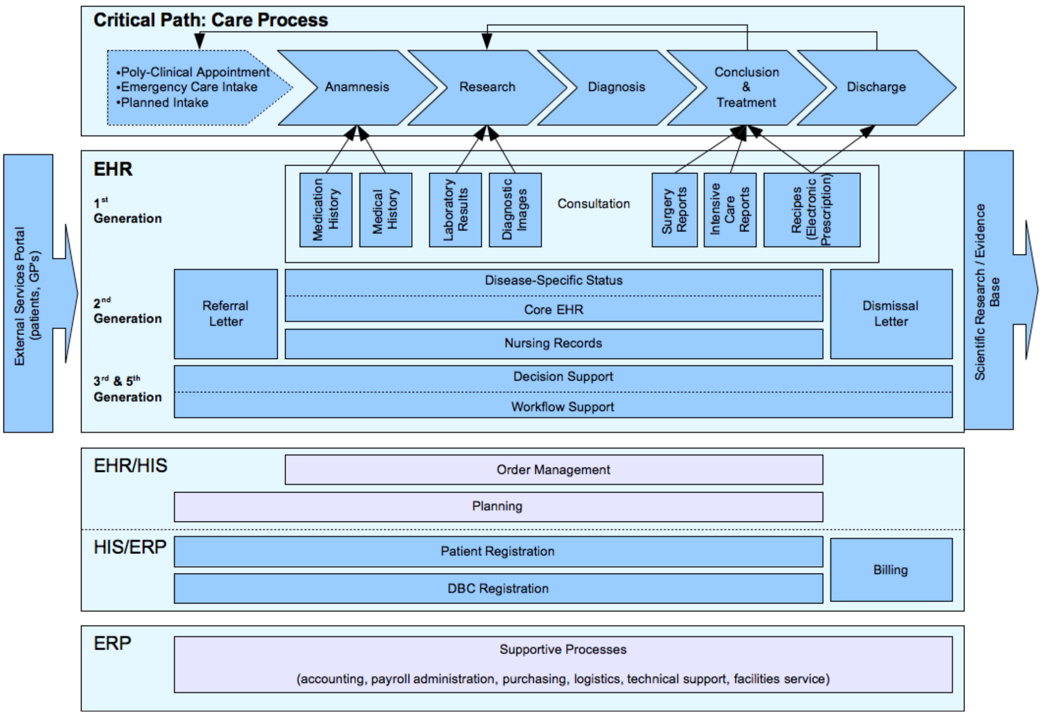


Figure 31: Generalised overview of EHR implementations in Dutch hospital care [Ginneken, Eekeren 2010]

IX *N.B. The term ICEHR is hardly used in the Dutch hospital landscape. In order to keep terminologies understandable, we stick to 'ISO20514 level3'.*

In 2010, Ginneken and Eekeren composed a generalised model of the hospital's EHR implementations. It is based on years of consultancy experience and on analysis of a large number of medical centres. It represents however a fictitious situation since developments on EHR implementation are far from finished.

4.2 Interoperability

In the ISO 20514 documentation, interoperability is extensively described from a perspective of standardisation. It states that the single most important characteristic of the EHR is the ability to share information between different authorised users. In technical terms, this requires interoperability of information in the EHR and interoperability of EHR systems which exchange and share this information. There are two types of shareability or interoperability of information:

1. **Functional Interoperability:** The ability of two or more systems to exchange information .
2. **Semantic Interoperability:** The ability for information shared by systems to be understood at the level of formally defined domain concepts (so that information is computer processable by the receiving system).

ISO 20514 states on interoperability:

"Note that semantic interoperability is not an all-or-nothing concept. The degree of semantic interoperability will depend on the level of agreement on terminology and the content of archetypes and templates used by the sender and receiver of information. Semantic interoperability is necessary for automatic computer processing to underpin the real value-added EHR clinical applications such as intelligent decision support and care planning.
One of the key requirements for shareability of the EHR is to break the nexus between the EHR and the EHR system (i.e. the EHR should conform to an information model independent of both the physical database schema used for local storage and the applications which create, maintain, and retrieve EHRs). This EHR information model should be independent of any particular implementation technology (i.e. it should be a logical information model). Technology independence is also essential to make the EHR 'future proof' to enable the possibility of lifetime EHRs.
In order to achieve semantic interoperability of EHR information, there are four prerequisites, with the first two of these also being required for functional interoperability:

a) A standardised EHR reference model
The EHR information architecture, between the sender (or sharer) and receiver of the information.

b) Standardised service interface models
To provide interoperability between the EHR service and other services such as demographics, terminology, access control and security services in a comprehensive clinical information system.

c) ***A standardised set of domain-specific concept models.***
Archetypes and templates for clinical, demographic, and other domain-specific concepts.

d) ***Standardised terminologies which underpin the archetypes****.*
Note that this does not mean that there needs to be a single standardised terminology for each health domain but rather, terminologies used should be associated with controlled vocabularies."

4.2.1 Information Models & Medical Terminologies

As partially described in the 'Domain Analysis' section of this document, information standards can be used to improve interoperability. The NICTIZ[X] organisation -*in cooperation with several standardisation organisations such as NEN and ISO*- works on a roadmap for the improvement of information-exchange between Electronic Health Records. It does so by using the medical information standards that are globally available. These standards cover different parts of the domain from different perspectives. Generally, three types of standards can be distinguished[XI]:

#	Type	Description
1	Code-systems, Classification Standards and Medical Terminology Standards	Providing unambiguous descriptions of medical terminology
2	Information Standards(models)	Providing detailed information of data-elements required for storing medical information in a particular context.
3	Structure,- and Communication Standards	Standardised data-models for exchanging or storing medical information.

The figure below is an overview of available standards and code systems. That are currently implemented in the health sector. Because of the case-study at the end of this document, some of these standards are emphasised.

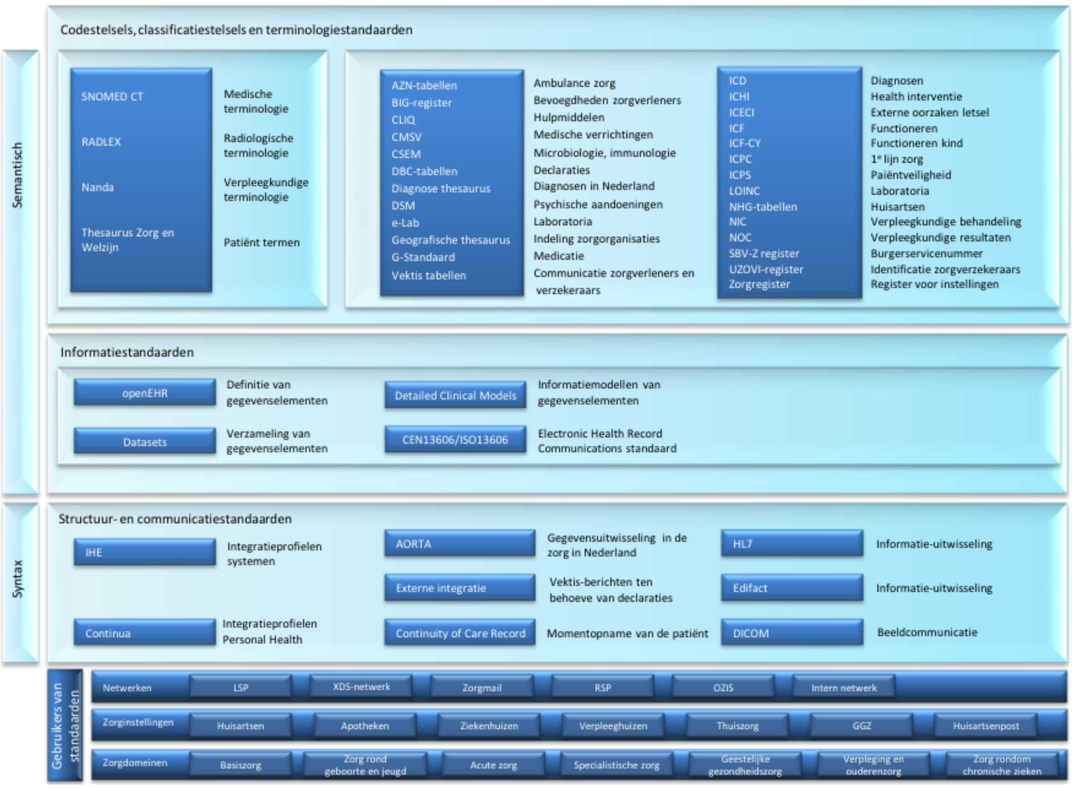


Figure 32: Medical Information Standards. [NICTIZ 2010]

X NICTIZ: Nederlands ICT Instituut In de Zorg: www.nictiz.nl

XI Medical Information Standards as classified by to NICTIZ[December 2011]: http://www.nictiz.nl/page/Standaarden/Standaarden-en-terminologie

4.2.2 HL7V3 – Reference Information Model

The main similarities between Information Standards and Code-systems can be found in the use of archetypes and ontologies. Using complex code systems, medical data can be used by information systems from different manufacturers. The American HL7 organisation has been developing information standards for health care systems for almost twenty years. The success of their xml-based HL7v2 is worldwide recognised and is implemented in the majority of Dutch hospitals. The version 2 standard aims mainly at transferring XML messages from one information system to the other. This enables software manufacturers to implement an interface that uses HL7v2 to provide interoperability. In 2005, the NICTIZ chose the HL7 version 3 Reference Information Model[XII] to be the new national standard for the exchange of medical data. This was backed up by an approval of the C.E.N.(European Committee for Standardisation).

> *The seven in 'HL7'(Health Level 7) stands for the seventh layer in the OSI model. Originally in computer science, this layer is best known from the TCP-protocol in which it is called 'Application Layer'. Within Hl7-v3, it is responsible for carrying messages using the XML markup format.* Within the medical field, HL7 covers all domains by providing identifiers. In this way, data can be stored or transferred without the need of addressing the entire data model.

CareProvision D-MIM

The information model produced by HL7 for use in clinical(hospital) care is the '*CareProvision Domain Message Information Model*'(D-MIM). The figure below describes the basic structure of this model:

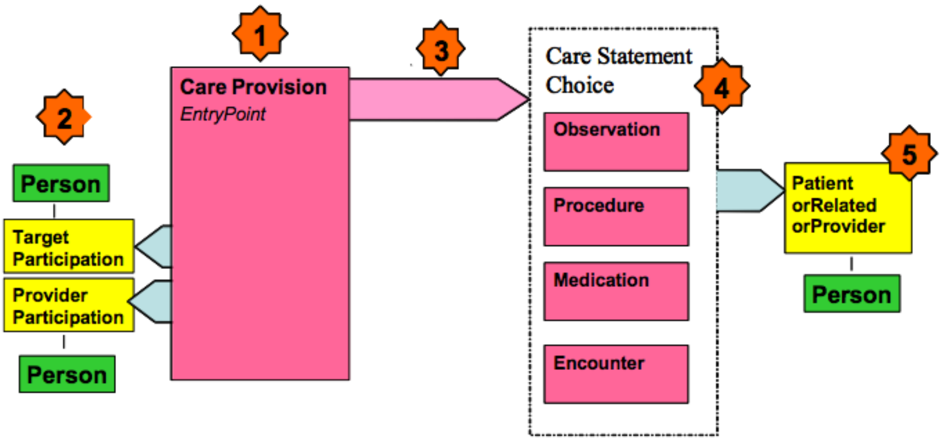


Figure 33: HL7v3-RIM CareProvision Domain Message Information Model [NICTIZ 2006]

1. ***Care Provision Act*** : *General act of care provision*
2. ***Targets of Care*** : *Patient or Practitioner*
3. ***Type of Care choice*** : *Classifies the type of care-provision-act*
4. ***Care Statement*** : *Relevant medical information on the patient including the 'Reason for Care'*
5. ***Related Party*** : *For administering information on related subjects E.G. foetuses in the case of pregnancy.*

Structures like the D-MIM can be transformed into data-models, used for storage and exchange of information.

XII Health Level 7-version 3: www.hl7.org

Medical terminology standards or code systems have been specifically designed with interoperability in mind. The use of classification standards in healthcare is not new, which has been proven by the WHO's successfully implemented ICD standard or the nationally used G-Standard for medical prescription.

4.2.3 ICD-10

The International Classification of Diseases(ICD) series of diagnostic classification standards was founded in the fifties of the 19th century. It is maintained and distributed by the World Health Organisation(WHO) and is meant for standardised registration in epidemiology and health management. These purposes include the analysis of the general health of populations and to monitor the incidence and prevalence of diseases and other health problems in relation to other variables, such as the characteristics and circumstances of the individuals who are affected. The ICD is used to prevent disease and other health problems by classifying all types of files being recorded, death certificates and hospital records included. In addition to the possibility of storage and retrieval of diagnostic information for clinical and epidemiological purposes, these records also provide the basis for the collection of national mortality and morbidity statistics by WHO. The most current version is ICD-10 which is publicly available in various languages.

4.2.4 SNOMED-CT

SNOMED-CT(Systematized Nomenclature of MEDicine Clinical Terms) is a medical code-system covering the entire medical domain. Due to it's formal hierarchical structure based on ontologies, users of the code-system can decide on the level of detail to be used in describing a medical condition. Enabling it's interdisciplinary implementation. SNOMED-CT is owned, maintained and distributed by the International Health Terminology Standard Development Organisation(IHTSDO) which is a non-profit association. According to the IHTSDO website, in 2012 eighteen countries worldwide were registered as member of the organisation.

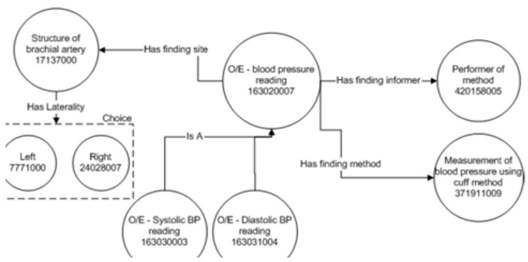


Figure 34: Ontology mapping in SNOMED-CT

Within the hospital environment, terminology standards or code-systems are used in various manners. NICTIZ researchers [Scholtens, Breas 2010][52] conclude that the extensiveness of SNOMED-CT makes it very usable for interdisciplinary use. It's downside can also be found in this extensiveness, since the level of detail used is crucial for interpretation. Different clinical disciplines might use the same topical information, the level of detail for each discipline however can be different. Distribution of these medical terminology standards/code-systems in The Netherlands hasn't been coordinated centrally. Typical examples include the development of the 'ICD-10 to DBC and SNOMED-CT mapping thesaurus' by the Dutch Hospital Data(DHD) foundation and the 'SNOMED-Bowser' by NICTIZ. Project manager 'Eenheid van taal' Henk Hutink of NICTIZ explains in an interview:

> *'Publishing of various medical terminology standards is done by various institutions that have different interests. The DHD thesaurus maps ICD-10 to the financial DBC standard so the cost of a diagnostic are instantly clear. Doctors are eager on this information for obvious reasons.'*

Researchers of the department of clinical information science of the Amsterdam Medical Centre [Keizer N, Cornet R 2010] find in their research that SNOMED-CT is the best choice for use in hospital information systems, since it's description of anatomies and pathologies is so extensive. When used as a meta-model ICD-10 can be mapped to SNOMED but as Pittsburg Medical Centre(UPMC) researchers state in 2011, this proves a daunting task. What can be a perfectly normal code in one discipline, might result in codes representing a 'pregnant male' in another depending on the mappings made.

Various publications on the 'Eenheid van taal' website by NICTIZ indicate that ICD-10 and SNOMED are expected to be the code- or terminology systems of choice for use in interoperable Electronic Health Records. In the European EHR roadmap [Stroetman, Kalra et al. 2009] SNOMED-CT is described as being the main terminology system to be used. Hutink [NICTIZ] declares though that due to standardisation being a gradual process, any implementation of available standards is regarded a plus.

4.2.5 Detailed Clinical Models

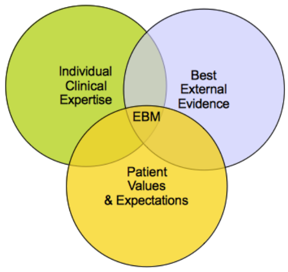


Figure 35: The Evidence Based Medicine(EBM) Triad

To enable clinicians to define the information required for the provision of care in a particular situation without requiring them to be computer scientists, Detailed Clinical Models are used.

Since 2006, the NICTIZ organisation follows Huff's[53] approach by trying to encourage and facilitate the development and the implementation of Detailed Clinical Models(DCM). DCM can be described as containers for the unambiguous description of disorder-specific medical information. Their composition is based on care-standards for specific diseases which are formed by patient-associations, medical specialists or other parties choosing the Evidence-based medicine approach. The NICTIZ DCM template ensures that a DCM always consist of the following elements:

- Purpose
- Evidence Base
- Information Model
- Instructions
- Interpretation
- Care Process
- Issues
- References

This Detailed Clinical Model can be implemented into a data-model to be used in a medical information system. DCM's are however designed to provide care practitioners with the most accurate information required for the execution of their specialism. When disciplinary medical knowledge changes, the DCM has to adapt to it, as well as the system's data-model. This is where the 'relational database problem' as described previously in this document can be noticed. Groningen University researchers [Goossen, van der Zel et al. 2010][54] did a study on the roles of DCM in which they state that critical factors involved with its successful implementation are the used code-systems and data-models and their embeddedness in the overall information architecture of the organisation.

Value Set Name	Codesysteem (OID)
DiabetesDiagnosis	SNOMED
44054006: diabetes mellitus type 2	2.16.840.1.113883.6.96
46635009: diabetes mellitus type 1	

Figure 36: Description of data elements required for the administration of Diabetes Mellitus as found in a Detailed Clinical Model [NICTIZ 2006]

```
<observation moodCode="EVN">
  <code code="DX" codeSystem="2.16.840.1.113883.5.4"/>
  <effectiveTime xsi:type="IVL_TS">
    <low value="20071111"/>
  </effectiveTime>
  <value xsi:type="CD" code="44054006" codeSystem="2.16.840.1.113883.6.96"
      displayName="diabetes mellitus type 2"/>
</observation>
```

Figure 37: HL7v3-RIM D-MIM: Data-model of the Diabetes Mellitus DCM implemented in XML [NICTIZ 2006]

4.2.6 Core EHR & Disease-Specific EHR

Before a Detailed Clinical Model can be transformed into a data-model, decisions have to be made upon its reusability in the hospital care-chain since multiple pathologies or medical specialisms might share elements of the same data-model. Therefore the choice is made to divide medical information into two categories:

1. Disease-Specific medical Information
2. Core medical Information

Continuity of Care Record

The American Society for Testing and Materials *(ASTM)* has created a set of clinical data-elements usable in various medical disciplines. This is the so called Continuity of Care Record *(CCR)* which has been formed after years of research into medical information interoperability. The CCR's layout was based on the traditional *'Referral Letter'* as used by physicians. The CCR has been used as a reference by standardisation organisations that have adopted it in their information models.

Continuity of Care Document

In cooperation with ASTM, the Health Level Seven *(HL7)* organisation formed the Continuity of Care Document *(CCD)* that can be regarded as the technical implementation of the conceptual continuity of care record.

NICTIZ: Core EHR

As described in previous sections about the definition of the Electronic Health Record, Attempts to implement a core-model into an EHR system have resulted in the development of the so called Core-EHR. Though it's concept is present in the ISO20514 definition, the data-elements required in a Core-EHR are heavily dependent on the variety of medical practitioners it was meant to serve. For Dutch hospital care this means that even Core-EHR systems -if present- are not based on standardised data-models.

In an attempt to unify the data-elements used in the Core-EHR, in 2011 NICTIZ published a document based on five hospitals that experimented with Core-EHR. The document uses the definition of the proposed Core-EHR as given by the UMC Groningen:

> *"(...)the core EHR includes patient data that is inter-disciplinary relevant to all practitioners dealing with a patient both at present and in the future(...)"*

Figure 38: Hospitals contributing to the NICTIZ Core-EHR v0.1 document [NICTIZ 2011]

The publication [NICTIZ, 2011][55] relies on the items from the global CCR standard since these are already available. Out of the original 17 CCR categories, the NICTIZ Core-EHR definition only uses 12 items. A significant item that has been left out is the subject's 'Care-Plan' since this is likely to be different for various doctors. Also, insurance- and payment information has not been considered because of the emerging trend of ERP-like systems in Dutch Hospitals.

The table below reveals the difference and similarities between the NICTIZ Core-EHR data-elements and the items from the Continuity of Care Record(CCR):

Continuity of Care Record	Core Electronic Health Record
1. payment Information	1. appointments
2. treatment Constraints	2. treatments
3. support	3. treatment Constraints
4. functional status	4. contact
5. Complaints and diagnoses	5. Diagnoses (and complaints)
6. family history	6. vaccinations
7. social history	7. intoxication
8. warnings	8. lab results
9. medication	9. medication
10. medical aid	10. medical aid
11. vaccinations	11. social history
12. vital functions	12. warnings
13. Results	
14. treatments	
15. appointments	
16. Care Plan	
17. care providers	

4.2.7 EHR Care Chain Scenario's

The Core-EHR sets out to be a solution to two possible scenario's that are considered to be the most likely in hospital care. The scenario's are described in two Use-Cases *[11090, NICTIZ 2011]*:

Use-Case 1:
A patient is treated by several specialists, because he has different syndromes.

Use-Case 2:
A patient is treated by several specialists, since the treatment of a disease requires knowledge of various specialisms.

4.3 Digital Architecture

Alignment of business processes and information systems in a controlled manner has become a renown discipline involving the concept of Business Architecture.

The IEEE 1471 describes architecture to be:

> *"The fundamental organization of a system embodied in its components, their relationships to each other, and to the environment, and the principles guiding its design and development"*

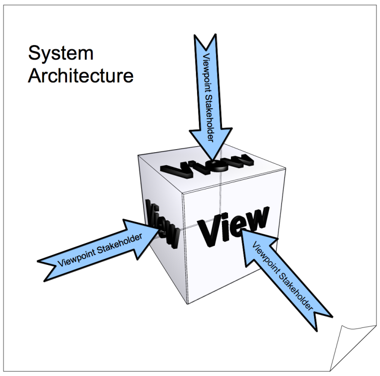


Figure 39: System Architecture [Twynstra, Gudde 2010]

The Open Group's Architecture Development Method as part of TOGAF9 assumes architectures to embody the views of various stakeholders regarding a situation from a different perspective as can be seen in the table below:

Perspective	Description
Business Architecture	Defining the business strategy, governance, organisation, and key business processes of the organisation
Application Architecture	Providing a blueprint for the individual application systems to be deployed, the interactions between the application systems, and their relationships to the core business processes of the organisation.
Data Architecture	Describing the structure of an organisation's logical and physical data assets and the associated data management resources.
Technology Architecture	Describing the software infrastructure intended to support the deployment of core, mission-critical applications.

Table 2: TOGAF ADM perspectives [Twynstra, Gudde 2010]

Though examples are known of Business Architecture being adapted to Application- Data- or Technology Architectures, it is assumed that Business Architecture is the leading factor in designing the other three. IT-pioneering giant IBM calls these three: "Business Aligned Services" [IBM, 2006][56]. The IBM definition of Service Oriented Architecture(SOA) will be the leading definition for this document:

> *"A Service-Oriented Architecture is an enterprise-scale IT architecture for linking resources on demand. These resources are represented as business-aligned services which can participate and be composed in a value-net, enterprise, or line of business to fulfil business needs. The primary structuring element for SOA applications is a service as opposed to subsystems, systems, or components."*

4.3.1 Service Oriented Architecture

Both the proposed system architectures of Ginneken, Eekeren et al. and the domain reference model of NICTIZ start from the assumption that the critical care path is supported by several independent services *(information objects, doc 11010A NICTIZ 2011). ZIS(Hospital Information System),* PACS(Picture Archiving and Communication System) [Andriole, Luth et al. 2002][57] and hospital laboratory systems are implemented with service orientation in mind. Their services can be extended by other systems with a more specific medical purpose. Examples of which are disease-specific Electronic Health Records. In support of a business process, SOA can be deployed using two different approaches [Kruiswijk, 2010][58]:

I. **Orchestration**
   Alias *'conductor',* central coordination synchronous, tight coupling. Like clock cycles in a microprocessor.
II. **Choreography**
   Alias *'relay race',* no central coordination, Loose coupling. Process emerges from communication of messages (events).

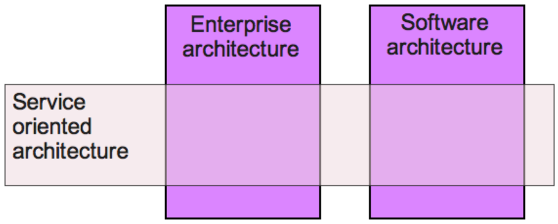


Figure 40: Service Oriented Architecture connecting Enterprise- and Software Architecture [Kruiswijk, 2010]

Middleware / Service-bus

The concept '*Enterprise Service-bus*'(ESB) is often referred to as *'Software Glue'* and is typically implemented as a step towards IT-maturity [Twynstra, Gudde 2010]. Other than ESB, the term *'Middleware'* is used to describe the same concept. As the figure below reveals, it is used to structure a proliferated landscape of interconnected information systems. The ESB resembles both concepts of orchestration and choreography by acting as a message broker. Events are processed as requests by the ESB according to a predefined set of business-rules. Services are not called directly but via the ESB using a design pattern known as *'chain of responsibility'* [Gamma, Helm et al. 2005][59].

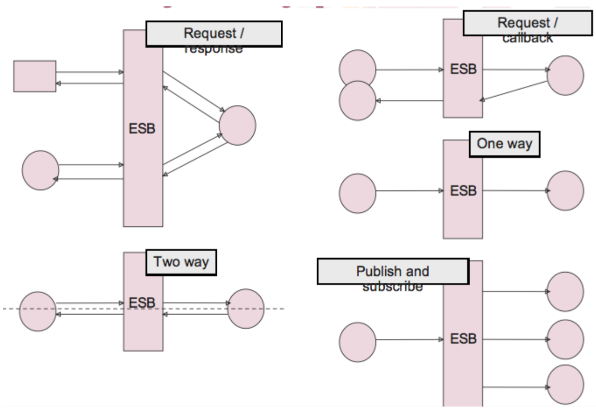


Figure 41: Message patterns in the ESB [Twynstra, Gudde 2010]

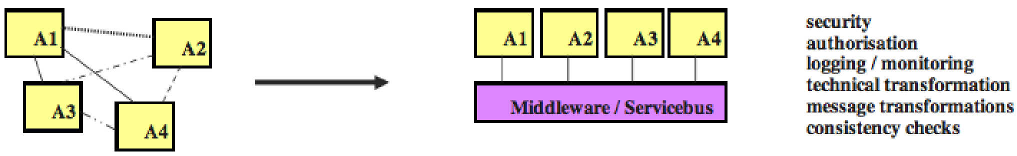


Figure 42: Effects of Middleware / ESB implementation [Twynstra, Gudde 2010]

Having the advantages of process orchestration, ESB/Middleware solutions demand unambiguous predefined couplings to be made between systems for the object-relational mappings to be made in a processes that is known as *'object-relational mapping' or 'mapping'.*

Object-relational Impedance Mismatch

As referred to earlier in this document(*Domain Analysis: Systems*), interconnected information systems can use a message information model(MIM) to achieve interoperability. Requiring the presence of a predefined set of business-rules that are mapped to the system's relational database. In which information is categorically stored. Changing the database will therefore affect all the other systems dependent on the object-relational mappings made. In computer science, this problem is known as the '*Object-Relational Impedance Mismatch*' [Oracle 2009].

The figure on this page shows the common solution for this problem, the ESB/Middleware implementation: A common(shared) data model. Dividing information into application specific- and business-generic information. Improving business-agility and reducing complexity considering ROC's(Request For Change).

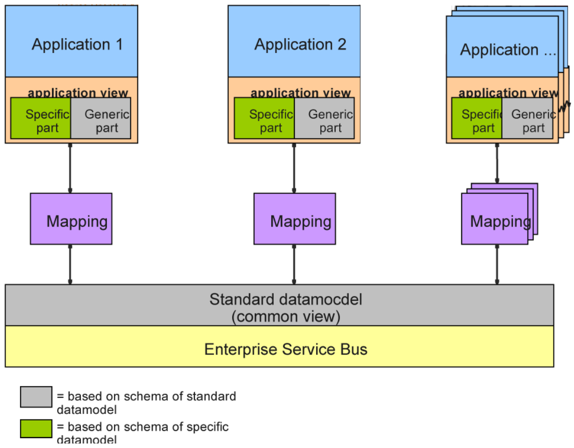


Figure 43: Object-relational mapping using ESB [Twynstra, Gudde 2010]

In the Health Care industry, the opportunities of Service Oriented Architecture are becoming more and more apparent [Medifacts, 2012][60]:

In December 2011, the British Trafford Healthcare NHS Trust has transformed it's IT-infrastructure by creating a list of available systems and connecting them using a SOA based Enterprise Service Bus to which they referred as 'Healthbus'. The relational MS-Bizztalk database was transformed to hold a generic shared data model only to which was referred as the 'Enterprise Master Patient Index'.

4.3.2 Application Architecture

Developing a software system for the enterprise is not an 'as-is' process. For each case, meticulous preparation is required involving a requirements analysis, functional and technical designs [Fowler, 1997][61]. Software theorists Kruchten, Boog et al. define application architecture as:

> *"the set of significant decisions about the organization of a software system including: Selection of the structural elements and their interfaces by which the system is composed. Behavior as specified in collaboration among those elements. Composition of these structural and behavioral elements into larger subsystems. Architectural style that guides this organization. Software architecture also involves functionality, usability, resilience, performance, reuse, comprehensibility, economic and technology constraints, tradeoffs and aesthetic concerns."*

On various levels of abstraction, design-decisions are to be made. On application-level, recurring designs are known as 'design patterns' [Gamma et al. 1994][62].

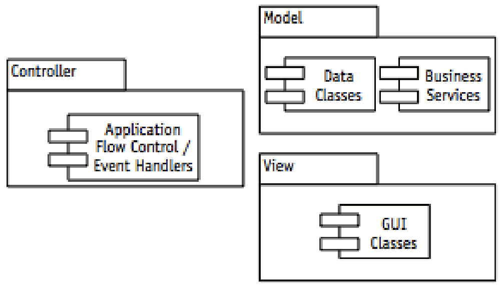


Figure 44: Model View Controller pattern [Riehle 1997]

MVC Pattern

In use with most contemporary IT-Systems is the Model View Controller(MVC) design pattern [Kramer, Pope et al. 1988][63]. The MVC is a Composite Pattern, describing how different functional building blocks of the application work together. It defines three basic components: Model, View and Controller.

Model

The data structure of the application. Typically this is represented by the tables and rows of a relational database.

View

The application's presentation-layer often referred to as Graphical User Interface(GUI). This is where the user interacts directly with the application.

Controller

Comprises the application's 'Business Logic'. When users require information from an application. A query entered in the 'View' will be dealt with by the 'Controller' who decides on the access level of the user and will then send it's own query to the database. Retrieved data will then be modified to fit the format required by the user-interface or 'View'. In MVC architecture, the controller is said to be the 'brain' of the application.

4.3.3 Reference Architecture

The Organisation for the Advancement of Structured Information Standards(OASIS) describes [Mackensey, Laskey 2006][64] reference models to be:

> *"A reference model is an abstract framework for understanding significant relationships among the entities of some environment. It enables the development of specific reference or concrete architectures using consistent standards or specifications supporting that environment."*

When an organisational landscape of interconnected information systems is described using a reference model, the term '*Reference Architecture*' is used. One purpose [2010 Kruiswijk, Wendel de Joode et al.][65] of IT reference architecture is to create a unified and comparable model of systems to which can be 'referred' from various levels of complexity. These levels of complexity are often described to be 'layers'. Reference Architecture also enables organisations to control changes in IT-systems, regarding them a business unit. UvA researchers [Truijens, 2002][66] refer to Reference Architecture to be a vital instrument for the successful optimisation of Strategic Alignment, being considered to be a prerequisite for information interoperability.

4.3.4 NICTIZ: Domain Reference Model for Hospitals

Realising that information-technical solutions like the Core-EHR are not enough to guarantee the successful improvement of information interoperability, the NICTIZ institution initiated the development of a *'Domain Reference Model for Hospitals'[11010A, 2011]* in which the combined visions of six hospital information architects are incorporated into a single design. Providing a view on information architecture from various perspectives, the document uses the following abstractions:

- **Activities** : Business Processes and Functions
- **Information Objects** : Coherent information *e.g. surgery report*
- **Information Domains** : Set of coherent business activities

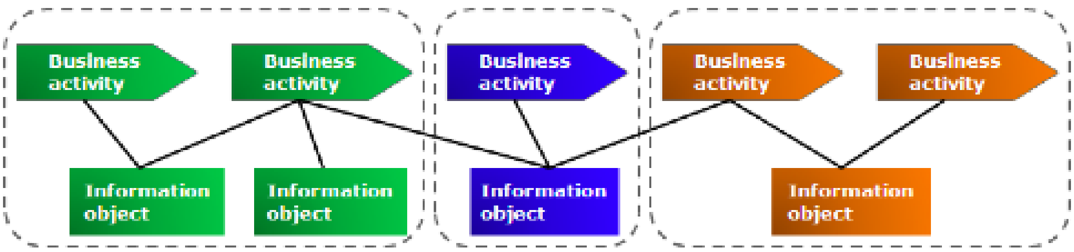


Figure 45: The relation between: Business Activities, Information Objects and Information Domains [11010A, NICTIZ 2011]

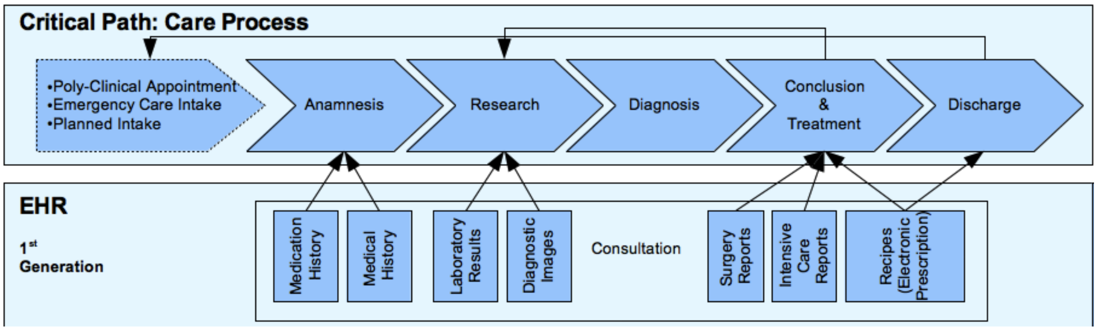


Figure 46: [Ginneken, Eekeren 2010]

In support of a business process, information is transferred with the aid of information objects. As can be seen in figure the figure on this page, this information is likely to go across information domains. To enable this, shared information objects are required. In hospital care these objects can be referred to as data models in support of transmural care. The assumption of this generalisation is invigorated when the 'EHR architecture sketch'*[Ginneken, Eekeren 2010]* is considered. It shows the 1st generation of EHR systems are information objects as well, supporting the critical path of the care process. Deciding to which information domains an information object applies is simplified by the creation of a Create-Use(CU) matrix.

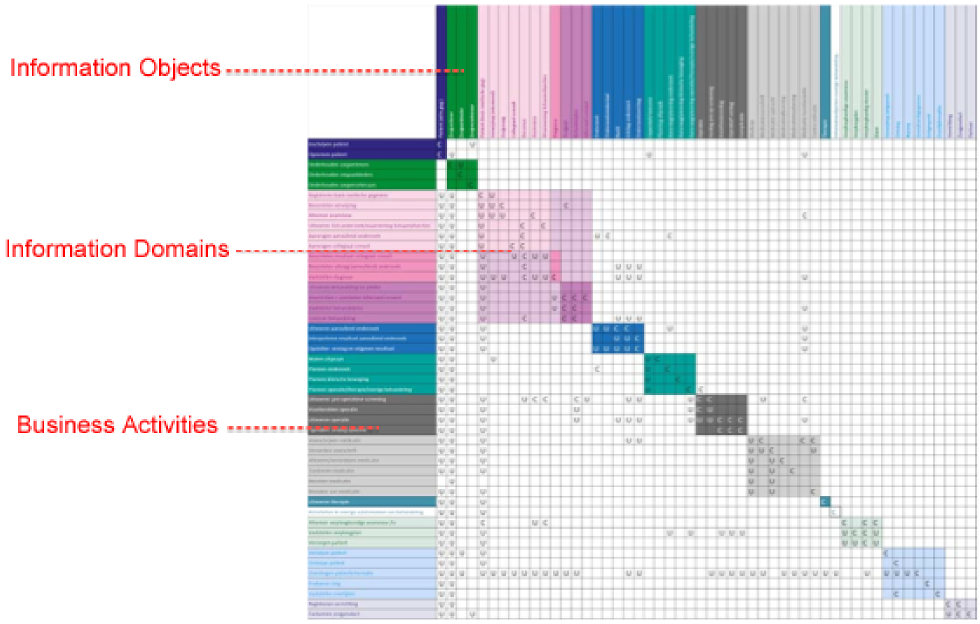


Figure 47: Create-Use matrix of the domain reference model [NICTIZ 2011]

The matrix provides an overview of the Activities, Objects and Domains in the organisation and can be used to map the information domains of a particular hospital. The domain reference model describes the direct care*(critical path)* process only. Support- and management processes are regarded to be 'out of scope' as can be seen in the blue areas in the figure below. The eventual model has been abstracted to a level in which it can be used like a template for mapping a hospital's information architecture regarded from various perspectives:

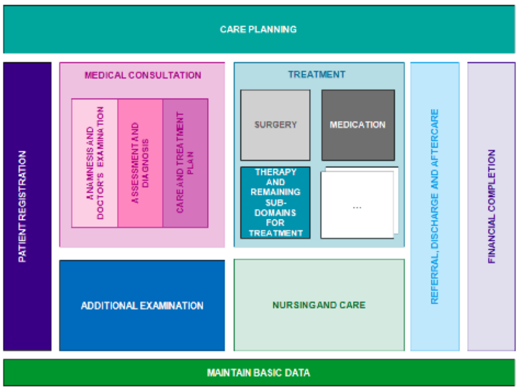


Figure 49: DRM → Plain

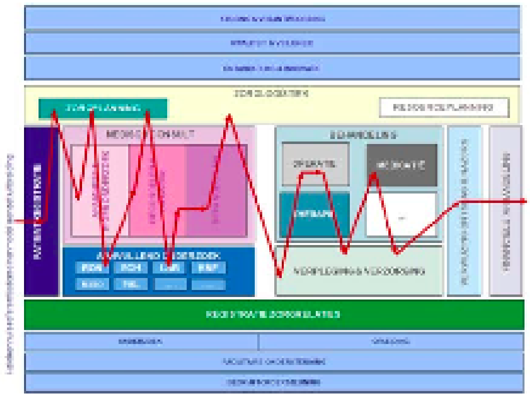


Figure 48: DRM → Care Process

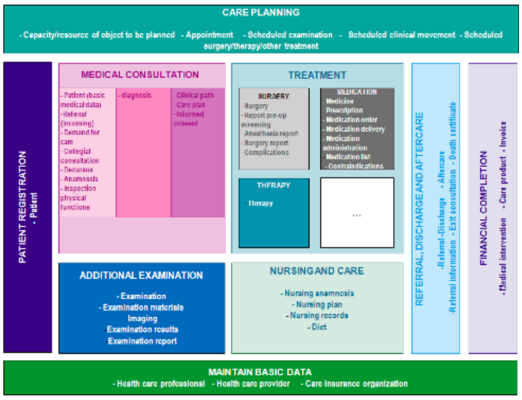


Figure 50: DRM → Information Objects

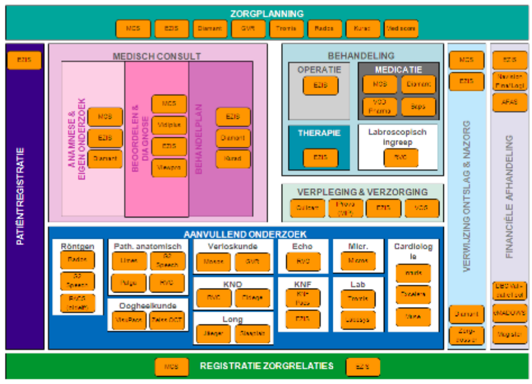


Figure 51: DRM → Applications

4.4 Intermediate Conclusions

Having described the current aspects involved with electronic medical record keeping, the questions asked at the beginning of this chapter can now be answered:

4.4.1 EHR-Theory

What is the definition of the term 'Electronic Health Record'?

The formal definition of EHR-system as used in Dutch hospitals consists of the ISO-20514 EHR description, it's maturity level and amount of decision support are described using 'Gartner's five generations' model. An informal definition used more often by system vendors and medical personnel: Any system replacing the conventional cardboard folder is regarded to be an Electronic Health Record.

What is meant by (semantic) interoperability?

Using information from one disease-specific EHR system in another disease-specific EHR system is called 'interoperability' or 'shareability'. Physicians prefer the term 'transmural interoperability'. Traditionally in computer science this discipline is known as 'systems integration'. ISO*(*20514*)* which discriminates interoperability in Functional- and Semantic Interoperability. The latter comprises exchanging concepts rather than data; e.g. the coherent meaning of medical information assembled on a sheet of paper for one specialist can *-when categorised in a relational database-* lose it's semantic meaning if presented to another clinician. This reveals the rational problem of semantic interoperability when humans interact with computers.

What instruments are available for achieving (semantic) interoperability?

In The Netherlands, the NICTIZ has become the central organisation providing advice on EHR-implementation- and interoperability by means of standardisation, mostly using international standards. The list of available means is considerable:

1. **IZI-pyramid**

   The IZI pyramid describes the information requested from an EHR system by various stakeholders involving patients, physicians, scientists, insurance firms and policy makers.

2. **Care Standards**

   Patient-associations and researchers tend to produce specific treatment guidelines that can be chopped into usable blocks of information known as Detailed Clinical Models(DCM). These also involve information on scientific parameters required for a successful Evidence Based Medicine(EBM) approach.

3. **DCM Template**

   DCM's unite a *-for physician's understandable-* information requirement in written text and in a HL7v3 class-diagram enabling it's transformation to an information- or data model. The NICTIZ created a standard template for use with hospital information systems.

4. **Standardized Flexible Data Model(HL7v3)**

   Because a fixed data model does not allow for flexible data structures, information on how to use the HL7v3 XML-based data model has been made available to hospitals and system vendors.

5. **Standardized Dataset Core-EHR**

   Based on the CCRb and CCD of Huff, the NICTIZ provides a basic Core Dataset consisting of common data-elements that are reusable on an interdisciplinary basis.

6. **Medical Terminology Standard(SNOMED-CT)**

   The HL7v3 data model provides a structure only. The actual medical data is transferred using terminology standards. SNOMED-CT has been chosen by both the European Commission and the NICTIZ as the terminology standard of choice.

7. **'Best-Practise Scenarios' Transmural Hospital Care**

   The hospital care-path mainly consists of two scenario's:

   1. *A patient is treated by several specialists, because he has different syndromes.*
   2. *A patient is treated by several specialists, since the treatment of a disease requires knowledge of various specialisms.*

8. **EHR Reference Architecture**

   In order to supply information architects with the means to describe the hospital's IT landscape, the Reference Domain Model for Hospitals was composed. The model makes important generalisations on the hospital's organisation architecture. Business activities(processes) and required information objects can be mapped.

What does a generic medical record keeping process look like?

The research of Ginneken and Eekeren shows a generalisation of a hospital's core process. Two most likely treatment scenario's are described by NICTIZ proving that hospital care is often transmural, involving a multitude of specialists.

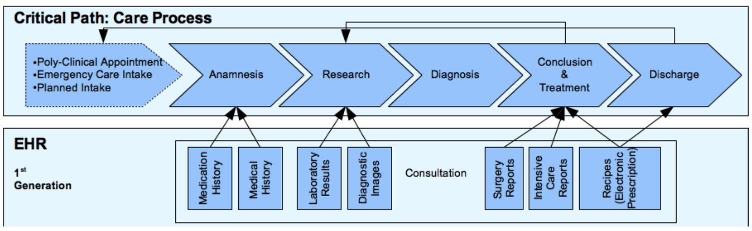


Figure 52: [Ginneken, Eekeren 2010]

How does Information Architecture affect semantic interoperability?

When designing a software system with interoperability in mind, technological choices tend to be vital. Specific flexible medical data models and code systems are nullified by the requirement of object-relational mappings. The Service Oriented Architecture(SOA) approach is specifically meant for interconnecting incompatible systems. Yet the currently popular implementations of HL7v2 medical messaging prove not to be flexible since object-relational mappings and orchestrated requests to various data models have to be made.

4.4.2 *EHR Challenges*

The potential of health care optimisation by means of the Electronic Health Record has been apprehended globally. The *'European Union Semantic Health Report'* [Stroetman, Dipak et al. 2009] urges the implementation of Electronic Health Records for the direct improvement of hospital care in the fields of interoperability, security, quality and effectiveness. Recent research on the topic described in the Central European Journal of Public Policy [Mensink, Birrer 2010][67] states that cost-efficiency, quality of healthcare, macro use of data and the transition from supply-driven- to demand-driven care are the anticipated goals for European countries. On the developments of EHR interoperability they state:

> *(...)"unfeasible strategy is chosen. Not only in the Netherlands, but also in other western countries, the progress with EHRs is remarkably slow, in view of the fact that apparently its construction is viewed as relatively unproblematic. One explanation of this slowness lies in underestimated technical difficulties. Strategic considerations of various actors involved represent another potential source of delay. For instance, many physicians feel that their practice cannot be decontextualised. For this reason, or simply because they feel their position is threatened, collaboration in the medical branch may not be easy to get by."(...)*

How do the available means for improved interoperability relate to the Dutch hospital-EHR market?

Combined findings of Stroetman, Dipak et al. and the Dutch healthcare inspectorate [Inspectorate VWS, 2010][68] point at the slow pace of EHR integration. Apparently even with all the means available and with the correct incentives present, creating an interoperable Health Record for use in hospital care is hard. NICTIZ documents assign the slow state of EHR-integration to the diversity of 'information stakeholders'. We can define seven major actors/stakeholders involved with EHR interoperability. Using the NICTIZ IZI-Pyramid, the required types of information for each for these actors is categorised. When the pyramid is subsequently extended with the different types of information required from hospital EHR-systems, the complex task of these systems becomes clear.

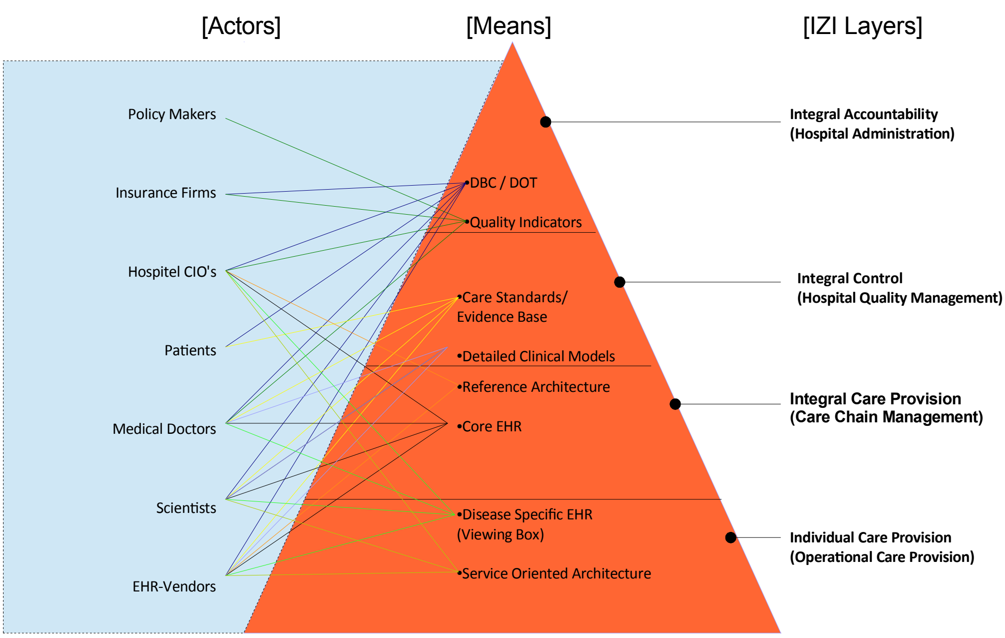


Figure 53: IZI Pyramid with added Actors and EHR means

4.4.3 GAPS

European planners indicate in a roadmap *-on this page-* that by 2013, centralised repositories for the distribution of Archetype-Based Detailed Clinical Models should be available. The introduction of open standards and Service Oriented Architecture*(SOA)* is also expected to change the business models of health care automation from the Total Cost of Ownership*(TCO)* model to the Total Cost of Value*(TCV)* [Stroetman, Dipak et al. 2009] model. The TCV approach renders corporate IT a service that can be valued dependent on it's use. Commercial businesses have already chosen this approach in which IT services -like water and electricity- become utility goods.

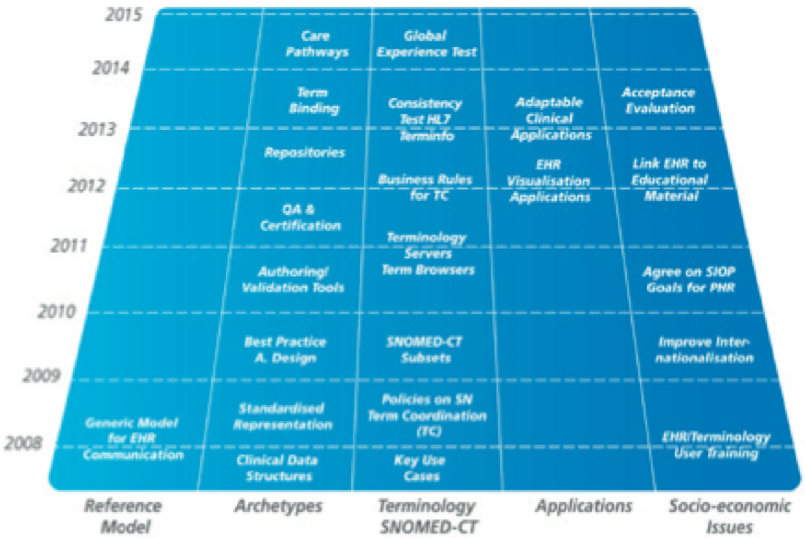


Figure 54: European Union EHR Roadmap [Stroetman, Kalra et al. 2009]

Implementing the available means for improved interoperability is considered to support the national paradigm-shift from public- supply-driven care, to patient-centred- demand-driven- liberalised care. When publications of various experts are studied thoroughly however, several 'gaps' can be identified in 2 major areas:

I. Distribution of Standards

a) A central distribution and version-management of Detailed Clinical Models have not been solved*[Goossen, van der Zel et al 2010]*.

b) The consultative role of the NICTIZ organisation in which it cannot force IT-suppliers and hospitals to use the means available for interoperability and standardisation.

c) Technical difficulties that come with implementing medical information standards are slowing down the developments. No central knowledge-base for the administration of technical EHR-solutions exists.

2) Technical Difficulties

a) The Object-Relational Impedance Mismatch that occurs when using HL7v3 with a relational database complicates the use of this flexible data model.

b) Medical terminology standards have different structures and cannot be mapped directly.

c) The implementation of a Core-EHR poses difficulties since existing systems do not share the same data model. Uncertainty exists on how to implement an 'enterprise service-bus' using 'orchestration' or 'choreography' principles.

5 Case-Study: open source EHR-System

The previous chapters of this document set out to clarify the problems at hand along with the available solutions. These solutions however, mostly seem to be purely theoretical and lack a profound technical reference- and application-level architecture.

Still, no answers are found to the questions:

- *How can HL7v3 be implemented in an EHR system?*
- *How can the Object-Relational Impedance Mismatch be solved?*
- *How to setup a Core EHR?*
- *How to integrate transmural disease-specific data in different systems?*
- *What can Software As A Service(SOA) mean for a hospital's IT-landscape?*
- *What is the role of a hospital's IT department in maintaining and developing EHR systems?*

5.1 Introduction: the AEXIST firm

Having spent considerable parts of his career at Andersen Consulting, Atos Healthcare and NICTIZ, e-health consultant and EHR entrepreneur Remko Hoekstra has founded the AEXIST organisation for the development of Electronic Health Records. The company regards EHR-systems to be the most important asset for gaining a sustainable competitive advantage in a landscape of competitive hospitals. With full knowledge of both available standards and EHR pitfalls, AEXIST has chosen a fundamentally different approach which can best be explained using the well-known Strategic Alignment model [Henderson, Venkatraman, 1999][69]:

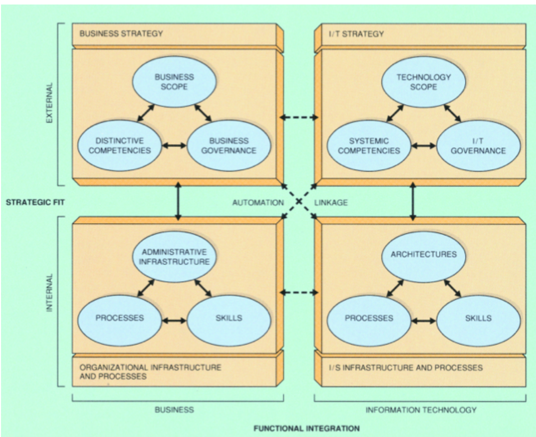


Figure 55: Strategic Alignment Model [Henderson, Venkatraman 1993]

5.1.1 Strategic Alignment Model

Already in 1993, Henderson and Venkatraman wrote about a new insight on the valuable role of information technology against which *-they claimed-* managers tend to be sceptical. Their definition of strategic alignment is therefore more extensive than the traditional one [Ward, Peppard 2002][70]. First they point out that IT strategy should be articulated by focussing on internal and external domains. The internal domain consists of the organisation's internal techno-architecture, processes and human capabilities. The external domain means the position of the organisation in the IT marketplace, focussing on business supportive technologies, systemic competences and IT governance.

Addressing the IT systems' capabilities to support the internal organisation is called Functional Integration. Describing the amount to which IT systems improve the firm's market position is called Strategic Fit. These are the two prerequisites on which the H&V strategic alignment model is based.

In order to describe the alignment of the internal- and external domain for different types of organisations and different markets, four Dominant Alignment Perspectives are distinguished for each of which the Driver, the Role of top management, the Role of IT management and Performance Criteria are mapped. The assumption is made that the model can be projected on a specific business-case or sector from the point of view of Business Strategy or from the viewpoint of IT Strategy. For each of which two dominant alignment perspectives are available:

'Strategy execution alignment perspective'

The case described in this document is that of a sector rather than a business. One in which policymakers like Patient Associations, VWS and NICTIZ are the 'Top Management' formulating a strategy top-down. 'IT management' can be translated to be the hospital organisation. In this situation, performance criteria are the cost/quality of care. This traditional 'top-down' Business Strategy approach does not seem to comply with the current situation in hospital healthcare which is not controlled by policymakers but rather by medical specialists, insurance firms and patients.

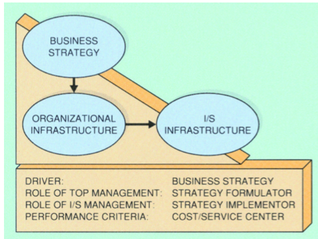


Figure 56: 'Strategy execution alignment perspective'

'Competitive potential alignment perspective'

Strategic alignment can also be viewed from the viewpoint of the competitive firm rather than a sector. Assuming that the available means for EHR-interoperability are developed in a joint-venture between organisations, the creation of a Business Strategy is driven by the chosen IT strategy or available technology creating increased functional integration and a strategic fit.

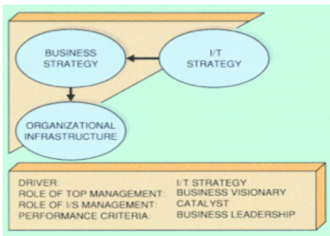


Figure 57: 'Competitive potential alignment perspective'

The 'competitive potential alignment perspective' is basically the approach chosen by the AEXIST firm. Using a different business model and system-architecture, the organisation manages to tackle most of the 'gaps' left by the policymakers and other consultative organisations. The two major competitive-technological advantages of the AEXIST firm are the use of:

- **P**latform **A**s **A** **S**ervice (PAAS) service level.
- **X**forms **R**EST **X**query (XRX) application architecture.

How these technological differences enabled the firm to use all of the available interoperability-means while keeping cost low will be described in the next chapters.

5.1.2 Baseline Assumptions

EHR Definition

When using the theoretical definitions of ISO and Gartner, the AEXIST EHR-System can be formally described as being a:

Gartner 3rd generation EHR-System implementing ISO20514 level 3 share-ability applying to the four ISO requirements of Functional Interoperability featuring process support capabilities comparable with CMMI level 3.

As emphasised by the strategic alignment model, the firm maintains a 'bottom-up' technology-perspective rather than a 'top-down' managerial point of view. AEXIST CEO Remko Hoekstra states:

"Although not all problems considering hospital EHR interoperability have been solved, with the means available, we can now certainly improve interoperability on several critical area's in which this was not possible before."

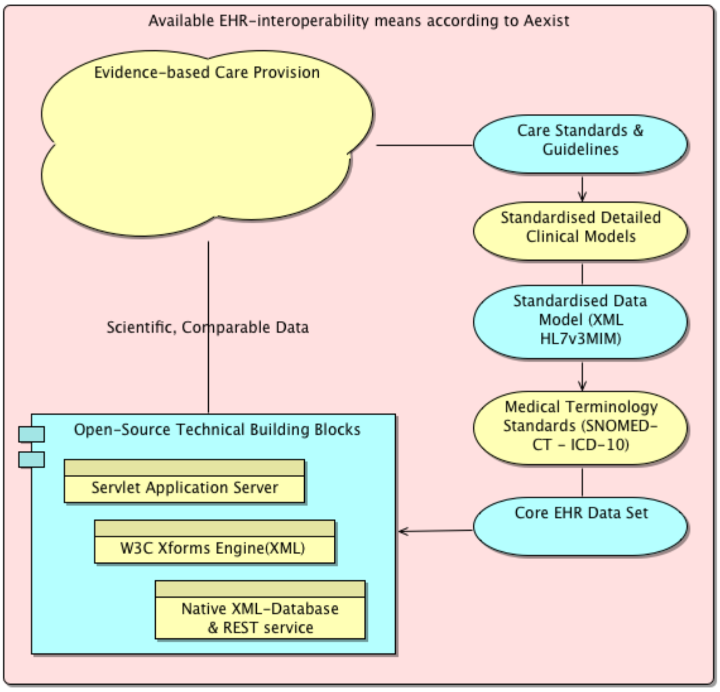


Figure 58: AEXIST EHR Approach

open source

A major problem as identified by various EHR theorists [Mensink, Birrer 2010] is that technical implementation of a standardised EHR data model is hard. Hoekstra solved this problem by using newly available open source technology that enabled the use of the HL7v3 XML data model throughout an entire system.

Though choosing these open source technologies exposed other problems: security and credibility. In an environment where personal medical data is used by multiple users, system security is given paramount importance [Washington Institute of Medicine, 1991][71].

Apparently these security issues did not outweigh the advantages gained by the shared XML data model. In order to understand the architectural choices of the AEXIST firm, a description of the various levels of their EHR-systems would be valuable. Divulging the question: How to describe these seemingly incoherent EHR-building blocks as seen in the figure on this page? The SOA Reference Architecture might offer a robust solution:

5.2 SOA Reference Architecture

In order to describe the architectural choices made by AEXIST in an understandable and comparable manner, the industry-standard TOGAF-ADM structure is used but in a different model. Due to the emerging trend of Software As A Service implementations, in 2009, The Open Group (TOGaf) compiled a Draft Technical Standard based on the ADM method that was tailored for use with SOA architecture. It is named: the 'SOA Reference Architecture' [The Open Group, 2011][72]. The document comprises the findings of software architecture in the past 25 years. From the pioneering work of Bell, Newell and Sieworek to today's business applications. The Open Group claims SOA implementations will lead to:

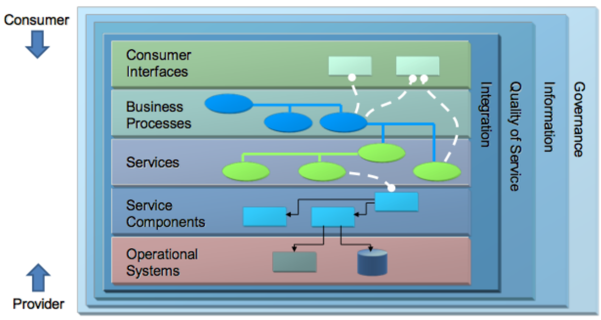


Figure 59: The Open Group SOA Reference Architecture [The Open Group 2009]

- ➔ Reduced Cost
- ➔ Improved Agility
- ➔ Increased Competitive Advantage
- ➔ Shorter Time-to-Market
- ➔ Consolidation: Integration between organisational departments
- ➔ Improved Alignment

As displayed in the figure on this page, the SOA Reference Architecture document addresses different levels of abstraction viewed from four layers of abstraction. These layers are identified as 'Cross-Cutting layers'. The cross-cutting layers can be found vertically in the image on this page. For each cross-cutting layer, the same set of sub-layers can be seen. These are ranged from consumers at the top, to providers at the bottom. These layers are identified as 'Horizontal-Layers.' For use in this document, the SOA Reference Architecture is perfectly suitable since the structure of the cross-cutting layers matches the structural levels of abstraction of the IZI-Pyramid as can be seen below.

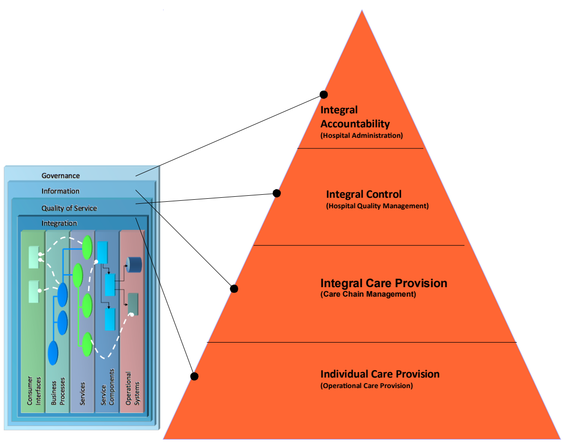


Figure 60: The SOA Ref. Arch. cross-cutting layers align with those of the NICTIZ IZI-pyramid

We can therefore use the acknowledged SOA-Reference Architecture for the description of the AEXIST case. Making it applicable to Dutch hospital-IT while still understandable on an international level. Note that the cross-cutting layers 'Information' and 'Quality of Service' are swapped in the IZI-Pyramid with respect to the model of the Open Group. The next sub-chapters will systematically address the various solutions chosen by the AEXIST firm. Each beginning with a definition of the cross-cutting layer by the Open Group.

5.2.1 Architecture Building Blocks

To make the SOA-Reference Architecture usable by information architects, it consists of several Architecture Building Blocks(ABB) providing a comprehensive checklist. In this document the ABB's are referred to using [SOA-RA, Layer Abbreviation, ABB Number].

5.2.2 Governance Layer

According to the SOA-RA documentation, this layer's added value is to ensure that mechanisms are in place to organise, define, monitor and implement the governance from an enterprise architecture and solution architecture view. The governance layer is particularly important when working with SLA's based on Quality of Service and Key Performance Indicators(KPI), capacity and performance management policies and design-time aspects, such as business rules.

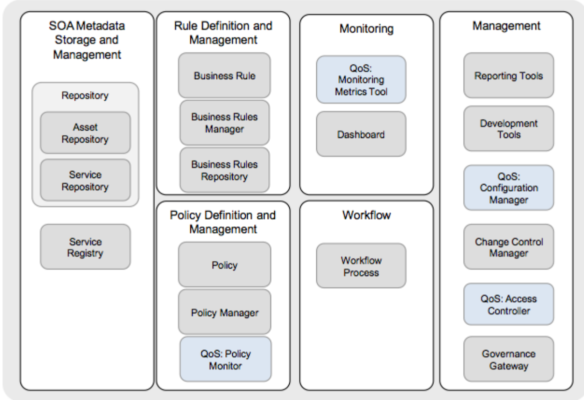


Figure 61: ABB's in the governance layer

Metadata Storage & Management

Main principals for the AEXIST EHR systems are the hospital's medical practitioners. When the demand for a system has been acknowledged, information analysis(requirements-engineering) is performed. The result of this information analysis is processed into a Create-Use matrix in which the required data-elements are displayed alongside their formal definition expressed in a medical code-system(ontology), involving ICD-10, SNOMED-CT and the G-Standard for medicine prescription. These matrices form the base of the Detailed Clinical Models and data-models on which the system is built [SOA-RA, GL, ABB8]. Centralised storage and reusability is safeguarded using Google Apps and the Subversion versioning system [SOA-RA, GL, ABB7, ABB9].

Definitie	Code	Code stelsel	Code	Code stelsel
Geen allergie			Allerg0000	G-Standaard
Jodium	294914009 | iodine allergy	SNOMED	Allerg1000	G-Standaard
Pleister	405649006 | tape allergy	SNOMED	Allerg1010	G-Standaard
Bruine pleister			Allerg1015	G-Standaard
Nikkel	93419003 | contact dermatitis due to nickel	SNOMED	Allerg1020	G-Standaard
Metaal	300915004 | metal allergy	SNOMED	AllergMet	G-Standaard
Handschoenen			Allerg1030	G-Standaard
Latex	300916003 | latex allergy	SNOMED	Allerg1040	G-Standaard
Rubber, rubber eczeem		SNOMED	L23.5	ICD-10
Parfum	300908007 | perfume allergy	SNOMED	Allerg1070	G-Standaard
Medicatie	416098002 | drug allergy	SNOMED	Allerg2000	G-Standaard
Salicylaten			Allerg2050	G-Standaard
Aspirine	SCT | 293586001 | aspirin allergy	SNOMED	Allerg2052	G-Standaard
Antibiotica-			Allerg2100	G-Standaard

Figure 62: Create-Use Matrix of the AEXIST Preoperative Health Record

Rule Definition & Management

The HL7v3 clinical building blocks define the data-elements that are required. This involves the presence of an 'author' attribute ensuring each stored piece of information can be traced back to it's author [SOA-RA, GL, ABB15].

```
<author typeCode="AUT">
        <time value="20111121121549328"/>
        <modeCode code="ELECTRONIC" codeSystem="2.16.840.1.113883.5.1064"/>
        <signatureCode code="I" codeSystem="2.16.840.1.113883.5.89"/>
        <assignedParty1 classCode="ASSIGNED">
            <id root="2.16.840.1.113883.2.4.6.1.6020502.13" extension="100"/>
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                <name>
                    <given>Piet</given>
                    <prefix qualifier="VV">de</prefix>
                    <family qualifier="BR">Koning</family>
                </name>
            </assignedPerson>
        </assignedParty1>
</author>
```

Figure 63 Each HL7v3 electronic record involving a patient holds an 'author' element.

The HL7v3 data-model uses the Extensible Markup Language as can be seen in the figure above. Business-rules in the form of tolerances and data-formats can be applied to this language using XML-Schemas. Using the NICTZ-provided HL7v3 'Care Provision Event' XML-schemas AEXIST EHR-systems are able to validate entered data directly on input. With these schemas being instantly replaceable, business-rule flexibility is ensured. [SOA-RA, GL, ABB16, ABB17].

Policy Definition & Management

Policies are implemented on various levels. The HL7v3 XML-Schemas as mentioned before, enable policy definition and implementation on data-level while the available open source technical building blocks (web server, xforms engine, REST database) enable service-level policy execution. e.g. Using Apache2httpd's(web server) configuration tools, the system can be configured so that the database's REST service is accessible by registered systems or services available in the hospitals Local Area Network. In fact, the other technical building blocks(application server, xforms engine) are already separate services that form an integrated system only by their configuration and use of web-standards [SOA-RA, GL, ABB18], [SOA-RA, GL, ABB19], [SOA-RA, GL, ABB20, ABB21].

Monitoring

These capabilities provide the ability to monitor application of policies, governance processes, and effectiveness of governance. Healthcare CIO's are authorised to formulate IT-governance policies autonomously. A system that is frequently used in hospital-IT is the BIV[XIII] classification for NEN7510 which is the leading European quality norm in healthcare [SOA-RA, GL, ABB23, ABB24, ABB28, ABB29].

Availability:

Using three system-critical open source components that operate platform-independently, the system's availability is maximised. Comparable commercial products (Microsoft, Oracle) are unlikely to have an equally-sized developer community but also have a large installed-base. Using platform-independent components ensures flexibility in the hospital's internal server installations.

Integrity:

In order to live up to the NEN7510 guideline for omni-retrievable information, the EHR's native XML database will store information in a separate document:

algemene-registratie2011-11-21T121549.3280100.xml (form name, date, unique timestamp)

Using this format, information entered by patients or physicians will always be retrievable and distinguishable since the HL7v3 format always requires the presence of a 'subject' and an 'author' data element. Using the database's built-in backup mechanism. Compressed versions of the entire system are compiled into a backup nightly after which they are stored for several years. Supplementing to conventional paper health records and adding new valuable functionality in the form of consistent subject and author discrimination, which can be vital from a legal viewpoint.

Confidentiality:

AEXIST's open source EHR-systems are deployed internally(in-hospital) on a single server after which they can be accessed from the organisation's LAN solely, by means of a browser. Using signed secure connection certificates, client-server connections are scrambled making eavesdropping by means of package-interception

XIII BIV (Beschikbaarheid, Integriteit, Vertrouwelijkheid): Availability, Integrity, Confidentiality virtually impossible. For situations that require external system-access. The system uses the national DIGID[XIV] internet security mechanism which has been approved by the Dutch government.

Management

Involving the system's ability to be subject to controlled changes. The HL7v3 core schemas enable the system's administrators to implement flexible tolerations and business-rules. In the 'Theoretical Background' chapter, the paradigm of Software As a Service(SAAS) is explained. An extension to this philosophy is Platform As A Service(PAAS)[Bonifas, Nasser et al.][73] which can be defined to be:

> *"(...)the provision of a development platform and environment providing services and storage(...)*
>
> *(...)PAAS aims to be a developer's friend. The idea is simple, even if the execution is complex: multiple applications share a single development platform and common services, including authentication, authorization, and billing. PaaS developers build web applications without needing to know or care about the complexity of buying and managing the underlying hardware and software layers(...)"*
>
> *(...)Many PAAS providers exist today such as Google AppEngine, Microsoft Azure, Salesforce.com Force.com, Rackspace Sites, Bungee Connect, EngineYard, Heroku, Intuit, Cloudera, Aptana, VirtualGlobal, LongJump, AppJet, Wavemaker, Aprenda, etc.(...)*

Though this PAAS description is not implemented unambiguously, the AEXIST EHR systems aim to offer Platform As A Service as well. This can be enabled by the combination of te web-browser, open source components and the use of XRX [O'Reilly website, 2012][74] architecture. In order to fully comprehend this architecture, the following technical presentation of XRX is required:

- ***X****Forms on the client*

  The W3C standardisation organisation's flexible data markup format XML was designed for flexible integration of digitised information. As described in the 'Application Architecture' section, in traditional MVC architectures data-models are composed in the 'Controller' layer after which they are stored in the 'Model' layer. With XForms1.1 the W3C organisation attempted to breach this convention in 2004. XForms offers a web-form(accessible by the browser) in which the data-model is already present. In MVC terms, this means having a data-model in the 'View' layer. This model is called a 'XForms-Model' and can be composed out of multiple XML files providing a scaffolded model. Each data element of this XForms-Model can then be bound to a web control e.g. input field or a button. When the model is filled with data, it is no longer a scaffold but a data-instance. W3C calls this the 'XForms-Instance'. This XForms-Instance can then be posted by the web-browser to a HTTP-server offering a REST service. AEXIST EHR implements the Orbeon-Forms solution which can best be described to be a XForms-Engine.

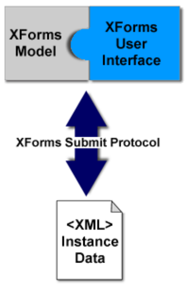


Figure 64: XForms structure [W3C.org 2011]

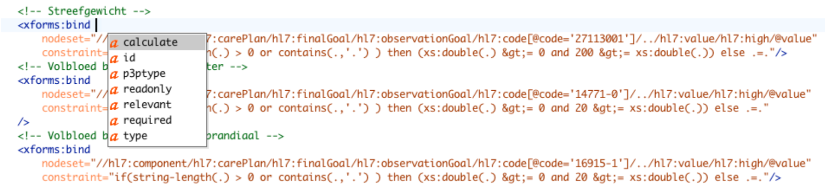


Figure 65: AEXIST EHR depends heavily on XForms technology

XIV DIGID: www.digid.nl

- ***R**EST interfaces*

  Representational State Transfer(REST) was defined by Fielding [Fielding, Taylor, 2002][75] as a supplement to his previous creation the HTTP-protocol. REST is based on the 'Web-Service' belief stating that the user's web-browser is not the only technology for accessing HTTP web-servers. Web-Services offer a centralised interface for data-exchange amongst software applications. REST is a standardised open protocol for using Web-Services. In AEXIST EHR systems, the native XML-Database 'Exist-DB' offers a rest service to which XForms-Instances (HL7v3 XML documents) can be 'posted' by means of the HTTP-protocol.

- ***X**Query on the server*

  The XQuery specification for querying XML documents was developed by the W3C web standardisation organisation and published in 2007. It features a scripting-language that relies on a XQuery interpreting-engine for its execution. It enables querying multiple XML documents that feature a consistent data-structure. Since such a structure is present in HL7v3-RIM, AEXIST EHR systems use the Exist-Database's XQuery interpreter engine to assemble data from different XML documents.

From an IT-governance perspective, a physician accessing the AEXIST EHR requires no more than a web-browser to be present on the client's computer system. This reduces performance-requirements of client-computers in the hospital and makes them easy replaceable. Without threat to security since no data is stored on the physician's computer. The AEXIST server is setup within the physical hospital organisation. Making it easy accessible to maintenance and *-since all software components are platform-independent-* easy to replace with newer or better hardware.

The three main components of AEXIST's EHR, enable separation of concerns within the system's architecture. The development of EHR XForms does not require a profound understanding of software engineering or a specific programming language. The major activity of a XForms developer is connecting the XForm's controls (buttons, input fields) to the XForms-Instance using another W3C standard known as XPath e.g:

```
<assignedPerson classCode="PSN" determinerCode="INSTANCE">
        <name>
          <given>Piet</given>
          <prefix qualifier="VV">de</prefix>
          <family qualifier="BR">Koning</family>
        </name>
</assignedPerson>
```

A HL7v3 XML document's 'family' name element as displayed above can be accessed using the following XPath statement:

```
'/assignedPerson/name/family'
```

By using XForms, the AEXIST EHR is no longer an as-is system requiring expensive adjustments for every new functionality after it has been installed. It is rather a platform that can be extended by its users for it does not require a developer's high level of technical ability. This means that the system's free open source components together with its ability to autonomously modify and extend it's functionality and business rules, make it a Platform As A Service or PAAS [SOA-RA, GL, ABB30, ABB31, ABB32].

Workflow

Involving the ability to capture governing processes as workflow documents and to automate governing processes. Within the evidence-based care cycle, the implementation of a new detailed clinical model can be compared with traditional change requests [Keller, 2005][76] as used in major commercial organisations. The DCM describes the required functionalities, the reason for change and the changes with respect to older versions. Since DCM's are not bound to physical information systems, they support process-changes transcending specific medical domains supporting transferral care-paths [SOA-RA, GL, ABB33, ABB34].

5.2.3 Quality of Service Layer

The SOA-RA states on the Quality of Service(QoS) Layer:

This layer provides solution QoS management of various aspects, such as availability, reliability, security, and safety as well as mechanisms to support, track, monitor, and manage solution QoS control. The Quality of Service Layer provides the service and SOA solution lifecycle processes with the capabilities required to ensure that the defined policies, Non-Functional Requirements (NFRs), and governance regimens are adhered to.

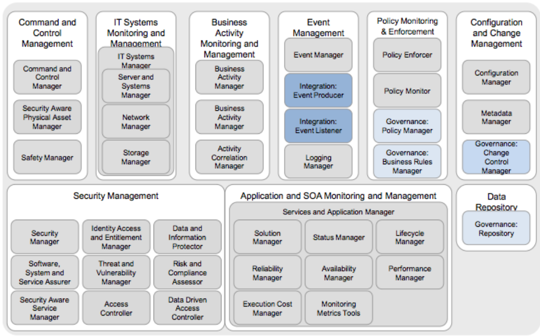


Figure 66: ABB's in the quality of service layer

Command & Control Management

As stated before, AEXIST EHR systems are hosted within the physical hospital organisation. The systems do not require a specific hardware configuration and can run on high-end network servers, as well as on middle of the road desktop hardware dependant on the performance required. This means that replacing- or extending hardware is similar to other IT-systems present in the hospital. [SOA-RA, QoSL, ABB1-8]

Security Management

Access to the EHR system is provided using the web-browser. Communications between the AEXIST server and the browser are protected by a signed encryption key. Today, hospitals tend to use Computers On Wheels(COW's) for daily clinical operations. Since doctors have to be flexible enough to leave a computer at any given time, access to the system is only granted when the physician's UZI-pass[XV] is present in the computer's card reader. Like a conventional MVC architecture based system, access is only granted to browsers using the HTTPS protocol[SOA-RA, QoSL, ABB9-22].

Application & SOA Monitoring & Management

AEXIST EHR foresees in monitoring and error-tracking mechanisms on various levels of technical sophistication. First there are the logging capabilities of it's open source technical building blocks. Both the Apache web server, the Tomcat application server and the two servlets (Orbeon XForms-Engine and Exist-XML Database) have their own logging mechanisms enabling error tracking and monitoring. [SOA-RA, QoSL, ABB9-28]

Business Activity Monitoring & Management

XV Unieke Zorgverleners Identificatie(UZI) means unique care practitioner identification and consists of a registration of doctors in a specific hospital. Using a UZI-pass featuring the unique doctor's number, secure computer identification is assured.

Business-level activity monitoring is provided solely by the 'document-based' structure of the database. Every time a web-form is submitted, it's data-model is stored making it a unique timed cross section of entered data [SOA-RA, QoSL, ABB9-47].

Event Management

A glimpse into a scenario where hospital information architecture would comprise standardised HL7v3 data-models and code-systems is offered with AEXIST's preoperative pilot project. Based on the belief in the reusable data elements of the CCR based core-EHR, the preoperative system sets out to assemble information required to start surgery. This information can be 'mined' from the core-EHR dataset of various systems. Such as a nursing record or a diabetes dossier. When integrated correctly, the preoperative EHR system informs the coordinating physician (surgeon) about the status of imminent preparations while other medical practitioners use systems that are meant for their own specialism. This way, the amount of time and effort lost in redundant registrations is reduced to the bare minimum.

Chronic diseases are characterised by repetitive checkups and recurring tasks to be performed by the patient. Using the DIGID secure authentication method, data on diseases can be introduced into hospital systems by means of the Internet. In the case of diabetes, modern glucose-monitoring devices have the possibility to export their measurement data in XML format. This format can be processed to the HL7v3 structure by the Orbeon XForms engine and validated using the NICTIZ XML-schemas [SOA-RA, QoSL, ABB9-48-51].

Policy Monitoring & Enforcement

Since AEXIST's EHR systems aren't part of a larger centrally coordinated IT-system, describing it's role on stored (warehoused) events is rather difficult. For such a description, a study of a hospital featuring only standardised systems is required.

Configuration & Change Management

The organisational process of capturing business rules and data-elements from care-guidelines and clinical pathways to DCM's, CU matrices and finally data-models has been explained. The easily replaceable XML-schemas providing tolerances have also been described.

A major challenge taken up by AEXIST is using open source software components in a domain that does not allow mistakes to be made. The company does so by avoiding the latest unstable versions of the available software. Older stable and thoroughly tested releases are preferred. Another big threat of open source software is the 'liveness' of the community of active developers. The communities of the low-level technical AEXIST building blocks like the web- and application server are characterised by large international corporations. Who contribute to the software's healthy 'ecosystem' by detecting bugs, solving them and providing new maintenance releases that are better suited for demanding corporate use. Though both have been around for almost a decade, the implemented XForms engine and XML database used by AEXIST EHR are still experimental technologies. The company manages to use and implement them because of their substitutability. Both feature W3C standards like XML and XForms that can be replaced by other high-end commercial products. Using these standards is the key element enabling rapid changes of technology and a potential scale up of the system [SOA-RA, QoSL, ABB9-80].

Data Repository

As explained in the 'Theoretical Background' section of this document, currently new medical insights are largely gained using controlled medical trials. Trials being funded by pharmaceutical organisations is not uncommon. Gathering data using the Evidence Based Medicine approach has two major advantages:

1. Data can be gathered from interdisciplinary care rather than from a single pathology.
2. Data is gathered from the real world in which unknown factors might influence outcomes.

In order to get the data required for implementing EBM, a typical business solution would be the expert-system in which hooks are made to various non-interconnected systems. When using the HL7v3 Reference Information Model in EHR systems, the need for medical expert systems expires since the Detailed Clinical Model on which a specific HL7v3 data model is based, already incorporates the data building blocks for the provision of quality indicators and scientific data [SOA-RA, QoSL, ABB9-85,86].

5.2.4 Information Layer

The SOA-RA states on this layer:

This layer includes information architecture, business analytics and intelligence, metadata considerations, and ensures the inclusion of key considerations pertaining to information architectures that can also be used as the basis for the creation of business analytics and business intelligence through data marts and data warehouses(...).

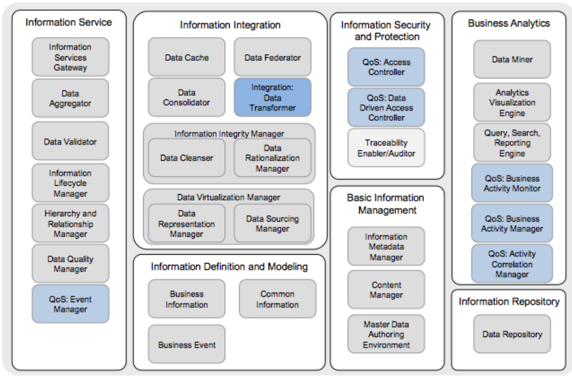


Figure 67: ABB's in the information layer

(...)In particular, information virtualization and information service capability typically involves the ability to retrieve data from different sources, transform it into a common format, and expose it to consumers using different protocols and formats(...).

Information Service

Accessing the REST service of the XML-based database from other hospital applications or services require it to do little more than an authorised HTTP request. The AEXIST system's REST service can then determine for each collection in the database, if the requested data can be accessed by the other system or service [SOA-RA, IL, ABB1].

Information Integration

Both the system's XForms engine and XML-database are able to perform eXtensible Stylesheet Language (XSL) transformations of XML documents. An Extensible Stylesheet can be regarded to be a template transforming the markup of an XML document to fit a predefined format. XSL transformation extends the system with data from virtually anywhere, as long as its data structure is XML and it is submitted using the HTTP protocol. [SOA-RA, IL, ABB2-7]. The system's XML-database provides functionality for scheduled- or triggered events. Enabling it to perform tasks triggered by external HTTP calls or internal schedules [SOA-RA, IL, ABB9-14].

Basic Information Management

The SOA-RA indicates that this is about performance-indicating metadata As explained earlier, the HL7v3 structure enables the extraction of quality indicators and scientific data [SOA-RA, IL, ABB16-18].

Information Security & Protection

As described in 'Information Service', data access by external hospital systems is possible using HTTP. This feature is however secured by two mechanisms. The collection-specific database credentials are required to access it externally and the system's web server will accept connections to the database's REST service only by systems of which the IP-address is known. Meaning that accessing database patient-data directly from a COW in the hospital is not possible. Another safety measure of the AEXIST system is the nightly backup schedule which is performed autonomously by the database [SOA-RA, IL, ABB19-21].

Business Analytics

By the SOA-RA, 'business-analytics' is described as abstracted information about performance and statistical operations. The AEXIST systems offer no specific functionalities on this behalf.

Information Definition, Modelling & Information Repository

[SOA-RA, IL, ABB19-28] indicates that this is about leveraging interoperability by sharing a common information model and making it accessible organisation-wide. Internally, AEXIST has such an information repository in the form of CU matrices and DCM's. A central hospital knowledge-base in which the used information models in the form of DCM's can be found is currently unavailable.

The NICTIZ Domain Reference Model's CU-matrix currently provides a guideline about how these 'information objects' would interact with installed systems but a technical standard for storing DCM's isn't available [SOA-RA, IL, ABB19-29].

5.2.5 Integration Layer

SOA-RA states on this layer: This layer enables the service consumer/requestor to connect to the correct service provider through the introduction of a reliable set of capabilities (...). And:

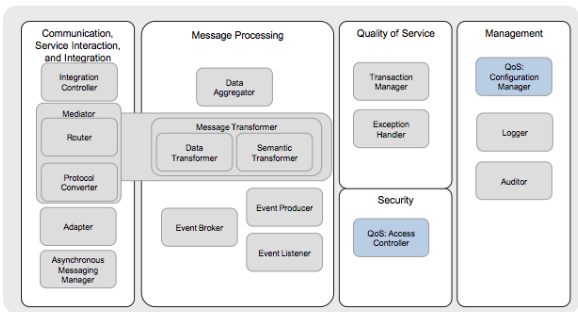


Figure 68: ABB's in the integration layer

- *Provides a level of indirection between the consumer of functionality and its provider. A service consumer interacts with the service provider via the Integration Layer. Hence, each service interface is only exposed via the Integration Layer (e.g., ESB), never directly and point-to-point integration is done at the Integration Layer instead of consumers/requestors doing it themselves.*
- *Consumers and providers are decoupled; this decoupling allows integration of disparate systems into new solutions.*

Communication, Service Interaction and Integration

According to the SOA-RA document, a web-service's behaviour is normally described using the Web Service Definition Language(WSDL). For web-services that are based on the SOAP definition, the provision of a WSDL document is compulsory for each service. REST does not require this description and in the case of the AEXIST system, the HL7v3 data format reduces the need for such a description. A single system's data model however, is based on a multitude of detailed clinical models, each responsible for a disease-specific metric e.g. blood pressure. Other hospital systems cannot discover services offered by an AEXIST system autonomously, since they do not offer WSDL-like metadata on available services.

This only applies to the disease-specific data-models that are used in AEXIST systems, since the core-EHR data-model is fully compatible with the twelve-elements of the CCR-based Core-EHR template as provided by NICTIZ. Successfully implementing vendor-independent interoperability for HL7v3 based hospital EHR systems [SOA-RA, IntL, ABB1-8].

Message Processing

Aware of the fact that interoperability in disease-specific systems is still very difficult due to semantical incompatibilities with medical terminology- and code systems, AEXIST decided to grant interoperable access to these systems using the Gartner 'diorama' paradigm. In conjunction with the physician who needs to access a system outside of his/her specialism, AEXIST's consultants compose a data model containing elements that can be compared to those of a referral-letter.

This way, practitioners can access the medical summary of a patient from a system that was originally designed for another medical specialist or specialism. This could be used when a patient is treated by several specialists because he has different syndromes or if a patient is treated by several specialists since the treatment of a disease requires knowledge of various specialisms. Scenarios that have been emphasised by NICTIZ to be frequently reoccurring [NICTIZ, 2011][77] [SOA-RA, IntL, ABB9-12].

Quality of Service

AEXIST has proven that core-EHR interoperability is possible in a hospital setting. However, it has only been deployed using a 'hard-wired' SOA-Orchestrated approach. This means that a single system has control over the most recent information on a patient. This system then decides what information should be used by other systems. In the case of the AEXIST Electronic Health Records, none of the systems performs a dedicated Orchestration / Service bus role, or is known to have a SOA-Choreography implementation. Rules about leading patient information are 'hard-coded' into the systems.

Figure 69: SOA Choreography vs SOA Orchestration

Security & Management (message routing)

When it comes to message-routing, AEXIST EHR does not have a special authorisation mechanism other than described previously in this document.

5.3 Intermediate Conclusions

When using the description of the AEXIST firm -*with the SOA-Reference Architecture-*, answers can be given to the questions that were posed in the introduction of this chapter:

How can HL7v3 be implemented in an EHR system &
How can the Object-Relational Impedance Mismatch be solved?

Various ways of implementing the HL7v3 data- or information model are available. In the past, HL7v3-RIM mappings to object-classes for use with relational databases in different programming languages have been made. An example of which is the RIMBAA project [Gul, Afzal et al. 2009][78]. When mapping the HL7v3-RIM to a relational database, the Object-Relational Impedance Mismatch occurs, prohibiting flexibility and adding more tables with every change of data structure.

The AEXIST approach of using a native XML database, circumvents this problem since the XML's document based structure offers the flexibility of adding and removing data-elements without corrupting the data-model. The second major advantage of XML documents in the way they are used in the AEXIST database, is that they preserve the semantical meaning of a form. It is stored in the exact way it was viewed by the user and provides contextual metadata about it's subject, author and the pathological context in which it was created.

How to set up a Core EHR?

Using the NICTIZ provided core-EHR template, the data-elements required to setup a core-EHR can be found. A hospital's IT-landscape however is diverse and proliferated. A core-EHR is only useful if it is used in a multitude of systems. When used in a SOA, the core-EHR data-elements are not enough to provide interoperability, profound choices on which system is holding the leading patient-data also have to be made. The SOA models of Orchestration and Choreography can help with solving this problem.

How to integrate transmural disease-specific data in different systems?

Due to incompatibilities of medical terminology- and code-systems, integration of disease-specific pathological data remains hard. Especially since ontology-based systems like SNOMED-CT provide different codes for 'items' that have the same name but that are interpreted differently in different medical specialisms. i.e. they are of different semantic significance. The AEXIST firm used Gartner's 'diorama' paradigm to solve the problem of transmural integration for disease-specific Electronic Health Records.

What can Software As A Service(SAAS) mean for a hospital's IT-landscape?

Since hospital workers are characterised by their deeply rooted specialistic medical knowledge, generalisations in IT-systems supporting a specialism are hard to make. Service Oriented Architecture provides a way to interconnect medical systems without loosing specialism-specific data. Share-ability is improved by systems that share the same data-model.

What is the role of a hospital's IT department in maintaining and developing EHR systems?

Figures from a survey [HIMSS, 2007][79] amongst 306 American hospital CIO's, summarise the situation at hand. Due to the various IT-products and services that need to be kept online, staffing resource availability is scarce. Patient-centred care is given more attention and quality indication has top priority. Implementation of Electronic Medical Records is given a significant amount of effort, though creating a centralised data repository or encouraging EBM-care support is given less attention. While system vendor delivery problems are regarded to be a significant barrier together with a lack of staffing resources, adoption of new technology does not appear to be the biggest issue.

These figures reveal that using open source technology might not only cut purchasing cost. When implemented Platform As A Service to which a hospital's IT-staff can contribute not only by configuring but by actively contributing to the system, high cost involved with tailoring the system to a hospital's specific needs can be avoided. Because external IT-vendors are needed less for configuring and extending a system.

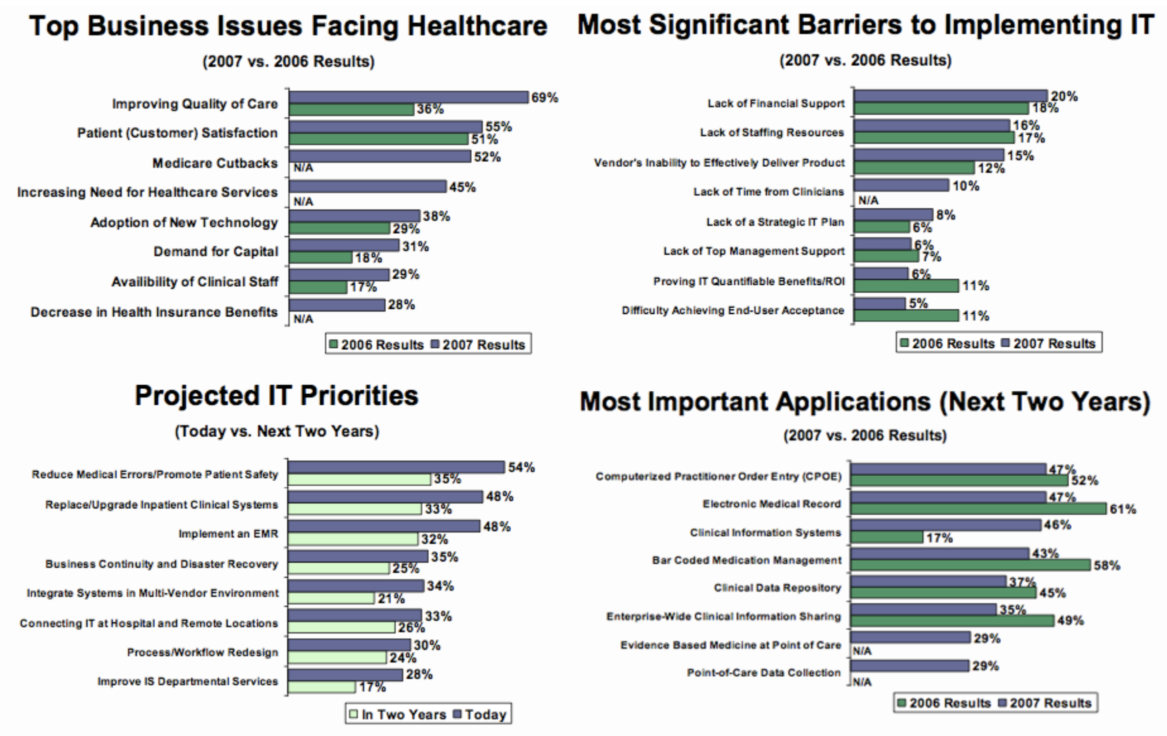


Figure 70: Figures from an 2007 interview with 306 American hospital CIO's [HIMSS, 2007]

5.3.1 Architecture Overview

In order to get a helicopter view of the various components of AEXIST's Electronic Health Records and their mutual relation, the figure below was created. It shows the SOA-RA's horizontal layers corresponding to the cross-cutting integration layer. The left side of the model provides a textual representation of the Architectural Building Blocks while the right side displays images of the implementation of ABB's that are currently available. These can be systems, concepts or models.

The main insight that is given by the model below is that the 'ingredients' and guidelines needed to develop an electronic health-record for use in a hospital's IT-Architecture are freely available. The AEXIST case study showed that the precondition to their successful implementation is a profound knowledge of the health-care system and knowledge on how to combine the available ingredients, guidelines and means.

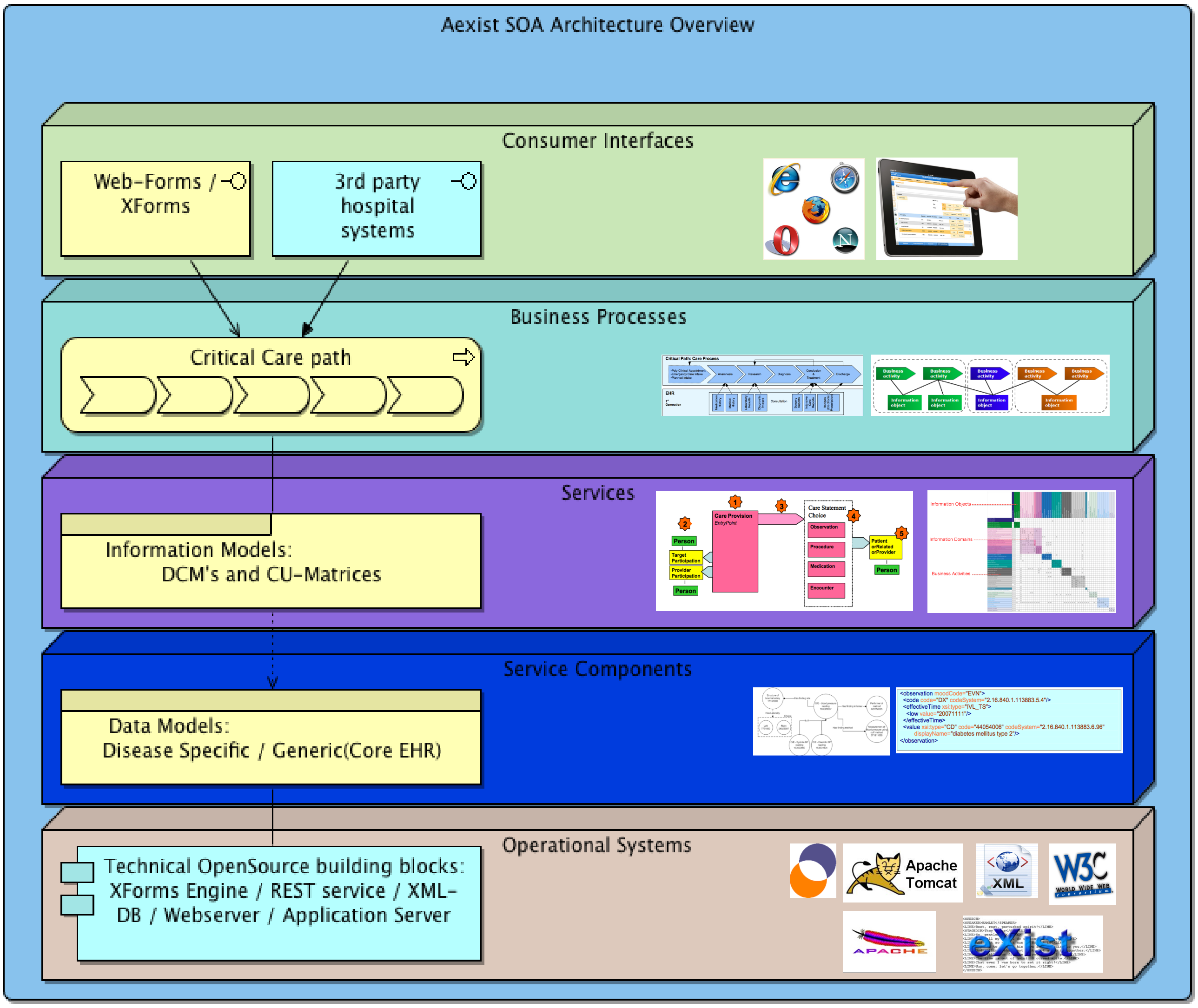


Figure 71: An overview of the architecture of AEXIST EHR projected on the SOA-RA horizontal layers

6 Overall Findings

This short chapter is intended to summarize the findings of the items described. From the high-level of policy makers down to the technical implementations of the case-study. It aims at answering the main research question being:

'What can be the role of a disease-specific Electronic Health Record featuring HL7v3, SNOMED-CT and W3C standardisation within the Information Architecture of Dutch hospitals?'

Increasing cost of health-care in the decades to come seem to be due to the demand outgrowing supply as stated in the 'motivation' chapter. A proportional increase in available medical doctors is not expected. In The Netherlands, hospitals are semi-public organisations. A system that has been *-and still is-* subject of debate. The introduction of business- and management principles in public hospitals meets considerable resistance. Which can be said to have several causes including the 'Professional Bureaucracy' organisation model and the organisational culture that is determined mainly by medical specialists. A culture that *-according to Porter-* even exists in the more liberalized U.S. healthcare system. The hospital organisation as described on paper seems to have a horizontal power structure. In practice, the specialised divisions in which specific knowledge is critical render it rather a 'Divisionalised Form'. The critical path or 'Care Path' in a hospital is known for situations in which patients visit various specialists for treating one- or multiple diseases. Common procedure for 'transferring' patients amongst specialised divisions is writing a Referral- or Dismissal letter. These letters cost physicians precious time and offer a summarised view on the patient only which based on the frame of reference of a particular medical specialism. Automising medical record keeping will save costly time by removing redundant procedures. It will also standardise patient-data which is useful for scientific research or Evidence Based Medicine and provide quality indicators that foster hospital quality and competitiveness.

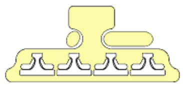


Figure 72: Divisionalised Form by Porter

Digitally integrating/exchanging standardised data however conflicts with the human ability to semantically categorise information. Although standardised data models and medical terminology systems improve transmural integration, their implementation solves the semantical interoperability problem only partially. When using a standardised core-EHR dataset, common data-elements can be exchanged between specialists. Integrating disease-specific data-elements can be achieved by providing 'diorama' functionality.

The AEXIST case has revealed that standardised EHR-systems can be used in the hospital IT domain. When using open source components and PAAS integration, cost can be reduced significantly while business-agility is dramatically improved by removing vendor-locking, by giving more control to hospital CIO's which can lead to more internal innovation. The AEXIST case has also shown that in order to support transmural integration digitally, disease-specific EHR-systems can support interoperability when featuring a core-EHR dataset. A problem that still hasn't been tackled by the company is the coordination of SOA deployment of it's systems with regard to the paradigms 'Orchestration' or 'Choreography'. Currently, the firm deploys all of it's disease-specific EHR's on a single server, bypassing the problem of coordination which system has the latest data on a patient.

7 Discussion

The Aexist case does not completely describe the big picture. Therefore, in this chapter, we try to broaden the things leaned from the case study to see what 'GAPS' are still left when it comes to policy and practice

7.1 The future of Interoperable EHR Standardisation

Describing the future of standardised EHR systems in a structured manner, a summary of the Strengths, Weaknesses, Opportunities and Threats is given. This type analysis was originally described by Humphrey in 1977 [Armstrong, 1996][80] is known as a SWOT analysis.

7.1.1 Strengths

Standardisation can be used for improving interoperability. Both the standardised data-models and medical terminology systems that have been designed for this task meet their expectations. Their success *-as learned from the case study-* is largely dependant on their adoption by other hospital systems and by the type of technical implementation. Several institutions have started with the provision of template documents on how to design and manage metadata repositories and how to furnish a hospital's IT-architecture.

The flexibility of HL7v3-RIM enables disease-specific Electronic Health Records to also have a generic- or core dataset. Opposed to current systems that are either medically specialised, support billing, are workflow oriented or are a core-EHR system by themselves.

7.1.2 Weaknesses

The use of international medical information standards yet poses questions on a national scale:

Who is responsible for distributing and maintaining Detailed Clinical Models?

Because they are regarded to be the solution for bridging the gap between doctors and information-architects, expectations about DCM's are high. There is however no centralized distribution and versioning system that controls which systems are based on which DCM's. Because EHR-vendors use their own data models, even within the hospital organisation, the management of DCM based systems remains a challenging task.

Medical terminology standards are not compatible. In their attempt to map ICD-10 to SNOMED-CT and DBC's. The Dutch Hospital Data foundation created the 'Diagnose Thesaurus'. A relational data-model using ICD-10 as the leading data set. In 2011, the Utrecht based Q-Consult organisation was given the task (by the foundation) to make an implementation plan for hospitals using the Thesaurus. This report does mainly focus on mapping the non-ontological ICD-10 standard to the financial 'Diagnose Behandel Combinaties' (DBC). The authors claim that emphasis is not put on SNOMED because it has not been deployed in either Hospital Information Systems (HIS/ZIS) neither is it a legally required standard. Which ICD-10 is.
This interesting case however reveals that mapping different non-ontological code-systems to SNOMED-CT can be done. Solutions on how to map different systems that use the ontological SNOMED standard but from a different medical discipline *-and therefore use different codes-*, have not been provided by either Dutch healthcare research institutions or policy makers.

7.1.3 Opportunities

In a hospital, SNOMED-CT and ICD-10 are not the only terminologies used. As shown in the 'theoretical background' section, roughly a dozen different terminology standards are being used. Therefore a medical terminology registry or server might be topic of future research. This approach would also comply with the SOA-Reference Architecture need for a metadata repository. The figure on this page shows an implementation of orchestrated SOA architecture in a U.S. Hospital. The question on how to solve the SOA messaging problem on leading patient information might be solvable with the industry's well known CORBA [Object Management Group website, 2011][81] standard.

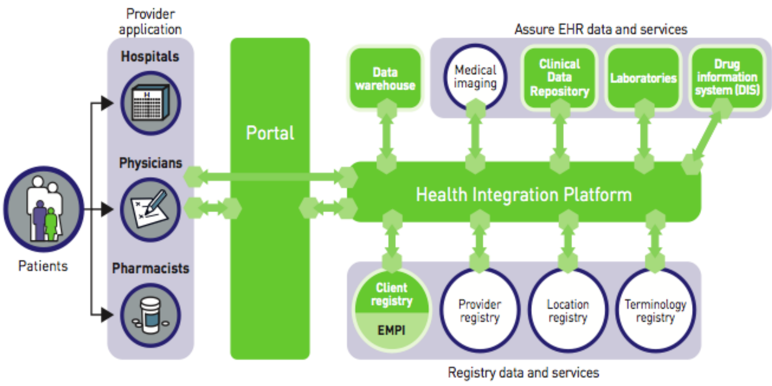


Figure 73: Hospital IT-Architecture of an orchestrated SOA implementation [Telus Health Solutions 2010]

Hospitals are autonomous organisations that now have to comply to new demands like patient centred care. Quality is becoming a performance indicator and in order to live up to the expectations of their patients, hospitals are trying to find new innovative ways of offering better service. Policy institutions like NICTIZ are not empowered to force hospital changes but they can offer a helping hand in the hospital's quest for improvement. Resulting in 'neural-network' like developments in which hospitals not only seek competition but start cooperations for joint cost-cutting or quality improvement. The role of open source and Platform As A Service might offer even more powerful solutions when used in a joint-venture between two or more hospital organisations. But in order to do so, standardisation and integration is a prerequisite.

7.1.4 Threats

Management specialists [Dicke, Steenhuisen et al. 2011] stated that changing public organisations to a more liberal model, is no easy task. It will take time and goes along with the process of cultural change, which cannot be enforced. Therefore it can be stated that the slow pace of current changes is understandable. However, according to the 2009 'Roadmap on Semantic Interoperability in healthcare' by Stroetman, Dipak et al, targets on EHR standardisation are not going to be met in The Netherlands.

7.2 Recommendations

Having studied this topic from various perspectives and seen from different levels of detail, some recommendations can be given:

- The NICTIZ organisation should take position in which it can focus more on technical implementation rather than policy-level solutions. Information on using open source, SOA and PAAS is valuable by hospital CIO's and especially by EHR manufacturers. Because most of the components of AEXIST's EHR systems are open source and freely available, institutions like NICTIZ might share this information with the market, boosting innovation.

- To meet the EU deadline of having centrally-managed repositories for the distribution of Detailed Clinical Models, one national organisation should be appointed. Since it is currently possessing most of the knowledge about DCM, NICTIZ should start off this process.

- A blueprint on how to make a generic 'Health Integration Platform' (as can be seen in figure 73) that communicates with a medical terminology registry, for use in hospital IT-architecture would be very useful. A community can be started to accommodate the development of such a platform. This community would be managed and maintained by the major marked leaders in EHR technology. The SOA-RA documentation of The Open Group can offer a set of quality criteria on which a health integration platform can be based.

8 Glossary

Item	Dutch Translation	Definition
EHR, Electronic Health Record	EPD, Elektronisch Patiëntendossier	Digital facility for the support of the patient-centred care process. Providing the right information to the right user.
Care Provisioner	Zorgverlener	Person in charge of providing care
Subject of Care	Patiënt	Individual receiving a medical treatment.
Medical Record Keeping	Statusvoering	Digitally administering information that is directly applicable to the process of health care
Patient Referral	Overdrachtsmoment	The administrative process of the subject of care(patient) who switches from care-practitioner
VWS	Volksgezondheid Wetenschap en Sport	Dutch ministry responsible for healthcare, sciences/education and sports
Dismissal Letter	Ontslagbrief	Used when medical specialists finish their treatment.
NICTIZ	Nederlands ICT Instituut in de Zorg	Organisation responsible for advising medical institutions about IT-developments and
Referral Letter	Verwijsbrief	Providing a summary when patients are transferred from one specialist to another
Ontology	Ontologie	In computer science and information science, an ontology formally represents knowledge as a set of concepts within a domain, and the relationships between those concepts. It can be used to reason about the entities within that domain and may be used to describe the domain.

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