



# State of the Art Clinical Pathway Definition: Gap Analysis

Deliverable D1.1

Sopheon (ed.)

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# Table of Contents

<b>1. Introduction.....</b>	<b>1</b>
<b>2. Clinical Pathway Representation .....</b>	<b>4</b>
2.1 Introduction.....	4
2.2 Traditional View on Healthcare Processes .....	4
2.3 Clinical Pathways.....	5
2.4 Process Modeling for Knowledge Workers .....	10
2.5 Self-Adaptation of Systems .....	11
2.6 Contributions .....	12
2.7 References.....	12
<b>3. Process Data Representation .....</b>	<b>16</b>
3.1 Introduction.....	16
3.2 Computerized Medical Guidelines.....	16
3.3 Software Overview.....	16
3.4 References.....	18
<b>4. Patient Data Representation .....</b>	<b>19</b>
4.1 Introduction.....	19
4.2 Electronic Health Records .....	19
4.3 Two Level Modelling with Archetypes and OpenEHR (NEN13606) .....	20
4.4 Virtual Patient Repository (EHR platform) .....	22
4.5 Applicable Standards and Normative References (ICOM).....	24
4.6 External Communication .....	25
4.7 Security and Data Privacy.....	25
<b>5. Dynamic Patient Model .....</b>	<b>27</b>
5.1 Introduction.....	27
5.2 State of the Art .....	27
5.3 Gap Analysis.....	27
5.4 References.....	28
<b>6. Conclusions.....</b>	<b>29</b>

## 1. Introduction

This document reports on the research done to analyze the state of the art of the technologies that are relevant to the objectives of the Edafmis project. It also analyzes the gaps between the state of the art and the envisaged Edafmis system.

It is the first deliverable of Workpackage 1 "Process and patient data representation". This is described in the project description as follows:

*It is clear that the conceptual and technical integration of various data producing and absorbing devices around the clinical pathway and the precise interpretation of their various datasets are conditional for meaningful communication and cooperation. This cannot be realized without having an agreed Reference Model, that allows for a stable and unambiguous "deep" definition of the clinical pathway "program", however while still allowing source systems to stick to their proprietary software languages. Therefore the WP will need close cooperation with those partners that deliver a device to the workflow such as the ERP system, the mobile scan exchanging system, the intervention system, the protocol management system, to agree the input/output schemata.*

*WP1's main objective: to deliver the conceptual data model (Reference Model) allowing to define and execute a clinical pathway for (semi-) automated intervention; where possible the WP will reuse existing industrial standards, however will develop related to additional needs; to deliver the protocol handling system that creates and manages the protocol in the form of a program that executes the clinical pathway; this can be used and evaluated during experimenting and prototyping;*

There are 4 dimensions or perspectives on the research route to the objective mentioned above. Together they form the structure that will be imperative for all the deliverables of Workpackage 1. These dimensions are represented in the Workpackage Tasks as described in the project description.

### Task 1.1 Clinical pathway representation

*This Task will deliver those models that define the medical aspects of the diagnosis and treatment of a disease. To do so it needs to establish the "language" in terms of function and form that can be used to express these aspects, both at a human level and at a technical (software) level. How to express the basic or starting configuration? The models will contain property-value combinations as well as rules that manage the behaviour of the treatment instruction. On one hand it should enable for medical experts to express their detailed definitions, on the other hand it should ensure the right data collection during diagnosis and intervention and the consequences thereof. For example to stop the treatment or to change strategy. The Clinical Pathway models will be tested by producing a Clinical pathway program, that will be used for prototyping and experiments in the integrated Edafmis environment.*

Task leader: Zorggemak

Other partners: Sopheon, CETIM

### Task 1.2 Process data representation

*This Task focuses on the flow-aspects of the diagnosis and intervention procedures. It will model the sequence and conditional aspects of activities and events in a way that we can*

*consider the Clinical Path to be a “secured” workflow. It will define in detail when which data sets should be pushed out to or pulled in from the various devices and tools participating in the process. The Task will deliver the conceptual interface requirements as well as the common reference model. The results will be input for WP4. It will also participate in making the experimental (softwarized) Clinical Pathway system.*

Task leader: Sopheon

Other partners: Sopheon, Zorggemak, CETIM

### **Task 1.3 Patient data modelling and communication**

*New and existing imaging modalities make an increasing amount of potentially important information available for any given patient. Furthermore, systems for image-guided minimal invasive surgery and therapy are increasingly being used in order to safely navigate surgical instruments into the human body for improved patient treatment. Essential questions in multi-modal navigation are: What information is needed for optimal surgical planning and guidance in the operating theatre? How should all this multi-modal information be presented to the surgeon? And how can technology ensure that information displayed in the navigation system represents an accurate picture of the intra-operative anatomy throughout the operation?*

*T1.3 main objective is to provide the underlying frameworks for WP3/4 and to support the patient treatment process described in figure 2, thus making it possible to provide optimal solutions to the challenges described above. Given a clinical case, this Task should provide the necessary methods / software algorithms to:*

- *Extract/segment the relevant anatomical/functional structures from the available image data*
- *Make sure that all the available and relevant images are registered to each other and to the patient throughout the treatment process shown in figure 2*
- *Be able to create integrated multi-modal 3D scenes using advanced visualization techniques needed for optimal preoperative planning (T2.1) and intra-operative navigation (T2.3).*

Task leader: Philips Healthcare

Other partners: Mobilera

### **Task 1.4 Dynamic patient model**

*When the patient is in the Intervention phase the body will be monitored on a continuous basis from various perspectives, in parallel. The dynamic patient model instructs or suggests the intervention systems what to do and what not to do within certain tolerance margins. This Task should define the patient model dynamics as a set of probable data combinations (patterns) that might appear and have preprogrammed logical consequences. It also should define how to handle “uncertain” or “unexpected” combinations of monitoring data. These rules need to be expressed in the Clinical Pathway software and executed by the Intervention System.*

Task leader: Sopheon

Other partners: Mobilera, Cetim, Zorggemak, Philips

**Focus of Research**

In practice the following professional areas were studied:

1. Process Description Languages and Systems for Clinical Pathways
2. Standardization of Interoperability in the Medical Sector
3. Protocol Management Metrics and Systems for Clinical Pathways
4. Decision Support in Health Care Diagnosis and Treatments
5. Multimodal Imaging for Intervention Support (Real Time Navigation Support)
6. Electronic Health Record Systems

This deliverable is chaptered according to the structure of the Workpackage Tasks. It reports the study findings for each dimension and ends with a chapter Conclusions. The chapter Conclusions formulates the most relevant gaps that the project has identified.

## 2. Clinical Pathway Representation

### 2.1 Introduction

Task 1.1 will deliver those models that define the medical aspects of the diagnosis and treatment of a disease. To do so it needs to establish the “language” in terms of function and form that can be used to express these aspects, both at a human level and at a technical (software) level. How to express the basic or starting configuration? The models will contain property-value combinations as well as rules that manage the behaviour of the treatment instruction. On one hand it should enable for medical experts to express their detailed definitions, on the other hand it should ensure the right data collection during diagnosis and intervention and the consequences thereof. For example to stop the treatment or to change strategy. The Clinical Pathway models will be tested by producing a Clinical pathway program, that will be used for prototyping and experiments in the integrated Edafmis environment.

In the following section we explain the history and background of clinical pathways, its implementations and the current issues in medical settings.

### 2.2 Traditional View on Healthcare Processes

The core concept of medicine, the doctor-patient relationship and the clinical practice representing a medical doctor's personal assessment, didn't change that much in the past. Historically, nowadays and not until intelligent robots fully take over medical intervention rooms, the strict picture of a practitioner assessing a patient to provide diagnosis and treatment using his clinical judgment, will remain a human-centered one.

As performed by a practitioner, a medical doctor, practicing medicine typically involves a diagnosis and prescribing a treatment aiming at improvement of medical condition. The doctor-patient relationship, the core concept to the practice of medicine, begins with an examination of the patient's medical history and medical record, followed by a medical interview (Coulehan and Block, 2005) and a physical examination. After a first diagnosis by stethoscope or tongue depressor, the practitioner does an examination for signs and interviews the patient for possible symptoms. Further medical tests (e.g. blood tests) can then be ordered to prescribe pharmaceutical drugs or other therapies. The resulting documentation of care processes in a medical record is an inherent part of the profession, and in many jurisdictions it is a legal document (Addison et al., 2005).

Although these concepts have been followed from early ages, medicine has been often revolutionized by advances in chemistry, laboratory techniques and equipment. In the 19th century old ideas of infectious disease epidemiology were replaced with bacteriology and virology. The microscope abandoned here the early and speculative claims about the existence of microorganisms thus forming the way of medical microbiology by the isolation of bacteria and viruses (Johnson, 2001). The discovery of X-rays opened the way for diagnostic radiology, allowing to produce images of the internal aspect of the body and noninvasive identification of stones in the gallbladder, pneumonia, lung cancer or fluid collection in the lungs.

Today new technologies constantly shape the possibilities in medicine, making interventions, noninvasive and less risky. But despite new medical systems, the work process didn't change much and expensive intervention support systems and specialists need to be scheduled accordingly and manually. Work support systems in such teams are yet stand alone and not interoperable, making them sensitive to human error, and knowledge work as in medicine is difficult to model. As a report (Baker et al., 2003)

discussing data gathered in the United States from the Harvard Medical Practice Study (HMPS) and the Utah-Colorado Medical Practice Study (UCMPS) (Studdert et al., 2002) points out, estimates indicate that medical errors result in 44,000 deaths annually - a number bigger than that of automobile accidents (43,458), or AIDS (16,516). These numbers, scary enough, also indicate that a majority of medical errors, in fact, result from healthcare system failures (Baker et al., 2003). It requires special attention to explore the group's appreciation to adapt a technology to their particular situation, and describing and modeling flexible routines in such teams is a major task. Therefore we need a change in structure.

Current models seek to understand organizing knowledge work by responding to environmental change, such as caused by new technology, or by conceptualizing them in theoretical structures, i.e. network structures or "boundaryless" organizations. There is an ongoing discussion calling for grounded approaches to cope with the dynamics of knowledge work, and models for automation of work processes could be a possible direction for comparable studies of work. While business process modeling (BPM) and information systems modeling (ISM) techniques enable decision makers to filter complexities of the real world, advances in coordination modeling notations allow addressing of dynamic constraints as particularly important in the domain of highly dynamic knowledge work.

With most governments recognizing the importance of public health efforts in reducing the incidence of disease, disability, and the effects of aging, the health care sector is one of the world's largest and fastest-growing industries. For most developed nations, health care represents with over 10 percent of the gross domestic product an enormous part of the economy. According to OECD data 2007 health expenditures consumed 16% of the GDP of the United States, 10.9% in Switzerland, and 10.7% in Germany (OECD, 2010). To make the best use of limited resources, whilst providing high quality in time is one of the main challenges facing healthcare professionals, managers and administrators today.

To support this, facing the growing challenges in organization, a specific approach aiming at optimization through process management came in into growing use in recent years in health policy - the growing use of clinical pathways in care planning.

### 2.3 Clinical Pathways

Clinical pathways, sometime also called care pathways, critical pathways, integrated care pathways, or care maps, are one of the tools designed to achieve standardization of care processes, aiming to improve quality of care, equity of treatment, optimal allocation of resources and a rational division of labor between health care professionals (Pinder et al., 2005). Their goal is to improve decision making and transparency in health care by embedding medical knowledge by sequencing practitioner's care and the respective patient journey.

*A documented sequence of clinical interventions, placed in an appropriate timeframe, written and agreed by a multidisciplinary team. They help a patient with a specific condition or diagnosis move progressively through a clinical experience to a desired outcome. - (The National Assembly for Wales, 1999)*

Clinical pathways first emerged in the 1980s in the United States aiming at organizational efficiency in hospitals by uniforming lengths of stay, standardizing treatment packages and thus enabling predictable costs (Zander, 1991). The concept appeared at the New England Medical Center (Boston, USA) in 1985, where Karen Zander and Kathleen Bower translated industrial Critical Path Methods (CPM) and Program Evaluation and Review Techniques (PERT) into case management plans and later clinical pathways (Zander, 1991). The intellectual origins of the method can be tracked back to the Age of Enlightenment and the social engineering model of society with constant improvement and rationality (Pinder et al.,

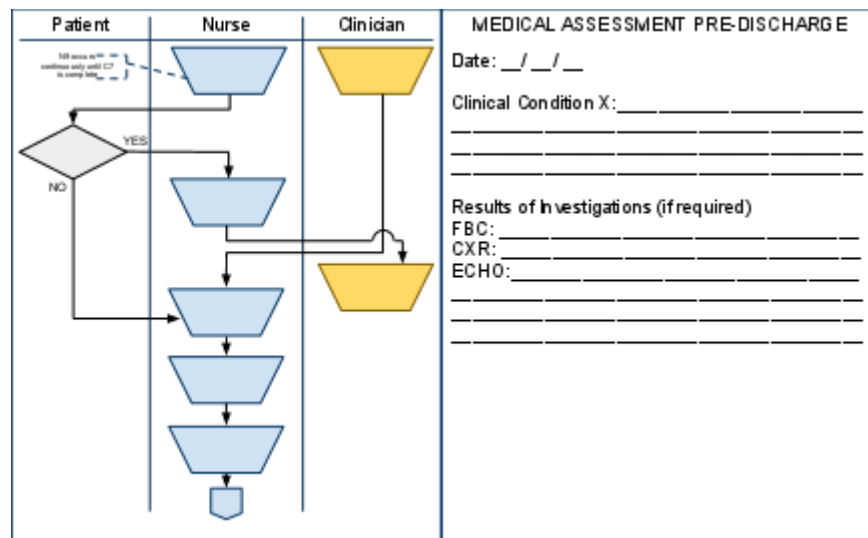
2005). Its organizational engineering roots on the other hand lay in the classical management theories of Scientific Management (Taylor, 1911) and business administration (Fayol, 1916), where it was possible to measure work by quantitative means. In this light, clinical pathways are descendants of Gantt charts as introduced by Taylor's assistant, Henry Gantt.

The current growth in application in Europe began with efforts of the UK National Health Service (Department of Health, 1997). While not initially referring to clinical pathways, a report describing large variations in quality and efficiency existing in care processes initiated efforts to implement a standard to improve national health services. As an emphasis has been put on the collection and use of clinical data, the pathway approach has been chosen to achieve this. This way the efforts were pushed focusing the multidisciplinary team on shared outcomes of care (Jones, 2000) and towards improvement of more detailed clinical efficiency rather than organizational aspects. Implemented through broader national agendas, as in case of the UK, pathways thus aim to improve efficiency, quality and local flexibility (Pinder et al., 2005; Department of Health, 1997) by continuous improvement based on best practice while reducing variations (Campbell et al., 1998).

### Current Implementations

Clinical pathways usually consist of several forms combining the nursing care plan with medical notes, and some sort of a process diagram visualizing the process. The diagrams provide a global view, while the loose forms guide the respective medical journey and embed the reports.

Within an international survey Vanhaecht et al. (2006) provide first insights on pathway implementations. According to their data, 91% of pathways used are paper based, while additional 57% are also being supported by IT.



**Fig. 1: Clinical Pathway Example**

There is quite some deviation in current pathway literature in regard nomenclature and definition (Vanhaecht et al., 2006) and scholars (Hunter and Segrott, 2008; Pinder et al., 2005) divide discussions regarding pathway design into four main themes: the multiple aims of clinical pathways; the process of initial development; pathway implementation in practice, and the impacts of pathways on client care, professional identities, and the nature of written documentation (Hunter and Segrott, 2008).



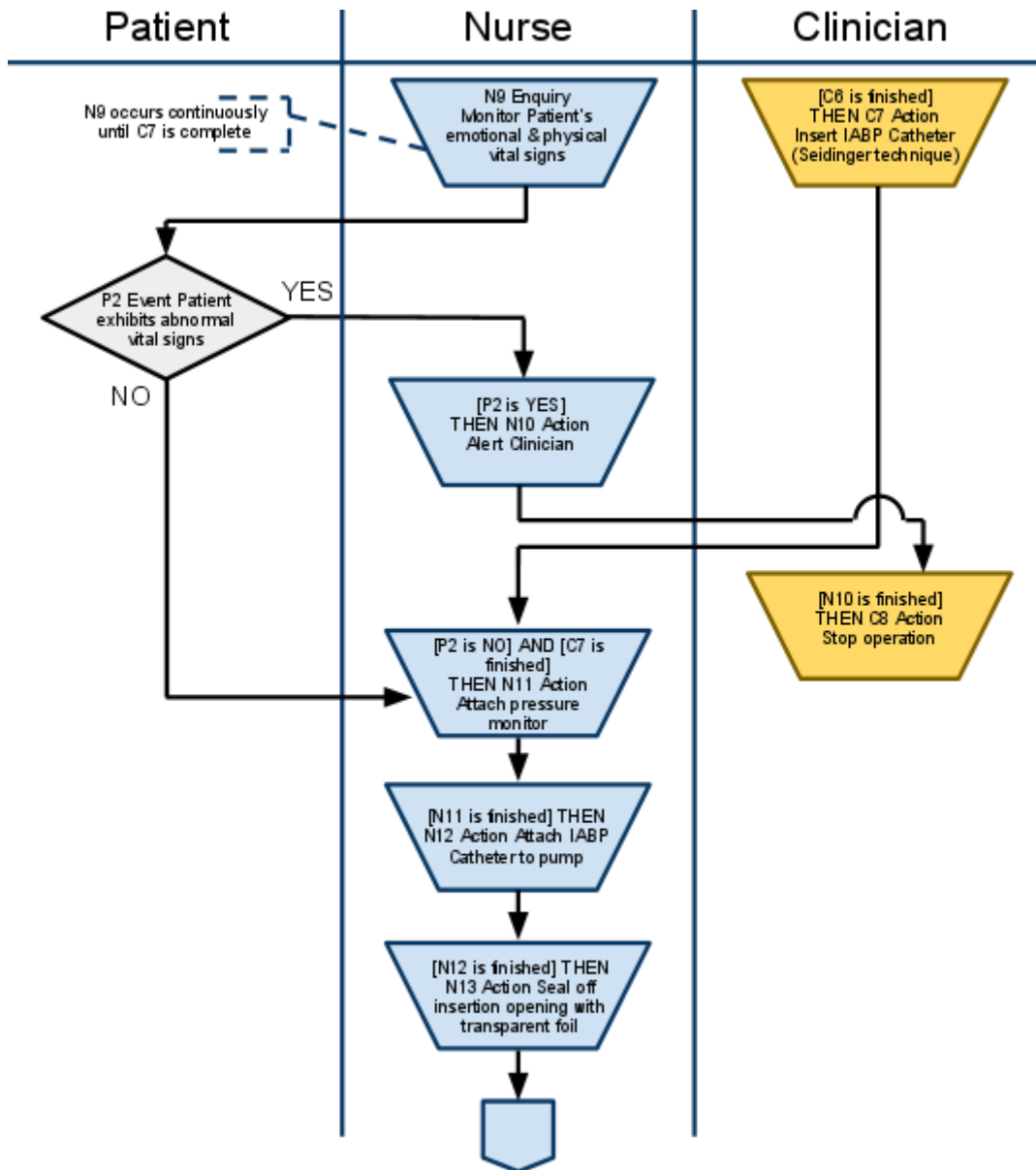
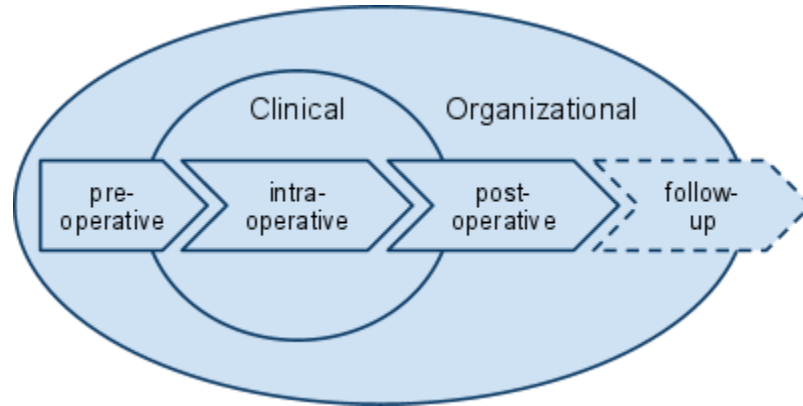


Fig. 2: Pathway Process Excerpt: Insertion of IAPB Catheter

### Dimensions and Goals of Clinical Pathways

As first appeared in the United States to control healthcare costs, pathways were developed in a manner of industrial Critical Path Methods (Zander, 1991), aiming to introduce standards of care, standardizing lengths of stay and enabling predictable costs. In most other countries, however, pathways were in the first case developed to improve quality of treatment (Hunter and Segrott, 2008; Atwal and Caldwell, 2002). In this light, clinical pathways can be divided into categories of two perspectives (Hunter and Segrott, 2008; Jones, 2000) and four phases (Lemmensa et al., 2009), thus aiming at organizational or clinical effectiveness, while covering four different phases of a care process: preoperative, intraoperative, postoperative and follow-up (Lemmens et al., 2009).



**Fig. 3: Different Scopes of Pathway Implementations**

Taking the position of Lemmens et al. (2009) and as represented in Figure 3, the preoperative procedures refer to the preparations taken before a surgery, including patient admission. Intra-operative phase discusses procedures within a medical intervention with the patient possibly being treated under anesthetics. The postoperative phase refers to the processes in the hospital after intervention to improve the patients' physical condition, and the follow-up phase discusses care after the patients' discharge. Within the two perspectives, pathways can either be aiming at medical and clinical effectiveness and reflecting on a particular diagnosis and improving the quality of care. Following the approach from an agency perspective and improving organizational effectiveness following the process from one care boundary to another (Jones, 2000).

From the broader organizational perspective pathways define content such as discharge planning, nutrition management, pain management and patient education. Taking the clinical perspective, pathways deal with the sequencing and timing of care, specifying each step of a medical intervention (Hunter and Segrott, 2008). In regard of pathway development there is quite some discussion concerning the scope and best suited conditions.

### Process of Initial Pathway Development

Following the two perspectives on pathway adoption, at organizational and clinical level, there has been some debate in literature how and where pathways should be developed. Hunter and Segrott (2008) especially contrast the aims of clinical against organizational effectiveness, evidence-based standardization against locally-derived solutions, and automatized documentation of care processes against intuitive nursery knowledge.

The suitability of pathways for complex and unpredictable conditions has been discussed by Currie and Harvey (2000). There is some controversy whether it is not possible to model complex medical practice with many potential variations by pathways or whether such complex cases are indeed those requiring the development. Lowe (1998) suggests that pathways for complex conditions and different pathologies, concentrate more on organizational than on clinical effectiveness. In that case they are rather mapping organizational processes than a particular diagnosis of treatment, thus they aim at organizational effectiveness more than clinical effectiveness.

Pathways are here especially promoted as a carrier for evidence-based practice (EBP), where effectiveness of a particular treatments has been confirmed by systematic empirical research. In case of external evidence, such as research or national guidelines, weighing of different sources of evidence is

crucial (Rolfe and Gardner, 2005). The quality of evidence underpinning pathways can vary and groups developing pathways may not have sufficient skills or resources conducting systematic reviews crucial (Currie and Harvey, 2000; Fox et al., 2003). External evidence may be less necessary while addressing on-site organizational problems. Wigfield and Boon (1996) suggest that development of pathways makes understandings of different practitioner professions and the sequence of care explicit and allows care processes to be critically reviewed (Cheah, 1998). When developed locally by a multidisciplinary team covering the process, development teams may not have the necessary resources and practitioners may question the underpinning evidence base. Enhanced communication and understanding of respective roles has indeed been found in practice. Surprisingly rather during the initial development phase than during later implementation (Currie and Harvey, 2000).

Due to its roots in protocols, pathways tend to collect data in a quantifiable way being easy to record as Berg (1997) points out. This however can easily lead to loss of the more intuitive nursing knowledge. The standardization of care processes and documents undermine the original holistic approach of individual care, while taking certain information out of their original context. This has been concerned by professionals, arguing that medical records are part of the thought process itself, not only a record of it (Berg, 1996).

### **Implementation in Practice, Variance and Individual Care**

According to literature the implementation phase is generally less researched and studies often take a simplistic view on the process, e.g. assuming positive responses from health care professionals (Hunter and Segrott, 2008).

The role of a pathway facilitator is being found central to a successful implementation (Hockley et al., 2005; Bragato and Jacobs, 2003), and the implementation as an active stage of development in which practitioners should reshape the pathway (Hunter and Segrott, 2008). Despite enthusiastic commitment of stakeholders to the implementation process, however, there can be a lack of commitment of staff involved. In his research Jones (2000) found this caused by structural changes and lack of familiarity with the concept. He also describes a more complex resistance caused by professional ideologies, as this approach conflicts with the thoughts of clinical judgment many professionals perceive as part of their occupational autonomy. Research points out (Bragato and Jacobs, 2003; Atwal and Caldwell, 2002; Berg, 1997) that practitioners rise concerns regarding the complexities and subtleties of healthcare work and may question the evidence base underpinning the pathway. In order to avoid this auditing variance has been discussed as an essential stage for a effective implementation. Variance analysis furthermore may potentially identify gaps in practice knowledge.

Variance is basically defined as the deviation from the defined, prescribed or predicted, pathway. There is a variable interpretation of variance in pathway literature. Definitions as to what variance means, do vary: may it be a change in a clinical condition, a treatment not being given or a delay in a particular treatment. Similarly there is some discussion whether the goal is to eliminate variance, while others argue that it is unavoidable. Recording and analysis of variance at local level can be a form of self-regulation, as a continually incremental improving process of self-optimization, but is highly dependent on staff involvement.

In practice, may it be consciously or not, protocols can be circumnavigated and interpreted in many different ways. Clinical settings are often out of control of the original design and in reality policies are made by workers adapting protocols to enhance their professional discretion as Hunter and Segrott (2008) point out. Considering professional ideologies of the medical world understanding of the impacts of pathways on medical practice and professions is crucial.

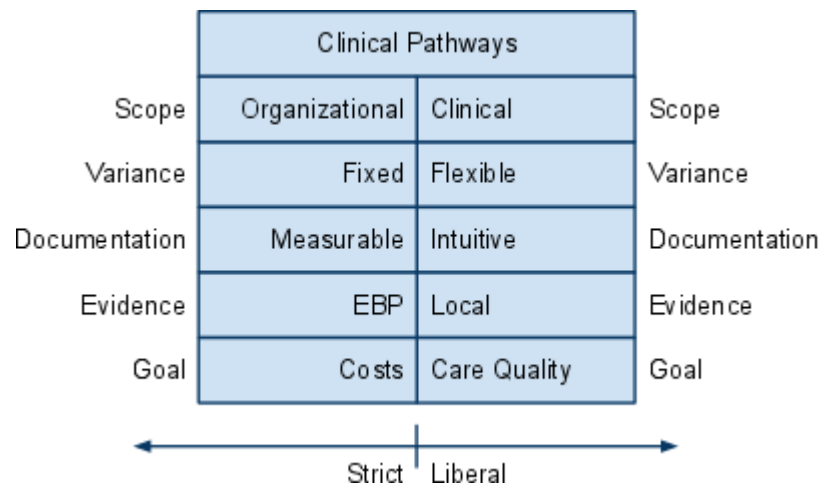
## Impact on Practice and Professions

Research on pathway effectiveness is limited and necessary long-term studies particularly rare (Vanhaecht et al., 2006). What is being observed by literature, however, is that pathways impact three areas of care: client care and satisfaction, professional identities and relationships, and written documentation (Hunter and Segrott, 2008). This can occur in sometime unpredicted ways, as caused by such impacts happening across boundaries.

Although it is being suggested that pathway development improves the understanding of different practitioner professions and thus their relationships, this seems to be mostly occurring within the development phase of pathways rather than their application. Instead, it has been indicated that pathways might rather increase interprofessional tensions, by reinforcing authoritative knowledge.

Taking the current findings into consideration it is necessary to look into the modeling aspects underlying clinical pathways.

## 2.4 Process Modeling for Knowledge Workers



**Fig. 4: Aspects of Clinical Pathway Implementation and Usage**

There is quite some discussion regarding different pathway approaches and how those should be defined. As outlined in Figure 4, besides of the organizational scope of pathways and their tightly aligned goals, it is most notably the level of flexibility in the approach being discussed. The variance allowed by a pathway, should it be allowed or tried to be eliminated, the form of documentation, either simplified or complete, and the mixture of local evidence and evidence-based practice.

Models allow decision makers to filter irrelevant complexities. Process modeling gained prominence at the core of organizational design and information systems development. Although both are natural partners and IT provides new opportunities to structure knowledge work their common strengths have not yet been fully exploited in practice (Giaglis, 2001).

Business analysts and IT professionals are respectively equipped with an own set of tools with little support to predict changes by one of the sides.

## Medical Work and Agility

In a sense pathways are a step towards the domain of Scientific Management (Taylor, 1911), and the historic approach where every step of a worker has to be measured and has to be in control of management in order to optimize working processes. Knowledge work, however, essentially differs from industrial, manual labor. As opposed to industrial work, knowledge work is valued for the ability to interpret information instead of performing manual labor. Knowledge work can especially be found in domains such as health care, law, education, science or engineering. Information technology increasingly allows physical operations to be performed remotely, thus shifting manual work towards knowledge work. The immateriality of knowledge and its dynamics require new approaches in the way the work is structured and studied.

Medical doctors and nurses need agility. Their tasks include collecting and analyzing patient data in order to formulate and provide a respective treatment, while working under expanded responsibilities and strict time constraints. Lawyers and their effort spent cannot be measured in terms of time, but rather on the insights created working on a particular case. In software engineering iterative processes and modeling languages help to cope with the complexity of software design, because architectural details can eventually only be revealed during development.

Medical teams, were found to successfully incorporate dynamic and self-adapting strategies. Studies have shown that successful resuscitation teams exhibit more leadership behavior and explicit task distribution (Marsch et al., 2005). If resuscitation team leaders administered the team structure directly the teams were found to be less dynamic and performed their tasks less effectively (Cooper and Wakelam, 1999). Self-organizing and dynamic teams are recognized as a premise for innovative projects for many year in industries (Moe et al., 2009; Guzzo and Dickson, 1996; Takeuchi and Nonaka, 1986) and virtual organizations (Volberda, 1999; Mintzberg, 1979)

Pathway development can be easily compared to development of complex systems and waterfall model in software engineering (Royce, 1970) as in such systems the requirements are too complex to predict all possible events within the initial development phase. There the complexity makes more agile and iterative approaches necessary to ensure appropriate outcomes (Dybå and Dingsøy, 2008).

Quick reaction to changing information and smooth self-adaptation is obviously crucial in a life saving environment and should be embodied in system as well as in team processes. To meet clinical effectiveness, auditing variance has to be done smoothly, quickly and without quiescence, and thus needs to be supported by the modeling language to allow ongoing collaboration.

## 2.5 Self-Adaptation of Systems

Dynamic adaptation, consisting of interactive, usually distributed components, heterogeneous and with variable configuration, obviously, adds significant complexity to the overall system. Dynamic adaptive systems (DAS) thus must be safety-critical, no failure is to be accepted, since it could result in loss of life. In literature Adaptation is viewed conceptually as a three-layered architecture (Kramer and Magee, 2007; Garlan and Schmerl, 2002).

As many systems today, medical equipment is affected by dynamic changes in its operational environment. Such systems cannot be simply shutdown to be changed, updated or upgraded and restarted again. This is particularly important for a live saving environment in which adaptation has to be done smoothly, quickly and without quiescence to support ongoing collaboration and meet clinical effectiveness. We argue that clinical pathways as they can be found today do not allow the needed

agility within complex medical interventions supported by ICT, we however believe that they can be used as a process skeleton suited for being enriched with agility.

The coordination modelling language Paradigm (Andova et al., 2010), as a possible approach, addresses coordination of collaborating components in terms of dynamic constraints. Its component McPal (Andova et al., 2009) allows the addition of new behavior, and, subsequently, gradually adapts the system dynamics without quiescence. We would like to model agile patterns observed in medical teamwork by thus enriching the existing process skeleton as provided by organizational pathways.

## 2.6 Contributions

We contribute to the quality of medical teams by flexibly integrating medical support systems into non-invasive intervention activities.

Medical pathways for non-invasive interventions exist today and we extend their organizational skeleton with more detailed, but flexible descriptions, as provided by the Paradigm-McPal approach for self-adaptive coordination. Thereby we follow the iterative set-up of an ethnographic study, to improve our understanding of applying highly agile coordination embedded in clinical pathways. We conduct a detailed study of medical work and use recorded routines to gather data about and acquire insight into structuring medical knowledge work. Our findings will be used to refine the coordination approach towards highly agile medical team work, to be carried out in conformity to relevant clinical pathways and supported by well-integrated ICT systems.

In addition, this is related to coordination of knowledge work in general, so it will lead to new insight into knowledge work. We consider medical workflows and clinical pathways as a good empirical case and starting point to address highly dynamic knowledge work modeling. By establishing a bridge-head for understanding and supporting flexibility within medical team work, we see great opportunities for generalizing such insight towards non-medical fields.

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## 3. Process Data Representation

### 3.1 Introduction

Task 1.2 focuses on the flow-aspects of the diagnosis and intervention procedures. It will model the sequence and conditional aspects of activities and events in a way that we can consider the Clinical Path to be a "secured" workflow. It will define in detail when which data sets should be pushed out to or pulled in from the various devices and tools participating in the process. The Task will deliver the conceptual interface requirements as well as the common reference model. The results will be input for WP4. It will also participate in making the experimental (softwarized) Clinical Pathway system.

### 3.2 Computerized Medical Guidelines

There are computerized medical guidelines that attempt to function like Expert Systems for decision making --- see the reference list hereunder, but they are typically isolated to one subject and miss in fact two relevant Edafmis points:

1. these systems don't manage the protocols as part of a "house of protocols" based on managing the protocol management process, and managing the relations and dependencies between many protocols, and
2. they do not contain instructions that deal with dynamic conditions of a patient in terms of defining the information sources and their contribution to the monitoring of the patient's dynamic condition during diagnosis and more special during treatment.

Actually we did not expect to find protocols that would meet the requirements of the Edafmis system like described in the introduction. An Edafmis protocol is part of a combination of potocols that are needed to support handling of a disease -- for example Clinical protocols have links to Lab protocols and Nursing protocols -- and is in fact the result of a standardized process. Protocols are typically "published" as paper documents, or HTML documents on an Intranet. The computerized medical guidelines we found don't support that. "Computerized" means in fact that today these protocols "are" software programs. In the Edamis project we need both: the "paper" protocols, that are edited, managed and approved following the usual process, as well as the publishing of these protocols in the form of computerized instructions for real time decision support. They have to be exactly consistent and therefore need to be based on the same data. This we could not find.

### 3.3 Software Overview

Below is a list of publicly available software investigated for this Task:

#### EHR Software

- LiU Archetype Editor
- Eiffel64

#### Imaging Software

- Aeskulap DICOM Viewer - <http://aeskulap.nongnu.org/>
- AMIDE (a Medical Image Data Analysis Tool) - <http://amide.sourceforge.net/>

- DVTk - <http://www.dvtk.org/>

Open Source project for testing, validating and diagnosing communication protocols and scenario's in medical environments. It supports DICOM, HL7 and IHE integration profiles.

- Mango - <http://ric.uthscsa.edu/mango/>

A viewer for medical image volumes. It provides tools to analyze images and an interface to navigate the image volume.

- MIPAV - <http://mipav.cit.nih.gov/>

Application which enables quantitative analysis and visualization of medical images of numerous modalities such as PET, MRI, CT, or microscopy.

- openDICOM.NET – <http://opendicom.sourceforge.net/>

Project which implements a new approach towards DICOM (Digital Imaging and Communications in Medicine) libraries.

- Osirix DICOM Viewer - <http://www.osirix-viewer.com/>

- Paraview - <http://www.paraview.org/>

An open-source, multi-platform data analysis and visualization application.

- Philips\_DICOM\_Viewer\_R2.6 - <http://www.healthcare.philips.com/connectivity/>

- Volview - <http://www.kitware.com/products/volview.html>

System for volume visualization that allows researchers to quickly explore and analyze complex 3D medical or scientific data on Windows, Mac and Linux computers.

- xmedcon - <http://xmedcon.sourceforge.net/>

Open Source toolkit for medical image conversion.

### Guideline-Based Decision Support Software

- ASBRU - [http://www.openclinical.org/gmm\\_asbru.html](http://www.openclinical.org/gmm_asbru.html)

Task-specific and intention-based plan representation language to embody clinical guidelines and protocols as time-oriented skeletal plans.

- CAREVIS - <http://ieg.ifs.tuwien.ac.at/projects/carevis/>

Project for the development of interactive visualization methods to support protocol-based care.

- DELT/A ; GMT - <http://ieg.ifs.tuwien.ac.at/projects/delta/>

The further development of the Guideline Markup Tool (GMT). The aim of this project was to develop a tool that supports the transformation process of clinical guidelines from their original textual form (HTML) over an intermediate and a semi-formal representation (XML) to a formal representation that can be further used to verify the semantics of the guideline.

- Many Headed Bridge (MHB) - <http://ieg.ifs.tuwien.ac.at/projects/mhb/>

An intermediate representation called the Many-Headed Bridge between informal representations such as free text and tables and more formal representations such as Asbru, GLIF, or PROforma.

- EGADSS - <http://egadss.sourceforge.net/>

Evidence-Based Guidelines and Decision Support System. System capable of providing patient specific guidelines at the point of care and reminding clinicians, as needed, of various pertinent activities that can improve care.

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## 4. Patient Data Representation

### 4.1 Introduction

New and existing imaging modalities make an increasing amount of potentially important information available for any given patient. Furthermore, systems for image-guided minimal invasive surgery and therapy are increasingly being used in order to safely navigate surgical instruments into the human body for improved patient treatment. Essential questions in multi-modal navigation are: What information is needed for optimal surgical planning and guidance in the operating theatre? How should all this multi-modal information be presented to the surgeon? And how can technology ensure that information displayed in the navigation system represents an accurate picture of the intra-operative anatomy throughout the operation?

T1.3 main objective is to provide the underlying frameworks for WP3/4 and to support the patient treatment process described in figure 2, thus making it possible to provide optimal solutions to the challenges described above. Given a clinical case, this Task should provide the necessary methods / software algorithms to:

- Extract/segment the relevant anatomical/functional structures from the available image data
- Make sure that all the available and relevant images are registered to each other and to the patient throughout the treatment process shown in figure 2
- Be able to create integrated multi-modal 3D scenes using advanced visualization techniques needed for optimal preoperative planning (T2.1) and intra-operative navigation (T2.3).

### 4.2 Electronic Health Records

Most EHR products, or technologies, in both the hospital and ambulatory market are currently deployed through a local client/server paradigm. The client software is installed on users' PCs and the server software, including the data storage, resides on site in the hospital data center or the clinic office (an asynchronous system from the telemedicine end-user point of view).

Vendors provide a total solution instead of an open system or 'building block' that can easily be integrated into existing healthcare applications. The existing closed systems have the following drawbacks:

- A lack of understanding and using (open) standards.
- Poor interoperability the existing applications are 'closed' in that they make use of proprietary protocols instead of standard protocols.
- Poor integration opportunities; it is hard to integrate these telemedicine applications with existing health information systems or telemedicine platforms, because they are closed systems that might result in possible mismatching of protocols and information needs.
- No real-time services; because communications are initiated by the medical device, it is not possible for clinicians to retrieve 'real-time' patient information when it is needed.

However, with Web 2.0 and Cloud Computing upon us, web based EHRs, Practice Management and Billing systems are sprouting all around. What is the key to succes?

When we talk about EHR, the most common type of Cloud is a "Vendor Cloud" - web based EHRs where the vendor manages the Servers in their own data centers, or in rented data centers.

SaaS EHR's:

- Google EHR
- Health Vault (MicroSoft)
- Practice Fusion
- Athenahealth
- Ingenix CareTracker
- Quest360
- eClinicalWorks
- Allscripts MyWay
- Synapse EMR

Most of these SaaS EHR's are (very) closed platforms.

The challenge for Edafmis is creating a fully open platform, able to communicate in different (spoken) languages, to different healthcare providers and their different clients where each person is unique. Even for wellness or for the chronic ill. And, even more important, be able to interpretate the data or present different view on the same data.

For Edafmis we are proposing a system that provides a communication interface, based on state-of-the-art open standards and technologies, to access home care devices. The purpose of the system is to enable the retrieval of patient/usage data from the medical equipment and in the future remote change settings of device parameters.

England is the first European country that broadly adapted the NEN13606. England's NHS has developed the Connecting for Health concept which is fully based on the use of this model. See <http://www.connectingforhealth.nhs.uk/>. The NHS Archetypes are open for re-use.

### **4.3 Two Level Modelling with Archetypes and OpenEHR (NEN13606)**

The key innovation in the openEHR framework is to leave all specification of clinical information out of the information model but, most importantly, to provide a powerful means of expressing what clinicians and patients report that they need to record so that the information can be understood and processed wherever there is a need.[citation needed] Clinical information models are specified in a formal way ensuring the specifications, known as 'archetypes', are computable.

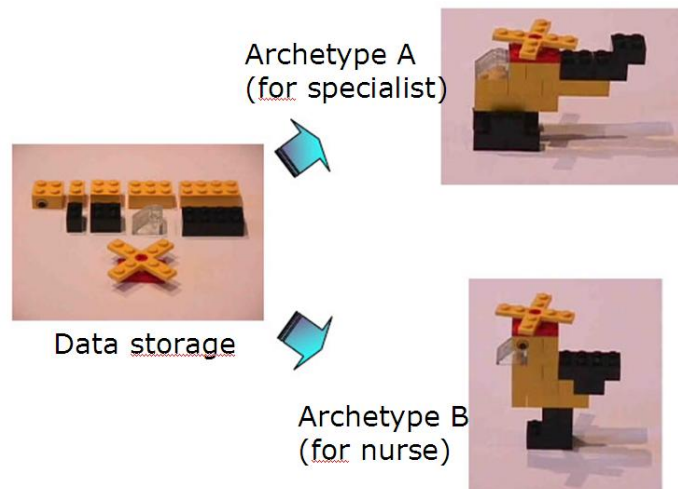
The set of openEHR archetypes need to be quality managed to conform to a number of axioms such as being mutually exclusive. The archetypes can be managed independently from software implementations and infrastructure, in the hands of clinician groups to ensure they meet the real needs on the ground. Archetypes are designed to allow the specification of clinical knowledge to evolve and develop over time. Challenges in implementation of information designs expressed in openEHR centre on the extent to which actual system constraints are in harmony with the information design.

In the field of Electronic health records there are a number of existing information models with overlaps in their scope which are difficult to manage, such as between HL7 V3 and SNOMED CT. The openEHR approach faces harmonization challenges unless used in isolation.

While individual health records may be vastly different in content, the core information in openEHR data instances always complies to archetypes. The way this works is by creating archetypes which express clinical information in a way that is highly reusable, even universal in some cases.

To get to the point where information is suitably presented for clinical care it always involves a number of archetypes. These combinations of archetypes are called 'templates'; aggregations of archetypes which may also be refined for use in a particular situation. Templates may be used to specify forms, documents or even messages.

The openEHR approach uses the CEN- and ISO-standardized "archetype definition language" (expressed in ADL syntax or its XML equivalent) to build archetypes; these are reusable, formal models of domain concepts. Archetypes are used in openEHR to model clinical concepts such as "blood pressure" or "medical prescription".



Archetypes are like the designs for Lego structures, which come printed on paper in a Lego box. Each Lego design expresses a meaningful structure, such as a house, a tractor or a dog. The designs constrain the use of the Lego pieces to a meaningful structure space, which although vast, is not nearly as vast as the total possible structure space, i.e. all possible (but mostly meaningless) combinations of Lego bricks.

In the picture the same data is shown differently to the different professional.

In the data warehouse a lot of data (lego bricks) are stored totally unstructured. The use of Archetypes will make this data semantic interoperable. So the Archetype will add medical data to the image, and will present this data in a different format to each health care professional.

In the same way, EHR Archetypes constrain the use of GOM objects to valid, agreed upon structures, such as for "blood pressure" or "audiology results". And in the same way that Lego bricks were standardized and manufactured prior to the development of many (or any) designs, the GOM can be standardized independently of its archetypes. Conversely, the development of both Lego designs and EHR Archetypes may continue forever, while still using the same basic building blocks. Old blocks can be used for new archetypes; new blocks can be used with old archetypes.

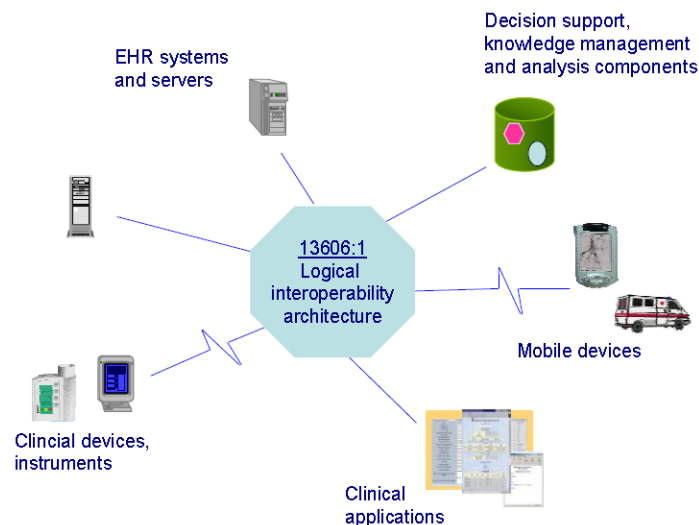
#### 4.4 Virtual Patient Repository (EHR platform)

The CEN/ISO EN13606 is a European norm from the European Committee for Standardization (CEN) also approved as an international ISO standard. It is designed to achieve semantic interoperability in the electronic health record communication. This standard will be the main standard for the platform to use.

The goals of the EN13606 norm are (except from the EN13606 introduction):

*"The overall goal of this standard is to define a rigorous and stable information architecture for communicating part or all of the electronic health record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:*

- *preserving the original clinical meaning intended by the author,*
- *reflecting the confidentiality of that data as intended by the author and patient."*



EN13606, this five part standard (near to final adoption at European and International levels) defines the logical models and interfaces required to support the generic communication of EHR data and archetypes between heterogeneous EHR systems. It adopts many of its constructs in a simplified form that are perhaps better suited to the more simple architectures within most contemporary EHR systems.

The five parts of the standard are summarized below.

##### Part 1: Reference Model

Comprehensive, generic model for communicating part or all of an EHR between heterogeneous systems



## Part 2: Archetype Specification

Constraint-based approach for defining clinical “business objects” that are built from the Reference Model - adopted from openEHR

## Part 3: Reference Archetypes and Term Lists

An initial set of inter-reference model conversion archetypes, mapping to openEHR and to the HL version 3 RIM Act classes. Vocabularies for the Part 1 model

## Part 4: Security

Measures and models to share the access control, consent and auditability of EHR communications

## Part 5: Interface specification

Message and service interfaces to enable EHR and archetype communications.

The table below summarizes the progress towards adoption of each of the five parts in CEN and ISO, as of October 2008.

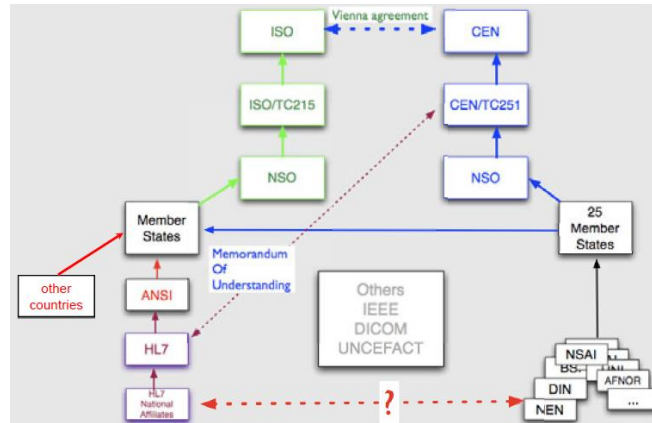
13606 Part Standard	Status in CEN	Status in ISO
1: EHR Reference Model	EN published in February 2007	Published in February 2008
2: Archetype Interchange Specification	EN published in July 2007	Out for FDIS ballot
3: Reference Archetypes and Term Lists	EN published in February 2008	Out for FDIS ballot
4: Security	EN published in March 2007	Passed DTS ballot: comments under review
5: Interface Specification	Passed ENQ/DIS ballot, under Vienna Agreement (CEN lead): comments under review	

The correct definition of demographic archetypes requires taking into account not only the clinical knowledge of the data, but also the legal and privacy constraints in order to have usable archetypes. Several ISO norms have been proposed to represent demographic information for health purposes, like norm ISO/TS 22220 “Identification of subjects of health care” which defines the identification requisites of the subjects of care within and between health care organizations, norm ISO/TR 11487 “Clinical stakeholder participation in the work of ISO TC 215” which defines the identification requisites of the service providers or norm EN 14822 “General Purpose Information Components” (GPIC) which defines the components based on HL7 RIM classes of an information system.

- ISO TC215 has defined the EHR, and also produced a technical specification ISO 18308 describing the requirements for EHR Architectures.

- openEHR - public specifications and implementations for EHR systems and communication, based on a complete separation of software and clinical models.

As can be noticed from the previous sections, there are many similarities and cooperation between the different organizations.



There exist agreements that bind the HL7, CEN and openEHR together:

- Memorandum of Understanding between CEN/TC251 and HL7. This agreement is about the harmonization between the RIM (HL7) and information model (CEN/TC251). All results will be made available to the ISO (harmonization only applies to HL7v3).
- Memorandum of Understanding between CEN/TC251 and openEHR. This agreement has resulted in the convergence of the GEHR/openEHR archetypes into the CEN EN 13606 standard and the development of a common reference model which is based on HL7 version 3 RIM. All results will be made available to the ISO.

#### 4.5 Applicable Standards and Normative References (ICOM)

What are standards for and how do we use them with local legislation:

- European standards and standardization are based on European legislation
- European standards play a special role:
  - Only National standards derived from European standards can be used in legislation
  - National and European standards play a role in procurement

##### ISO Standards

ISO/DTR 20514 – Electronic Health Record Definition, Scope and Context

ISO 18308 - "Requirements for an Electronic Health Record Reference Architecture"

ISO 704:2000, Terminology work — Principles and methods

ISO/IEC 1087-1:2000, Terminology work — Vocabulary — Part 1: Theory and application

ISO/IEC 6523-1:1998, Information technology — Structure for the identification of organisations and organisation parts — Part 1: Identification of organisation identification schemes

ISO 10241:1992, International terminology standards - Preparation and layout

ISO/IEC 15414:2002, Information technology — Open distributed processing — Reference model — Enterprise language

ISO TS 18308:2004, Health informatics — Requirements for an electronic health record architecture

ISO TR 20514:2005, Health informatics — Electronic health record — Definition, scope, and context

### **CEN Standards**

ENV 12265 Electronic Healthcare Record Architecture

ENV 12967 'Standard Architecture for Healthcare Information Systems' (HISA)20

Normative references

EN 12264:2005, Health Informatics — Categorial structures for systems of concepts

EN 12381:2005, Health Informatics — Time standards for health care specific problems

EN 13606-1:2007, Health Informatics — Electronic health record communication Part 1: Reference model

EN 13606-4:2007, Health Informatics — Electronic health record communication Part 4: Security

EN 14822-2:2005, Health Informatics — General purpose information components — Part 2: Non clinical

EN 14822-3:2005, Health Informatics — General purpose information components — Part 3: Clinical

## **4.6 External Communication**

In order to have two different EHR's to communicate there are several standards developed. Notice that these standards has no influence on semantic interoperability and the (re-) use of data, it is purely to transport data from A to B.

- ASTM CCR - Continuity of Care Record - a patient health summary standard based upon XML, the CCR can be created, read and interpreted by various EHR or Electronic Medical Record (EMR) systems, allowing easy interoperability between otherwise disparate entities.
- ANSI X12 (EDI) - Used for transmitting virtually any aspect of patient data. Has become popular in the United States for transmitting billing information.
- HL7 - messages are used for interchange between hospital and physician record systems and between EMR systems and practice management systems; HL7 Clinical Document Architecture (CDA) documents are used to communicate documents such as physician notes and other material.

## **4.7 Security and Data Privacy**

The security requirements of health data are likely to be greater, and more difficult to satisfy than for any other kind of data, including financial. This is partly because of the seeming paradox of conflicting needs of the two primary categories of health data stakeholders:

- clinicians: to do shared care, clinicians need more open EHRs;
- patients: need privacy, and are likely to prefer more closed EHRs.

**Dutch Standards for Data Security in Healthcare**

- EN7510, 7511, 7512
- WGB0; Regulation for Health treatment of patient
- The Wbp (“Wet bescherming persoonsgegevens”) was enacted in september 2001. The law describes what the rights are of those whose personal identifiable information is used by agencies or companies, and the duties of these agencies and companies in the processing and use of these data.

## 5. Dynamic Patient Model

### 5.1 Introduction

When the patient is in the Intervention phase the body will be monitored on a continuous basis from various perspectives, in parallel. The dynamic patient model instructs or suggests the intervention systems what to do and what not to do within certain tolerance margins. The patient model dynamics is represented as a set of probable data combinations (patterns) that might appear and have pre-programmed logical consequences. It also should define how to handle “uncertain” or “unexpected” combinations of monitoring data. These rules need to be expressed in the Clinical Pathway software and executed by the (Decision Support Module) of the Edafmis Intervention System.

### 5.2 State of the Art

A common clinical trend is to replace open surgery procedures with minimal invasive interventions, i.e., performing a procedure with instruments brought up via a minimal incision in the patient. This improves the success of the procedure, it leads to faster recovery and thus improves the well-being of the patient.

In minimal invasive interventions visual inspection of the anatomic structure under investigation is not trivial as was the case in open surgery. The need for visualization of the anatomic structure is shared amongst the large variety of minimal invasive procedures performed all over the world.

An example of such a procedure is treatment of atrial arrhythmias (heart rhythm disorders): Nowadays they are treated with catheter ablation therapy[1, 2]. These treatments can be very complex and use sophisticated equipment, like an X-ray fluoroscopy imaging system and EP recording equipment. Recently, CT, MR and rotational X-ray overlay techniques have emerged which aid the physician to navigate catheters in the left atrium[3-10].

### 5.3 Gap Analysis

#### 1) Data Fusion

The complexity of atrial arrhythmia treatments has increased over the past few years and conventional fluoroscopy does not always provide adequate information about the cardiac anatomy. Rotational X-ray is a technique which is able to provide more insight in the cardiac anatomy compared to conventional fluoroscopy.

Overlay of 3D anatomical data derived from such an intraprocedural rotational X-ray imaging on the live fluoroscopy can be used to add adequate insight of anatomy. Next to rotational X-ray a preprocedural CT or MRI scan may be used to generate the 3D anatomical structure. The 3D anatomical information can help to determine the size of equipment that can be best used during the procedure. Data fusion and 3D volumetric presentation of anatomic structures will be addressed in the Edafmis project in such a way that the representation of the data is optimal such that the doctor can perform the complex procedure with greater ease.

## 2) Decision Support

In the intervention room one finds next to the X-ray imaging system other systems like for supplying anesthetics, recording ECG signals, body temperature, oxygen saturation level etc. Most of these systems are standalone and therefore do not communicate with each other. The current workflow is that the intervention team gathers the scattered information from the various systems and makes decisions based on the information collected by themselves.

The X-ray system is a natural integration point of all the information available in the intervention room and it can also serve as the single user interface to interact with the various medical systems or to provide feedback from those systems.

The aim of the Edafmis project is to introduce a new generation of medical intervention support systems, where Philips can provide the interventional X-ray system with the user interface allowing the medical team to be completely informed at all times during the procedure. By creating a single communication channel information confusion in the intervention room can be reduced drastically and procedures can be performed better and faster.

## 5.4 References

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## 6. Conclusions

The State of the Art study and Gap Analysis have led to the following conclusions.

1. The project could not find an Edafmis like system on the market or in the research arena; there are elements of the architecture but even the elements as such are not mature enough as a building pillar for the Edafmis system. Apart from EHR systems, and subsystems like sensors for temperature or transpiration measurement. These are mature systems but in fact outside the scope of the Edafmis system. They serve as candidate sources of data for the Edafmis decision making.
2. There is no technology for Protocol Management that
  - (a) is usable for defining Clinical Pathways and Decision Support in such a way that doctors can use it in terms of required editing and management;
  - (b) can handle hundreds of diseases in parallel;
  - (c) has direct interfaces to clinical intervention systems.

We can see many historic attempts in the (academic) research arena, but these are typically focused on one disease only, in a kind of laboratory setting. These systems are used by expert users, people who had a special deep training, typically in knowledge engineering and data handling.
3. Multimodal Imaging for real Time Navigation is still in research mode. We could not find a system that already uses embedded decision support that helps the surgeon with alerts to oversee the many sources of information at the point of treatment.
4. General conclusion is that the Edafmis project needs to build:
  - (a) the envisaged protocol management system, in a manner that it can handle multiple clinical pathways, including output of decision support configurations;
  - (b) a Decision Support "hub" that can be configured to deliver real time Decision Support into the Intervention system;
  - (c) an intervention system module that can support the surgeon with real time multimodal visualization and integrated Decision Support at the point of operation;
  - (d) APIs (interfaces) to a series of sources that are relevant to treatment: EHR, various sensors. These can be addressed on the basis of the decision configuration valid for a certain treatment.
  - (e) an API between the Decision Support system and the Intervention system;
  - (f) an API between the Decision Support system and the Protocol Management system.
5. To realize the various APIs we will use standards as identified in the study (ISO, CEN, DICOM).