ABSTRACT

The task of ensuring Patient Safety is, more than ever, central in Healthcare. The report “To Err is Human” [Kohn et al. 2000], was revealing alarming numbers of incidents, injuries and deaths caused by deficiencies in healthcare activities. The book initiated assessment and change of Healthcare methods and procedures. In addition, numerous reports to Swedish HSAN (Medical Responsibility Board) have shown a high rate of information and communication deficiencies in Healthcare has a direct or indirect cause of incidents, injuries and deaths. Despite numerous new sophisticated tools for information management in recent years, e.g., tools such as Electronic Health Records (EHR) and Clinical Decision Support Systems (CDSS), the threats to Patient Safety have not been redeemed. Rather to the contrary. Underlying reasons for this paradox are twofold. Firstly, advancements in diagnosing techniques have given rise to increasing volumes of data at the same time as the number of patients has increased due to demographic changes and advancements in treatments. Secondly, the information processing systems are far from aligned to related workflow processes. In short, we do not at present have interoperability in our Healthcare systems.

In this doctoral dissertation, we present an in-depth analysis of two different “HSAN-typical” cases, where Patient Safety was jeopardized by incomplete information flows and/or information breakdowns. The cases are mirroring the apprehension of Simplicity, that is, Occam’s Razor of Diagnostic Parsimony. A well-known protocol used in Healthcare and implemented in most (knowledge based) CDSS. This rule of thumb is the foundation for the well-known adage: “when you hear hoof beats, think horses, not zebras”. Hickam’s Dictum is one well known objection to the simplifications of Occam’s Razor stating “Patients can have as many diseases as theydamn well please”. Of course, this Dictum is harder to implement effectively!

In the thesis we suggest a visualization tool Visual Incidence Anamneses (VIA) to provide middle out compromise between Ockham and Hickam but providing means to increase Patient Safety.

The findings of our Study for the thesis have resulted in a number of Aspects and Principles as well as Core-principles for future CDSS design. That is, tools and methodologies that will support designing and validating Interoperability of Healthcare systems across patient-centric workflows. The VIA tool should be used as the initiating point in a patient (individual) centered workflow, quickly visualizing vital information such as symptoms, incidents and diagnoses, occurring earlier in the medical history, at different times, to ground further vital decisions on. The visualization will enable analysis of timelines and earlier diagnoses of the patient, using visually salient nodes for visualization of causalities in context. Furthermore, support for customization of the tool to the views of stakeholders, members of healthcare teams and empowerments of the patient, is crucial.
On Decision Support in Participatory Medicine Supporting Health Care Empowerment

Kerstin Ådahl
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Doctoral Dissertation in Applied Health Technology

School of Computing
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On Decision Support in Participatory Medicine
Supporting Health Care Empowerment

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Abstract

The task of ensuring Patient Safety is, more than ever, central in Healthcare. The report “To Err is Human” [Kohn et al. 2000], was revealing alarming numbers of incidents, injuries and deaths caused by deficiencies in healthcare activities. The book initiated assessment and change of Healthcare methods and procedures. In addition, numerous reports to Swedish HSAN (Medical Responsibility Board) have shown a high rate of information and communication deficiencies in Healthcare has a direct or indirect cause of incidents, injuries and deaths. Despite numerous of new sophisticated tools for information management in recent years, e.g., tools such as Electronic Health Records (EHR) and Clinical Decision Support Systems (CDSS), the threats to Patient Safety have not been redeemed. Rather to the contrary. Underlying reasons for this paradox are twofold. Firstly, advancements in diagnosing techniques have given rise to increasing volumes of data at the same time as the number of patients has increased due to demographic changes and advancements in treatments. Secondly, the information processing systems are far from aligned to related workflow processes. In short, we do not at present have interoperability in our Healthcare systems.

In this doctoral dissertation, we present an in-depth analysis of two different “HSAN-typical” cases, where Patient Safety was jeopardized by incomplete information flows and/or information breakdowns. The cases are mirroring the apprehension of Simplicity, that is, Occam’s Razor of Diagnostic Parsimony. A well-known protocol used in Healthcare and implemented in most (knowledge based) CDSS. This rule of thumb is the foundation for the well-known adage: “when you hear hoof beats, think horses, not zebras”. Hickam’s Dictum is one well known objection to the simplifications of Occam’s Razor stating "Patients can have as many diseases as they damn well please". Of course, this Dictum is harder to implement effectively! In the thesis we suggest a visualization tool Visual Incidence Anamneses (VIA) to provide middle out compromise between Ockham and Hickam but providing means to increase Patient Safety.

The findings of our Study for the thesis have resulted in a number of Aspects and Principles as well as Core-principles for future CDSS design. That is, tools and methodologies that will support designing and validating Interoperability of Healthcare systems across patient-centric workflows. The VIA tool should be used as the initiating point in a patient (individual) centered workflow, quickly visualizing vital information such as symptoms, incidents and diagnoses, occurring earlier in the medical history, at different times, to ground further vital decisions on. The visualization will enable analysis of timelines and earlier diagnoses of the patient, using visually salient nodes for visualization of causalities in context. Furthermore, support for customization of the tool to the views of stakeholders, members of healthcare teams and empowerments of the patient, is crucial.
"Att läkekonsten har till fullo dokumenterade sjukdomsförlopp att tacka för sin utveckling är så visst, att tvivel därom icke kan råda."

"Till nytta kan de vara endast när dokumentationen är fullständig; halvdana, ofullständiga och i avsaknad av nödvändiga omständigheter gör beskrivningarna mera skada än nytta."

Nils Rosén von Rosenstein 1730

[Rosén von Rosenstein 1730]
"Without doubt, Medicine owes its development to the existence of thoroughly documented courses of disease. "They are only useful when the documentation is complete; when mediocre, incomplete and lacking essential context they do more harm than good."
"Att anföra dessa kriterier är skälet till denna skrift. Försåvitt en läkare vill nedteckna en i varje avseende fullständig sjukdomshistoria, får han inte utelämna någon omständighet som kan vara av betydelse; alltså må han anteckna."

Nils Rosén von Rosenstein 1730

[Rosén von Rosenstein 1730]
"To state these criteria is the reason for this publication. Provided that a doctor intends to note down a, in every respect, complete medical history (anamnesis), he may not exclude any circumstance that could be of importance; therefore he must note down."
“Computers are incredibly fast, accurate and stupid. Human beings are incredibly slow, inaccurate and brilliant. Together they are powerful beyond imagination.”

Unknown
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Furthermore, I appreciate the creative and innovative environment and the extraordinary inspiring atmosphere I was able to experience at Blekinge Institute of Technology (BTH) in Ronneby, Sweden, during the pioneering years in the 90’ies. In this creative and promising spirit, my insight of the importance and usefulness of this area, presented in this thesis, began to grow. As a result, in the year of 2000, I decided that I would like to enter the current line that I permanently have followed along my PhD studies in computer science; today forming the area Applied Health Technology. Eventually, in 2011, I also decided to change the official designation of my direction in research; from Computer Science to this emerging field.

Finally, it must be concluded that the basic foundation for my years as a Doctoral Student in Computer Science/Applied Health Technology was my four years of university studies in Computer Science and Work Practice (Interaction Design) at the inspiring and creative MDA-program, running in the 90’ies at BTH in Ronneby. The Interdisciplinary approach at the MDA-program made the step towards an Interdisciplinary science, consisting of my two rather different competences (as a registered nurse and as an interaction designer in Computer Science) rather self-evident to take in the year of 2000.
In memory of my mother Lilly, departed from this life in July 2009. Thank you for all your belief in and support of my work, unfortunately not able to take part of the results.
Healthiness is not an invariable condition. That is an inevitable reality that we must face. Consequently, everyone runs the risk of becoming a patient. This is the starting position for this doctoral dissertation.

In the foreword to my former Licentiate thesis [Ådahl 2007], I chose the quote "Life is a Fatal Disease". This is a familiar quotation known to be expressed four hundred years ago by the Native American princess Pocahontas to her English Husband, John Rolfe. The conclusion of this popular contribution is that life always results in death, which makes Life itself a lethal disease. This emphasizes the likewise discouraging conclusion that I chose to initiate the foreword with. We must all learn to handle Life, to stay or become healthy as much as we can and to handle situations of illness. This is necessary, not at least when we are transformed into the state of patients in our contact with Healthcare.

Accordingly, being a patient is not equal to being patient: Traditionally, the activity around a patient is incumbent on the physician and the other personnel. The patient is regarded as a “target for care”. In contrast to the traditional view, I claim that the activity should not be limited to Healthcare personnel and the patient should not be regarded as a passive receiver of care. The patient is important, as an information carrier [Ådahl 2007] and as a co-actor in his/her personal health situation, not at least in a long time perspective. However, to encourage the patient to cooperate (that is to derive important information from the patient and share decisions) is not similar to put more responsibility on the patient in Healthcare. The responsibility for every Healthcare action must still rest on the physician and the personnel. The Patient Empowerment movement, awoken and refueled for the last ten years, encourages the patient to be active, cooperative and learn.
In some respects, the patients’ new role in Healthcare seems to be crucial for the prevention of many issues related to information handling situations. Healthcare is built on information. Therefore, documentation of important information, as well as development of information extraction and information transferring methods, must be considered most important. The importance of carefully documenting the “course of diseases” has been known for centuries [Rosén von Rosenstein 1730], which relates to modern issues of Patient Safety. However, information misses do still occur, despite carefully notes in medical records and advanced ICT systems. Further more surprisingly, not until the last decade, Patient Safety has been explicitly highlighted. This late interest is based on the release of a report that worldwide has attracted much attention “To Err is Human – Building a Safer Health System” [Kohn et al 2000]. This report presents statistics that revealed shockingly high numbers of injuries and deaths in Healthcare caused by Healthcare; many of them related to information handling misses and breakdowns [O’Daniel & Rosenstein 2008; Socialstyrelsen 2008]. As a registered nurse since 1983, working in hospital care for 12 years, and also as a mother to a girl born in 1986, with a severe and complex congenital heart condition (Truncus Arteriosus Communis Type 1), I have experienced a great deal of situations where the patient (or relative) should have been more active in order to achieve accurate care for the actual health status. This is most apparent regarding the risks of information misses and, as a result, the possible outcome of treatment and recovery due to proper versus insufficient information handling routines. In the end, Patient Safety is affected. In my point of view, Patient Safety related to information handling issues depends on both correct methods and tools and adequate treatment and care.

My own interest in Health Technology began a long time ago: Being a nurse since 1983, I entered the area of Computer Science in the early 90ies due to my curious interest awoken by my young sons advanced programming activities at home. This change of direction in my professional career resulted in a master’s degree in Computer Science/Science of Work Practice in 1999. However, the knowledge I gained during my education in addition to some work with Computer Supported Cooperative Learning at Learning Lab (Blekinge Institute of Technology) in 1999-2000, started a process of reflection about my former area of work practice; Healthcare. In 2000, I immediately understood that this area was transforming explosively into a highly topical target for computing. Information Communication Technology (ICT) in Medical and Caring Science was developing really fast, changing Healthcare which seemed to be shaken to its foundations. Today, a decade after my insights, anyone may confirm if I was right.

My original idea in 2000 was that Virtual Communities on the Internet and the, at that time, upcoming concept “Web 2.0” should change the traditional passive role of the patient into the role of an active partner in occurring Healthcare situations [Ádahl 2003]. This was the line I entered when my PhD studies started. In 2003, I was introduced to the ideas of Patient Empowerment during participatory observations in a community for patients with burnout syndrome, guided by a physician in psychiatry and some other healthcare personnel, which strengthened my vision of the patient as
coworker. I immediately presented the Empowerment concept in my research group Societies of Computation (SoC) and further emphasized it in a paper on transparency of important information, presented as a keynote paper at the IRIS29 conference [Ådahl 2006]. The driving force for my licentiate thesis, defended in 2007 [Ådahl 2007], was the insight into how important the patient really is in healthcare. The patient should not be patient, rather impatient in the sense that s/he should be active within critical cooperative situations in the care process. This line has obviously developed through the years. Along with the Internet, the Patient Empowerment has spread worldwide and, as a result, the image of the patient as a passive object for care has started to cease: Participatory Medicine is growing from the Patient Empowerment direction. This is the opposite to the traditional: My own professional experiences since the beginning of the 80ies were that healthcare personnel have indeed been encouraged to set “the patient in the center” but, simultaneously, to regard him/her as a passive object for care and, at worst, as incapacitated. Patients were explicitly told not to read “medical books”, as such readings may confuse them and disturb the relation between physician and patient: the knowledge hierarchy should be protected. However, as mentioned, I had for many years, in my professional practice in healthcare, the opportunity to reflect on the role of the patient and my conclusion as a nurse is that the patient is much more than that. The patient is an important information carrier rather than an object for various Healthcare efforts. Furthermore, this was also one of the most important conclusions revealed in the preparatory study (Chapter 8) performed at Skåne University Hospital, Clinical Department of Paediatric Cardiology in Lund, and The Swedish Heart-Children's Association, for my licentiate thesis [Ådahl 2007].

With reference to the patient as being an important information carrier, my aim has been to find ways to utilize patient cooperation for Patient Empowerment by means of ICT. The reason for using ICT to extend the “health-literate” patients self-imposed use of the Internet for this purpose, was the rather alarming inconsistency I identified in 2006, latent within the Patient Empowerment concept [Ådahl 2006]. Maybe most of us, at least in Sweden, have sometimes heard the proverb “To be ill, one must be healthy”. The proverb points at the difficulty in being active – and proactive – in Healthcare in order to be well cared for, despite any kinds of hindering disabilities or severe illness. This is an unfeasible equation, which will not be solved until seriously disabled patients, in need for great quantities of care, are as active as less disabled patients. This statement could therefore be referred to as “The Patient Empowerment Paradox” [Ådahl 2006, Ådahl 2007]: The Patient Empowerment concept requires patients to be active, not patient and passive, to gain sufficiently efficient care, in cooperation with Healthcare. But to be efficiently active in this matter requires both strength and healthiness! How is that supposed to match? Consequently, grounded in my studies in Computer Science and my knowledge in and experiences of the area of Healthcare, I believe that this equation could be solved by support of ICT: ICT is appropriate for information handling tasks, in this matter between home and Healthcare as well as within Healthcare.

However, my view changed slightly during the “future work” after my Licentiate degree in 2007: I came to understand that Patient Empowerment was not only a matter
of empowering the patient, but also to empower Healthcare. In order to empower Healthcare as a whole, resulting in improved Patient Safety, Professional Empowerment should also be highly topical. In this matter, ICT should support the creation of critical information, i.e. extraction of information that each patient possesses. That is physical data from the patient in addition to the anamneses, containing contextual information that is critical to make the right diagnosis and decide the right treatment for the individual patient. This is data that must be gathered by the physicians and other Healthcare professionals. But the vital point in such data collection is that the patient must provide Healthcare professionals with continuous information about the health status measured over time, and the relevant context of this, as s/he is the most experienced in how to have a disease and how the personal Health Status develops. In the process of differential diagnosing, this kind of patient delivered “story telling” could be crucial.

Accordingly, in my doctoral dissertation I have chosen to focus on the medical history, i.e. the anamnesis, as the central point of view for the development of ICT tools for Decision Support in Healthcare. Basically, cooperation with the patient is necessary and decisive in the creation of the anamnesis and this is the fundamental cooperative task that can be referred to as “participatory medicine”. However, participatory medicine brings another dimension to the task. The anamnesis should not only initiate a period of care, but also clearly support it along the way. In addition, the anamnesis must be informative about the patients’ whole medical history over time. This thesis will bring an alternative view to the traditional; the patient as a resource in Healthcare not only a target for care. In other words, I claim that the patient is an important link in the information handling chain, and with ICT support for the task, able to contribute to Patient Safety. The introductory quotes, some pages before, tell us both. The physician and professor Nils Rosén von Rosenstein concluded 280 years ago that context related information is important for a complete understanding of a disease; missing information could threat Patient Safety! The patient is the key to this information. Furthermore, the unknown author to the last quote (sometimes, mayhap unrealistically, dedicated to Albert Einstein), tells us that we, as humans, in cooperation with computers can perform very much more than humans and computers separately. The apparent challenge of this, not available in Electronic Health Record-systems today, is to make the medical history more visible for the physician and the patient.

This thesis proposes a solution, a visualized representation of the anamnesis calling attention to important courses of events. My basic future aims are to provide ICT tools to increase Patient Safety but also to decrease average length of stay (ALOS). Efficient information handling protocols render more efficient treatment periods when the workflow is unbroken and the patients’ health status is optimally cared for. Information breakdowns are dangerous as they might hinder adequate treatment, treatment in time or result in false course of directions (misdiagnoses etc.) and must be avoided. To ground this reasoning, I present in Chapter 9 two different authentic cases regarding dangerous or lethal information misses. The cases are in-depth studies and could generally be compared with similar cases usually reported to HSAN. The basic difference between a study of such reports and this case study is the methodology.
Using a specialized ethnomethodological approach for this matter provides extended knowledge about a hidden context, otherwise not clearly visible or known, which is carefully studied and, consequently, deeply understood. Knowledge about such contexts is necessary to gain in order to identify critical information processes otherwise hard to narrow down in more commonly performed scientific studies of HSAN reports. The result is meant to form a basis for understanding of why and how the design of information management protocols in Healthcare might be decisive for increased levels of Patient Safety. Moreover, this is necessary in order to create requirements specifications, for the development of useful Clinical Decision Support Systems, or additional tools for such, supporting workflow in Healthcare.
Chapter 1 – Background

In this chapter, we present the background to the work of this thesis. We introduce the reader to the Interoperability concept and review Medicine in retrospect in order to turn the focus onto the Anamnesis as central to the further reasoning on Information. We elaborate on the important role of the patient as collaborator towards increased Patient Safety.

1. Introduction

Information management is the basic foundation for Healthcare management. Decisions should thus be fuel for activity. Without information, no decisions can be made as every decision must comprise the use of information. Accordingly, without decisions, no Healthcare interventions\(^1\) such as diagnosing and treatment would exist. Today, in Healthcare system analysis, the concept of Information is in focus. National strategies for information handling and issues related to the increasing use of Information Communication Technology (ICT) are discussed. ICT in Healthcare is a central theme varying conferences, fairs, Work Shops and exhibitions. For example, the annual Vitalis-conference\(^2\) in Gothenburg, Sweden, gathers stakeholders and authorities from both Healthcare and the area of ICT. Politicians, researchers and practitioners are gathering for discussions and information exchange about this area of rapid growth.

Healthcare systems are expected to operate in a reliable manner with a high level of service for all stakeholders involved. Reliability in healthcare systems is maintained and enhanced when the system is composed of personnel, components and procedures that are interconnected dependable and operating in an interoperable way. This entails with substitutable, and easily replaceable if they fail. Also, the system’s performance needs to be flexible and predictable and information about system conditions should flow smoothly and accurately to all who need it. Moreover, interoperability entails that much, or all, of that system can withstand or survive natural or malicious attack without extensive damage or abrupt failure and recover from such damage relatively quickly.


\(^1\) In this field of application, the word Intervention implies activities, i.e. interferences, to change the situation for a certain patient. For example, to diagnose and choose treatment.

\(^2\) Vitalis Conference and Fair (Retrieved 2011-05-04 at http://www.vitalis.nu/)
Interoperable eHealth is Worth it – Securing benefits from Electronic Health Records and ePrescribing³ [Dobrev et al. 2010].

Interoperability is the ability of systems and devices to work together easily and effectively by design. Interoperability is a necessary foundation for development of reliable healthcare systems. Interoperability has many dimensions, including physical and communication to informational interoperability (content, semantics, meaning, and format) and organizational interoperability (covering matters such as transaction structures, contracts, regulation, and policy). Interoperability is often achieved and institutionalized with support from formal technical standards and implementation testing.

Addressing and assuring Interoperability of healthcare systems is an important R&D (Research & Development) area addressed internationally and nationally. Examples include the efforts by EU ⁴. In the UK efforts are made by National Health Service (NHS)⁵. In the US, corresponding efforts are supported by National Institute of Health (NIH)⁶.

The following working definition of Interoperability is given by the US organization NIST – National Institute of Standards and Technology⁷:

"The capability of two or more networks, systems, devices, applications or components to exchange and readily use information, securely, effectively and with little or no inconvenience to the user. The system will share a common meaning of the exchanged information and this information will elicit agreed-upon types of response." [NIST]

At the core of Healthcare systems is Information processing system (i.e. Information Communication Technology, ICT). The purpose of such systems is to provide support to relevant workflows in an interoperable way. The Workflow Management Coalition (WfMC⁸) [in Allen 2000], define workflow as:

"The automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules."

Failures of present day Healthcare support systems can often be attributed to interoperability failures of relevant workflows. Typically those failures are due to information breakdowns; lost information or misinterpreted information.

⁸ http://www.wfmc.org/
The purpose of this thesis is to identify crucial such failures related to Patient Safety and to suggest interoperable Decision Support in Participatory Medicine Supporting Health Care Empowerment. Our suggestions are based on case studies related to present Healthcare systems and practises, Chapter 9. Interoperability failures of workflows from our case studies are illustrated in Figure 31 and Figure 32 (Chapter 9). Our suggested solution Visual Incidence Anamneses (VIA) is discussed in Chapter 10.

The identified Research Questions related to our investigation are given in Chapter 3:

1. What aspects of information misses and breakdowns in Healthcare systems have to be properly addressed to ensure interoperability?

2. Which principles are crucial to ensure interoperable support and empowerment of patients?

3. Which principles of healthcare systems are crucial to ensure Patient Safety and healthcare empowerment?

The following three shortcomings and barriers of interoperability of present day healthcare systems have been identified:

- The dominant stove-pipe architecture
- Inadequate decision support tools
- Inadequate alignment of patient related information into workflows

According to the definition provided by Reference.com, Stove-pipe architectures are characterized by a “legacy system that is an assemblage of inter-related elements that are so tightly bound together that the individual elements cannot be differentiated, upgraded or re-factored. The stovepipe system must be maintained until it can be entirely replaced by a new system”. Furthermore, a stove-pipe system is an example of “anti-pattern” with reference both to the area of software engineering and aspects of socio-technical systems. To overcome those limitations the concept of Service Oriented Architectures (SOA) has been introduced. In a SOA environment applications are configured from components (services). A SOA is a necessary, but not sufficient, condition towards interoperability.

A Framework for Interoperability has been proposed by GridWise Architecture Council (GWAC). The Framework is intended for future SmartGrids in the energy sector that has many common challenges with future Healthcare systems. Figure 1 visualizes the Interoperability Context setting Framework proposed by GWAC as a graphic representation. Accordingly, from Figure 1 follows that the Framework is

\[ \text{http://www.reference.com/browse/stovepipe_system} \]

\[ \text{http://www.reference.com/browse/wiki/Anti-pattern} \]

\[ \text{http://www.gridwiseac.org/} \]

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layered into *eight Interoperability Categories* belonging under *three main areas* (Technical, Informational and Organizational), and *ten Cross-cutting* (non-functional) issues are put across those categories:

**Interoperability Categories**

- 8: Economic/Regulatory Policy
- 7: Business Objectives
- 6: Business Procedures
- 5: Business Context
- 4: Semantic Understanding
- 3: Syntactic Interoperability
- 2: Network Interoperability
- 1: Basic Connectivity

**Cross-cutting issues**

- Shared Meaning of Content
- Resource Identification
- Time-Synchronization
- Security & Privacy
- Logging & Auditing
- Transaction & State Management
- System Preservation
- Quality of Service
- Discovery & Configuration
- System Evolution & Scalability

**Figure 1 - Interoperability Context setting Framework proposed by GWAC**

In this thesis we focus on the Organizational and Informational categories and selected cross-cutting Issues related to Patient Safety. Although, the GWAC Framework is specifically tailored for future energy systems it neatly supplements current models in Healthcare [Benson 2010]. From the latter reference it follows that current interoperability models in Healthcare, focus on the lower three Syntactical categories of the Framework. Issues related to understanding and sharing information in healthcare teams have, however, to also include contextual views based on higher levels of interoperability (Pragmatics and Semantics). Our VIA tool is based on that assumption (Chapter 10).

With a special focus on Interoperability Category 4, *Semantic Understanding*, with a pointer to the cross-cutting issue of *Shared Meaning of Content*, we lay stress on the importance of a mutual understanding in situations of communication. The outcome of such situations is utterly decisive as misunderstandings obviously occur, affecting Patient Safety negatively. Such communication might be oral but also written or transferred digitally. In Chapter 1.2, we will elaborate this further, referring to Situation Theory and “InfoSense” presented by Keith Devlin [2001]. Furthermore, in Chapter 7, we put emphasis on Interoperability with reference to Collaborative Patient-Centric Practice (Chapter 7.2). However, in the following, we will continue with a review in retrospect, a backward glance at Interoperability and communication in Healthcare almost 300 years ago, emphasizing the importance of collecting and understanding information carried and provided by the patient. We compare current Patient Safety
issues with recommendations for physicians of that time and relate it to the direction of this thesis according to information management and Patient Safety.

**A Historical Retrospect**

The significance of Information Management in Healthcare was acknowledged already in ancient history. Information, or actually *information representations* (i.e. *supporting interpretation of data*) [Devlin 2001], has been described in different shapes and forms throughout the years with an increased variation in the last decades. Furthermore, *information handling strategies* has varied due to the absence or development of technologies in society; early information transfer solutions viva voce turned into written patient data, and recent digital transmission, in modern history. Interestingly, the first medical records were originated in the 18th century [Nilsson & Nilsson 2003; Kuuse & Dahlin 2008] and on account of that, Nils Rosén von Rosenstein, a physician and professor in Uppsala, Sweden, 1740-1757, focuses on medical records, with the emphasis on the *anamnesis*[^12^], in his Doctoral thesis *Anno Domini 1730; “De historiis morborum rite consignandis.”* [Lindfors 1906; Nilsson & Nilsson 2003; Kuuse & Dahlin 2008]. He was surprisingly early to bring the importance of information and context for Patient Safety to light. He claimed that

> “Medicine without doubt owes its development to the existence of thoroughly documented courses of disease.” [Rosén von Rosenstein 1730]

but simultaneously with this reservation:

> “They are only useful when the documentation is complete; when mediocre, incomplete and lacking essential context they do more harm than good.”

[Rosén von Rosenstein 1730]

This is momentous, as lack of critical information could jeopardize Patient Safety. Surprisingly, this becomes evident today, as it is concluded that many of the HSAN[^13^]-cases reported every year [Socialstyrelsen 2008] are due to incomplete information and communication. Accordingly, due to its obvious importance, Rosén von Rosenstein’s doctoral thesis was noticed, and by promotion of a physician Abraham Bäck in 1746, it was basically the ignition key to the first hospital to embrace the use of medical records in Sweden, *Serafimerlasarettet* in Stockholm, launched in 1752 [Nilsson & Nilsson 2003]. Conclusively, after this launch, the medical records in focus for Rosén von Rosenstein have generally been in use over the past centuries and decades, recently radically transforming into something he would not easily recognize: today, advanced electronic medical records, with dynamical functionality and medical imaging, are put in practice (Chapter 6.7).

However, what seem to be less developed are the medical histories, i.e. *anamneses* [Van Tellingen 2007], which Rosén von Rosenstein attached especially importance to. Due to modern sophisticated (technology-driven) recourses for diagnosing activities, in

[^12^]: Anamnesis = “A preliminary case history of a medical or psychiatric patient.” [Merriam-Webster Dictionary]

[^13^]: HSAN = Hälso- och Sjukvårdens Ansvarsnämnd. (Medical Responsibility Board)
addition to the IT-revolution, the anamnesis has lost in importance [Ibid]. In respect to this, the value of *complete documentation* expressed in his almost 300 years old thesis, seems to be overridden despite any further attempt to enhance the modern Medical Record. Information handling methods reaches beyond documentation of what in common is denoted as “medical information”. Documentation is a critical point in any single information handling activity. But protocols and methods to share the information between different parts of the healthcare chain should be regarded as hazardous. This is grounded in the conclusion that Patient Safety (Chapter 1.4), in recent years along with the Patient Empowerment movement (Chapter 1.3, 7.1), has become highly topical. This awareness was initiated in 1999 when worldwide attention was attracted to the American report “*To Err is Human – Building a Safer Health System*” [Kohn et al 2000], revealing high numbers of injuries and deaths in Healthcare, caused by deficiencies in Healthcare. Further studies for example in Sweden, have similar results which concluded this to be evident also in other countries. Astoundingly many of the HSAN-cases reported to the National Swedish Board of Health and Welfare, concerning incidents and accidents in healthcare resulting in injuries and deaths, are results of information misses and breakdowns, that is deficiencies in communication and other information handling activities [O’Daniel & Rosenstein 2008; Socialstyrelsen 2008] (Chapter 1.4). Accordingly, there are reasons to believe that many of these injuries and deaths could have been prevented by different protocols and methods for information flow and communication, in turn supported by ICT based in deepened knowledge of work flow and cooperation between different parts in Healthcare (Chapter 10, 11). Furthermore, to identify which parts in Healthcare that should be involved in such activities seems to be momentous. In this view, the importance of *a coherent and progressive, longitudinal, anamnesis* becomes evident (Chapter 10). The *communicative role* of the anamnesis must be reappraised [Van Tellingen 2007]; supported, not depressed, by ICT. To achieve this, the patient must be involved.

Consequently, in the last decades and along with the influence of the developing Internet, Healthcare has changed from a rigidly hierarchic organization towards a more plain. By this approach, the role of the patient has changed. The patient is more often rather enlightened, knowledgeable in his/her own situation. The Patient Empowerment movement has led to the recent development of *Participatory Medicine*, embracing the patient as cooperator rather than passive receiver of care. Again, reviewing in retrospect Rosén von Rosenstein statement 280 years ago

> “Provided that a doctor intends to note down a, in every respect, complete medical history (anamnesis), he may not exclude any circumstance that could be of importance; therefore he must note down.” [Rosén von Rosenstein 1730]

It appears that he found a complete anamnesis, in relation to context, momentous for successful medical care. To understand medical information, an awareness of how important context is should be evident. To embrace “every circumstance of importance”, the patient must act to deliver information of importance, as s/he evidently in some sense is most appropriate for the task. The patient provides the physician with body data, but also with the history of the disease: s/he has the
knowledge of what has previously occurred and the experience in how the illness appears, not only for recognition of visible (or measurable) symptoms, but also for subjective, invisible such. The physician must collect patient related data (in modern time equivalent to, of that time, the meaning of “note down”) but will not be able to if s/he is not also informed about everything of potential importance. Furthermore, in contrast to the situation back in 1730, the patient of today often possesses medical knowledge to varying degrees and depths (levels of Health Literacy, Chapter 1.3), sometimes, in cases of more rare diseases, even more extended than the physician depending on which (type of) physician consulted and the cognitive ability of the patient. For example, this phenomenon is evidently occurring for such diseases as Mb Osler or rarer Congenital Heart Conditions. The new role of the patient has developed rapidly along with the growth of the Internet. The development of possibilities for extended information exchange and access to varying sources for (medical) enlightenment has given rise to (Health) Literacy among the public (Chapter 1.3), affecting the way people act in situations where they encounter health problems, i.e. when they are becoming “patients”. This is a key aspect, to be further considered as it comes to issues of information handling strategies in Healthcare. Considering information flow to be complete and unbroken, Healthcare personnel must collaborate with patients in a new way, accepting and utilizing this new role in order to collect a “complete medical history” of a patient. However, the cognitive variation among the population, as well as illness itself affecting cognitive or physical strength, must be taken into consideration. In this thesis the Anamnesis is in the forefront with focus on decision support by Innovative Healthcare Channels using ICT. Accordingly, we propose an additional tool to CDSS, supporting collection and input of Patient Specific data; the Visual Incidence Anamnesis (Chapter 10) [Ädahl & Gustavsson 2011].

The reminder of Chapter 1 is as follows: Section 1.1 – About the Thesis, Section 1.2 – Information – Foundation of Healthcare, Section 1.3 – The Changed Role of the Patient, and Section 1.4 – Patient Safety.

1.1 About the Thesis

The area of research
Addressing Interoperability in Healthcare systems, we benefit from selecting and addressing views of the GWAC framework Figure 1, specifically related to the categories Organization (work flows) and Information (semantics and shared understanding). The choice of cross-cutting issues related to Patient Safety involves models and methods assuring common situation sharing and security.

Initially, methods and tools from the area of Computer Science must be assessed and elaborated. Computer Science is a complex scientific and engineering subject. It is sometimes even questioned as being a science. In the 1940’ies, computers were merely regarded as tools in science. Not until the 1980’ies, the general view changed to regard computation as a method of science. In the 2000’ies, Peter J. Denning brought the intriguing idea of Computation as a process of nature [Denning 2007a, Denning 2007b]. This was rather revolutionary, as Computing, accordingly, could be regarded as
a Natural Science, one of the three branches of science (Natural, Social and Formal sciences). Information processes occur in many fields, evidently also in the field of computing. Denning describes Computing as

“... the study of natural and artificial information processes.” [Denning 2007a, Denning 2007b].

The concept “Computing” covers both the Computing Profession and the Computing Science, i.e. Computer Science. Denning claims that

“the discipline of Computer Science is the body of knowledge and practices used by computing professionals in their work.” [Denning 1999].

Denning’s definition of Computing and Computer Science [Denning 2007a, Denning 2007b], addressing his Great Principles of Computing GPC [Denning 2003], establishes both the eligibility for the area of Computing to be regarded as (Natural) Science and pinpoints the role in Computer Science for this thesis. In his view, the field of Computing covers varying aspects, further above Computation itself. In order to create an understanding of the complexity behind Computing (“GPC ...reduces apparent complexity of field (7 top level distinctions instead of 30+)...” [Denning 2004]), Denning presents five “Windows of Computing Mechanics” where Computing Mechanics are basically dealing with the structure and operation of Computation as such. The five windows are in fact five perspectives on each existing core technology (such as DSS, AI, HCI, Data Security etc.). These are Computation, Communication, Coordination, Automation and Recollection [Denning 2003]. On a higher level of abstraction, Denning describes seven windows of Computing: above the Mechanics, the perspectives of Design and Evaluation are also present. The Design perspective of Computing embraces aspects such as “how to design software and computing systems that are Dependable, Reliable, Usable, Safe, and Secure (DRUSS)” [Denning & Martell 2007]. To be able to communicate computing to other fields, or adopt interdisciplinary directions comprising this field, it is crucial to have a clear understanding of what computing is. Denning asks for a principle driven approach for IT professionals, to understand and explain the field. A structure is needed to handle the complexity, as well as adopting a language to communicate computing with other fields of science. Considered Dennings opinion, GPC is the answer to these issues.

Denning claims that Computer Science is a Natural Science, referring to information processes. On the other hand, Michael Buckley suggests that Computer Science could be regarded as Social Science [Buckley 2008], referring to the area of SRC14 (Socially Relevant Computing) [Buckley et al. 2008]. For example, computing is commonly used to solve real world problems in Healthcare as well as in other social settings. SRC is basically an approach to interest students in computing, as Buckley found that fewer students are choosing careers within this area [Buckley 2008]. This method involves the

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14 SRC is a unique paradigm in Computing. It focuses on the use of computation to solve problems that students are most passionate about. It presents computer science as a cutting-edge technological discipline that empowers them to solve problems of personal interest (socially relevant with a “little s”), as well as problems that are important to society at large (socially relevant with a “capital s”)” [Citation retrieved 2011-11-08 at http://src.cse.buffalo.edu/]
purpose of computing activities to be highlighted. The purpose might be to fit a computer system into a social system, to enhance the functionality of the social system.

Both views are interesting as they in different ways relate to context: Information Systems appear in social contexts, an insight that should be central for both the profession of computing as well as the science. Denning brings the social role of software to the “Design-window” to computing, DRUSS, by the worried notion of software as “being autistic”, i.e. is lacking context awareness [Denning & Hiles 2005]. Poor fitness is the result of a lack of tools and methods for design and evaluation of software in the social dimension [Ibid]. Moreover, insufficient correctness of software, evaluated along the engineering dimension, might be the result from varying attempts to design complex systems [Ibid]. In Healthcare, this is apparent. In Sweden, there are a considerable amount of complaints on varying types of information systems, mostly Electronic Health Record systems (EHR), jeopardizing the activity by unexpected system behaviour and a lack of fitness. One earlier example of problematic implementation related to design aspects was Cambio Cosmic, as the implementation has brought about considerable problems for the activity as well as for the users and the patients [UsersAward 2006]. However, an alternative implementation strategy was partially improving the functionality in context [Dagens Medicin 2007]. In the county council of Jönköping in Sweden, a recent evaluation\(^\text{15}\) points at remaining issues to solve.

Consequently, in this thesis, the perspective of design and development of Socio-Technical Systems (STS) provides a basis for research. STS is an approach to the area of (complex) work design and involves two different perspectives. On the one hand, technical (technological) factors are considered and, on the other, also human and social (in organizations). Originally, STS was an attempt to explain the complex relationship between people and technology in work places, with emphasis on the interaction in-between. In the 1960’s, Eric Trist and Fred Emery coined the term STS [Emery & Trist 1960], grounded in studies of British coe mines, performed by Eric Trist and the Tavistock Institute of Human Relations in the early 1950’s. They tried to explain why efficiency of the workers decreased despite heavy efforts to increase it by the use of new technology. A basic assumption in the STS approach is that

\[
\text{“organizations consist of the relation between a nonhuman system and a human system”} \\
\text{[Trist 1981]}
\]

Accordingly, to optimize an organization, the both systems must function jointly. Implementation and management of new technology (nonhuman system) in organizations entails the use of technology (involving the human system) which affects the functionality of those organizations depending on how technology is apprehended and used. New technology not only supports workflow, it also changes it or even restrains it. Therefore, the design of new technology should be grounded in work design

(or organizational design), considering the interaction between people and technology. STS theory refers to joint optimization, not to optimizing the human system or the nonhuman separately that seems to increase the injurious factors that decrease efficiency. Furthermore, the focus of STS design research is evolving towards attention to Socio-Technical Interaction Networks (STINs) of people, resources, organizational policies, and institutional rules that embed and surround an information system [Walker et al. 2007, Walker & Creanor 2009]. STINs could be defined as conceptual outgrowths of STS [Emery & Trist 1960], which are informed by Actor Network Theory (ANT) [Scacchi 2005].

The primary reason to use the STS approach in this thesis is that context of Healthcare is complex, representing a variety of pieces forming a functional whole for the basic activities of diagnosing, treatment and care. This context can be viewed as systems, including ICT (nonhuman systems) as well as human agents (human systems) using it. In such a context, the complexity entails a vulnerability that could be lethal if efficiency of the organization is affected in the wrong direction, jeopardizing Patient Safety, by the implementation of new technology. Consequently, in the Healthcare context, both social systems and technical systems must fit, not to cause breakdowns in existing information- and workflow structures or create breakdowns in new constellations developed by the appearances of new technologies. An STS approach in system development embraces ethnomethodologically informed ethnography, with emphasis on linking ethnography to Participatory Design [Crabtree 1998], understand and join both human and non-human systems aiming at Interoperability. Therefore, also the aim to empower Healthcare should be supported by a STS view.

To further understand context and describe the interrelationships between human, as well as organizational, factors and the technology to be used, Activity Theory16 (AT) [Ádahl 2007] is basically adopted in this thesis. AT is used for STS development, also in Healthcare, as it provides a basis for models aimed at narrowing the gap between development of work and the IS development in focus. For example, in the Finnish ZipIT project17, AT was the theoretical foundation for The Activity-Driven Information System Development (ISD) Model; made in the project, for Healthcare Organizations to be able to specify needs and requirements for IS [Mursu et al. 2007]. Another interesting STS informed view, embracing context in the implementation of information systems in social settings, is provided by Bonnie Nardi. According to this view, Nardi describes Healthcare settings, such as hospitals, as Information Ecologies [Nardi & O’Day 1999]. Furthermore, Nardi also addresses the possible application of AT in HCI [Nardi 1995], as AT provides an approach for handling complex phenomena such as human activity mediated by artifacts. In addition, in the late 1990’ies, Victor Kaptelinin, with Nardi and Macaulay, presented the Activity Checklist [Kaptelinin et

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16 Activity Theory (AT) is a psychological meta-theory, sometimes used to describe activity in socio-technical systems. AT is rooted in the Cultural-Historical psychology, founded by Lev Vygotsky.

17 The ZipIT project is “a collaborative project by four research teams from the University of Kuopio and Savonia University of Applied Sciences. The project is funded by the Finnish National Technology Agency …, the Finnish Work Environment Fund …, and a group of health care organisations and software companies.” (Retrieved 2011-06-11 at http://www.uku.fi/zipit/english/)
al. 1999], aimed for the understanding of the context in which computer supported activities will be developed and implemented. The checklist was intended to be used early in the development process. It is designed for support in the Design and Evaluation categories of Computing, referring to the earlier discussion about Peter Dennings GPC [Denning 2003] and issues about how to design DRUSS [Denning & Martell 2007]. Accordingly, this tool should be an answer to the worries about a lack of context awareness for software [Denning & Hiles 2005]. However, Activity Checklist was not intended to replace other tools. Instead, it was meant to be a complement. Kaptelinin, Nardi & Macaulay [1999] emphasized this as follows:

“...the Activity Checklist is not the only attempt to deal with context in the field of HCI, and it is not intended as a substitute for other approaches. From our point of view, the Checklist can be most successfully used together with other tools and techniques to efficiently address issues of context.” [Kaptelinin et al. 1999]

A scientific approach for development of Socio-Technical Systems is Computer-Supported Cooperative Work (CSCW). Therefore, we stress that the area of research of this thesis should be regarded as belonging to the CSCW community. Accordingly, the major part of the research methodology is informed by qualitative methods as context is central in such an approach: a phenomenon or activity is understood in the natural setting in which it exists or occurs. A qualitative, inductive, research approach, rather than a deductive, hypothesis-testing, was chosen, to be open to findings beneficial for ideas of design as a result of research, and in consideration of the importance of context. However, despite the perceptible aim of bringing about design ideas to bridge over information gaps in Healthcare settings, the thesis should not be regarded as an attempt to design but, instead, to discover and articulate design-related aspects and principles (Chapter 10, 11). In the following, previous related work by the author of this thesis is presented, to form a basic understanding for the direction of the current thesis.

Previous work
“Transparency of Critical Information for Patient Empowerment in eHealth” is the title of the Licentiate Thesis presented in 2007 [Ådahl 2007], pointing at Transparency as a key concept for the implementation of Patient Empowerment in eHealth [Ådahl 2007 p. 143]. Transparency is a term with multiple meanings and must not be mistaken for the denotation adopted in Computer Science. Instead, the interpretation used within the area of Humanities is addressed. Accordingly, “Transparency” describes information processes that, through design, are made explicit to the user of a system [Ådahl 2007 p. 66]. Consequently, to avoid a disrupted flow of information in Healthcare, the user should perceive actionable information by an “Empowerment System”, resulting in some kind of action of the user (Figure n).
Conclusion of the thesis was that the KIViC-model, presented and evaluated in the main study, embraced three different angles (design bases): Interactivity, Visualization and Coordination of Information, all invoking Transparency. For the development of Empowerment Systems, two aspects proved to be outstandingly important in the study. Firstly, Patients are extremely important as Information Carriers, appreciated by physicians, despite any information system. Secondly, the task as an Information
Carrier is generally very difficult to execute for Patients [Ådahl 2007 p. 145]. Figure 2 and figure 3 show the patient as an actor in Healthcare, potentially active or active depending on the level of transparency to critical information. (This can be referred to as an aspect of Interoperability.) To be knowledgeable and empowered (i.e. Health Literate and cooperative) requires support of Empowering Systems. Figure n describes a high level design context of such a system:

**Figure 4** - Design context for Empowerment Systems. (Presented at the defense of the Licentiate Thesis 2007)

The design context for an Empowerment System (Figure 4) was a description of important contextual aspects concerning design of a patient empowerment focused Healthcare Information System. For this aim, a number of different theories and methodologies were addressed. These were divided in groups, dependent on purpose. In the diagram (figure 4), they provide Function in Context and Meaning of transferred information. The foundation for the entire system is the KIViC-model of bilateral cooperation between diverse groups of knowledgeable human agents regarded as entities in virtual communities, however also entities in the Empowerment system. The Empowerment System is viewed as a Multi Agent System, with the emphasis on Human agents using Software agents for the achievements of their goals. The context of the system was analyzed by means of Activity Theory, which is highly important for the functionality of the system (context dependent) in which the tool for the activity was the system itself, viewed as a tertiary artifact [Ådahl 2007]. The foundation for this artifact was the KIViC-model, providing diverse perspectives on a shared goal for the activity (the intersection) and learning on the basis of theories of cooperative activities, related to theories of knowledge development (such as Legitimate Peripheral Participation, Zone of Proximal Development, the Concept of BA etc.). In one sense, in this view, Visualization of critical information for action was to provide meaning to information flows, in addition to functionality of the system, where situation dependent
information critical for action should be visualized. Visualization of information was one of three main aspects on design for Empowerment purposes, derived from the “Main Study” (in this thesis, presented as the Preparatory Study). The other two were Interactivity and Coordination. The revised CommonKADS model was proposed as a tool for design of the system, possible to couple to UML-diagrams for modeling the system. In this approach, Situation Awareness, i.e. the aim of highlighting context, was highly emphasized. By means of Situation Theory (Chapter 1.2) this could be achieved: By formalizing information in a situation dependent way, agents could be used for visualization of actionable information. Anyhow, to capture important aspects of situations (context) the basic tool in requirements engineering phases of the development ofEmpowerment Systems should be ethnomethodologically informed ethnography.

In this thesis, the line of the previous work is basically followed. An occurring indication in the former work was that Patient Safety was affected by insufficient structures for information flows. Today, this is evident in many cases reported to HSAN [Socialstyrelsen 2008]. Patient Safety aspects are highly topical for Healthcare, highlighting a need for new communication and information handling strategies. This raises a potential need for varying tools for Decision Support in Healthcare. The current thesis has, not only a focus on Patient Empowerment but also on Professional Empowerment that extends the perspective to embrace Healthcare Empowerment. The Patient Empowerment concept cannot stand alone in Healthcare; instead it has to be met in order to obtain empowerment for Healthcare as a whole. This also supports Patient Safety. It is to be noted that correct decisions are fundamental for this perspective. Consequently, focus and the title of this thesis is “On Decision Support in Participatory Medicine supporting Health Care Empowerment”, where Participatory Medicine basically refers to a recent development of the Patient Empowerment movement; the active and cooperative, not patient, patient. Accordingly, the current aim is to further focus on the patient as information carrier, with the perspective of involving the patient as a coworker in her/his Healthcare situation. We propose the use of “Empowering Systems” in the shape of a “visualized anamnesis” as a tool for cooperative information elicitation of patient specific information, supporting more correct Healthcare decisions (Chapter 10).

Organization of the Thesis
This thesis is organized as follows: In Chapter 1 (Background), we introduce the reader to the aim of the thesis by describing the area of research and the background to the chosen focus. Chapter 2 (Methodology) is an overview of methodologies used in the thesis. In Chapter 3 (Problem definition) some barriers to successful diagnosis and treatment of patients are identified. Furthermore, workflows and the three Research Questions (RQs) addressed in the thesis are identified and presented. In Chapter 4 (Models of improving Patient Safety. A Change of Focus.), Patient Safety is further elaborated, as in Chapter 1. Furthermore, a change of focus in diagnosis methods and tools is proposed. Principles of Decision making are assessed and discussed in Chapter 5. Corresponding tools are assessed in Chapter 6. The following Chapter 7 introduces and proposes Patient Empowerment (PE), Patient Centered Medicine (PCM) and
Quality Assurance (QA) of Data and Reasoning as tools supporting increasing of Patient Safety. Chapter 8 presents a, for this thesis considered preparatory, study, performed at Skåne University Hospital (SUS\textsuperscript{18}) in Lund and the Childrens Heart Association\textsuperscript{19} in Sweden in 2006-2007, and in Chapter 9 we present the Case Study of the thesis. Our solution to identified problems and barriers of Chapter 3 is presented in Chapter 10 – Visual Incidence Anamneses (VIA). The thesis ends with Chapter 11 (Conclusions) and finally with Chapter 12 (References).

In the following, we present our view of the importance of Information in Healthcare by describing the nature of information and the importance of understanding the difference between data (information) and Information [Devlin 2001] in communicative tasks. We continue with emphasizing the changed role of the patient as an important turning point in the history of Healthcare, a resource to utilize in order to increase Patient Safety. Finally, we present our perspective on Patient Safety and how it is defined.

1.2 Information – Foundation of Health Care

Healthcare is built on Information management. Without information, purposeful Healthcare should not be able to exist. Every single decision made by any Healthcare provider must be based on a set of reliable information units. Information is obviously the most important and vital aspect of Healthcare. Accordingly, Information and Communication Management becomes crucial. Clinical Information Systems are today common in Healthcare settings, integrated in the activities as well as coordinating biomedical devices of many kinds [Shortliffe & Cimino 2006]. A direction in recent years, in Sweden, is the rise of a new field in Medical Technology denominated MIDS (Medical Information Data Systems) and supported by the Swedish Society for Medical Engineering and Physics\textsuperscript{20}. MIDS\textsuperscript{21} is, en clair, the area of Medical Devices and equipment/IS cooperating with IT products/IS, designed for diagnosis, monitoring and/or treatment. The communication is networked, using servers, databases and/or different kinds of storage media. For example, electrocardiographs are today equipped with ICT functions for a first analysis of the ECG and for networked communication with the EHR-system. Another example is ultrasound images, sent over remote networks. Given our Interoperability Framework of Fig 1, the focus of MIDS and similar efforts is on the lowest category Technical (basic Connectivity, Network interoperability and Syntactic interoperability).

However, it is to be noted that information comprises meaning that is not self-evidently obvious. A successful transfer of information in Healthcare is extremely dependant on a correct understanding of what is communicated. The sender of medical information must be confident of the receivers’ ability to interpret the information properly and correct. The receiver, on his/her part, must be able to rely on his/her ability to interpret the information, to be able to put it into safe practice; i.e. to act correctly. This is central

\textsuperscript{18} The recent name is Skånes Universitetssjukhus (SUS) i Lund.
\textsuperscript{19} In swedish: Hjärtebarnsförbundet.
\textsuperscript{20} Svensk Förening för Medicinsk Teknik och Fysik http://www.mtf.nu/ URL retrieved 2010-06-29
\textsuperscript{21} MIDS portal http://www.mtf.nu/MIDS-portalen.htm URL retrieved 2010-06-29
to issues of Patient Safety. Information systems, developed for Healthcare, must support such communication, coordination and interpretation tasks. In short, this means ensuring Interoperability. A building block of semantics and understanding is ontologies. Therefore, questions of ontology representations and semantics are highly prioritized in many Healthcare development projects. For example, in National eHealth (Nationell eHälsa, former Nationell IT-Strategi) in Sweden, this is prominent. The project is divided into a number of working areas, aiming at a holistic solution for the national ICT development in Swedish Healthcare. One of the working areas is focusing technical language and ontology related issues: “Information structure, terminology and standards – the fundamental condition structured and unambiguous information”. In the description, it is stated that the surplus value of technically refined methods of information transfer is lost if the information transmitted is not of high quality and not unequivocally interpreted by the personnel in need for it [Socialdepartementet 2010]. Regarding “Nationell Patientöversikt (NPÖ)”, the importance of information interpretation is evident. Not only health professionals will receive information but also patients. NPÖ is national, within the National eHealth-project, which will limit some of the interpretation perils as the medical language has a Swedish base, to be used at various locations domestically. However, the idea of information sharing tasks in Healthcare, unlimited by geographical borders, is extended in the epSOS-project (Smart Open Services for European Patients) where twelve EU-member states are participating towards a semantic solution (concerning patient summaries and ePrescriptions). The semantic aspect becomes obvious and evidently important in this view. The medical information must be interpreted in different European countries, avoiding misunderstandings to occur. Moreover, the information must not be violated during transmission. Issues such as interoperability of Electronic Health Record (EHR) systems (concerning both computer interpretable data and human interpretable information and knowledge), cross-border interoperability and semantic interoperability (the meaning of exchanged information is preserved independent of which system or application in use) are central issues in this aim. A closer look into these, by some examples, reveals considerable challenges for the task:

“For example a term such as chronic ischemic heart disease may be expressed using different terms originating from different code systems:

• 414 Other forms of chronic ischemic heart disease (ICD9CM)
• I25 Chronic ischaemic heart disease (WHOICD10)
• 413838009 Chronic ischemic heart disease (disorder) (SNOMED CT)”

[epSOS WP 3.5 2010]

“Another important consideration is that the display names of these codes are different in each language. For example the chronic ischemic heart disease has also the equivalencies as:

• Chronische ischämische Herzkrankeheit, nicht näher bezeichnet (German)
• Χρόνιες ισχαιμικές καρδιακές παθήσεις (Greek)

[22] URL Semantic web: http://semanticweb.org/wiki/Main_Page
[24] epSOS (former S.O.S) is an european eHealth project co-financed by the European Commission within the Competitiveness and Innovation Programme (CIP) URL retrieved 2010-06-30 at http://www.epsos.eu/about-epsos.html)
In short, basic semantic considerations such as shared meaning of terms and/or names in EHR systems pose well-known challenges [Benson 2010]!

Considering the perils of information transmission and interpretation in Healthcare, we have chosen to focus on a theoretical framework, “Situation Theory”, developed by Barwise and Perry [1983], further interpreted by Keith Devlin [1991] into a “common sense theory” InfoSense [Devlin 2001]. Among other aspects of Information, this theory explains what information really is and highlights the value of context for interpretation. In the following, we will elaborate such ideas, starting with a general discussion on semantic theories followed by a more comprehensive description of Situation Theory and InfoSense, which is one of the theoretical bases for this thesis.

The Semantics of Information

Information contains pointers to meaning. Meaning is basically the elusive aspect of information that makes it understandable by the receiver of information. In other words, meaning is “hidden information” tacitly related to the information to be understood. Words, as well as sentences, contain implied meaning interpreted by a receiver. Accordingly, for successful and secure communication, this shared background information must exist at the receiver of information and the sender of the information must be confident that it does. The IS must support this and not violate (corrupt) the information during transfer. Semantic Theories are theories basically helpful to convey meaning in information transferring situations. In Healthcare, this should be important for the development and implementation of ICT and IS. Large amounts of information are processed every day and information, critical for life threatening conditions, must not be misinterpreted, or missed. Again it must be stated that the semantics of information, i.e. interpretation of information that is to be transferred by ICT, must be in focus. If not, Patient Safety might be jeopardized by potentially defective information structures and communication tasks [Socialstyrelsen 2008] (Chapter 1.4).

Four basic perspectives seem to be prominent in a Semantic Theory: Ontology, Semantics, Learnability and Communication [Gärdenfors 2000]. The ontological perspective is described by the question “What are meanings?” Two general traditions in semantics are considered referential; the realist approach (the meaning is within things in the world) or the cognitive approach (the meaning are mental entities) [Ibid]. On the other hand, there is also a non-referential view, a functionalist approach, defended by (most well-known) Wittgenstein [1953/2001]. According to this, related to the nature of language, meaning is within use. The semantic perspective is described by the question “What is the relation between linguistic expressions and their meanings?”. The answer depends on the adopted approach. According to Gärdenfors [2000], Situation Theory is considered a branch of realist semantics. However, Situation Theory refers to situations in the world, not things. Meaning is true or false, independent of how an individual understands the meaning of an expression. In the following, a
A mathematical view on information is presented, in a “verbatim cut” from the authors Licentiate Thesis [Ådahl 2007]. The mathematical view, that is an elaboration of Situation Theory (“InfoSense”), should be considerably important in any attempts to transfer semantics of information by ICT:

“What is mathematics? Is it solely the art of theorem-proving, as traditionally is related to the area, or is it something much more comprehensive to scientific thinking? Mathematics is said to be the study of patterns [Devlin 1991]. The world consists of patterns, so, accordingly, the world must be possible to view mathematically. Keith Devlin, a senior researcher in CSLI and its Executive Director and a Consulting Professor in the Department of Mathematics at the Stanford University, has adopted the latter view. He has studied the phenomena of information and meaning in “Situation Theory”, first formulated in 1983 by Jon Barwise and John Perry [Barwise & Perry 1983], to identify and mathematicize abstract patterns for further computation. Information is a concept full of nuances and moreover a concept in the center of various discussions; the concept is interpreted in various ways depending on the scientific direction. In Computer science, there is a considerable difference between data and information. But it is less common to distinguish between information and Information. In Situation Theory [Devlin 2001], information is solely representations of information (i.e. data) until it is decoded and processed in a “cognitive agent” (a “knower”; a human being; or devices etc. that pick up information and react accordingly). Information (with a capital “I”) is information with meaning (data + meaning) [Ibid]. Consequently, information is decoded and further on internalized and externalized [Nonaka, Takeuchi 1995] by (human) cognitive agents for meaning and towards Information and varying knowledge development goals; Knowledge = Internalized information + Ability to utilize the information [Devlin 2001].

Nevertheless, the internalizing process of information might be a problem, as information remains coded in the form of representations until the individual receiver (cognitive agent) decodes it (gives the representations some meaning) [Devlin 2001] and the decoded information might be considerable apart from the senders intentions and objectives. Essentially, the result from the decoding process differs between different receivers with respect to varying cognitive functions, skills and experiences in the receiving (human) agents, resulting in different meaning (Information). A match between Information sent by one (human) agent and received Information (perceived) by another (human) agent much be as close as possible.

“Information arises and flows as a result of the interplay of things in the world and things in minds. Situations/objects/configurations/systems/etc. are in the world. Types/concepts/constraints/etc. are in the mind.” [Devlin 2006_a]

Referring to Situation Theory, grounded in an apprehension of a mathematical nature of Information possible to formalize and analyze by logic, a basic framework (ontology) is developed in order to process information; situation semantics. The basic framework (ontology) consists of: individuals, relations, situations, types, and infons. Situation Theory should be regarded as a framework for describing, analyzing, and understanding information flow rather than solely a theory of information. More
clearly, situation theory is a mathematical theory to support analyses of how things in the world can represent and convey information. Situation theory provides a set of mathematically-based tools to, for example and in particular, analyzing the way context facilitates and influences any rise and flow of information. Also, situation semantics is best approached as a method for analyzing phenomena related to semantics.

Consequently, Situation Theory is a mathematical theory of meaning [Devlin 1991]. The world is viewed as a collection of objects, sets of objects, properties, and relations. Individuals are conceived as having properties, which are standing in relations and persist in time and space. Objects are the parts of individuals. All individuals have properties (what they are) and stand in relations to one another (how they are). In Situation Theory, one uses a “situational perspective” on the world to explain the flow of information within [Ibid]. There is a basic assumption that, in the world, there is a phenomenon that is named “Information” [Devlin & Rosenberg 1996]. Cognitive agents perceive and process that information in order to react and act accordingly on it. In situation theory, [Ibid], information is viewed as commodities that flows by way of different representations, and comes in discrete units named “Infons”, that is items of information. Cognition and Communication are means in the process and are described as the acquisition of information (flow) by an agent from its environment and the flow of information from one agent to another respectively. Devlin & Rosenberg claim that

“...situation theory is regarded as a resource. It is needed to show the way of dealing with the problematic relation between knowing how to build interaction facilities and knowing how they can be used in a real-world information environment.” [Devlin & Rosenberg 1996]

As described above, information in situation theory is considered as coming in the form of infons or compound infons, which are ‘items of information’. They are not true or false in themselves. But a certain item of information may be true or false in relation to a given situation. One aim in the use of Situation Theory is formalization of context. For a proper understanding of the information sent, context must be taken into consideration. A “context diagram” (“conversation diagram”) [Devlin 2001] is used to graphically describe what kind of context is related to each sender and receiver of information. The meaning of Information is context dependent to each agent receiving information. In Situation Theory, context is formalized by the use of “types” (of situations), referring to the ontology. Information (representations) is decoded by virtue of “constraints”; i.e. implicit threads that connect Information with its representations. Consequently, constraints enable agents to transform information into Information, as the foundation is the agents’ former knowledge and experiences of the world. Situations are the context in which information occur: A situation provides the receiving agent with information that, by means of the receivers’ apprehension of constraints, is transformed into Information.

Situation theory describes transmission of Information using ontology usable for logical reasoning on Information. In short, the ontology comprises the variables described above. To begin with, the equation for Information is expressed by following:
Information = Representation + Procedure for encoding/decoding  
\[\text{i.e.}\]
Information = Representation + Constraint

In more familiar terms, this is Information = Data + Meaning. The ontology related to Situation Theory transforms this equation towards

\[\text{Information = information + constraint}\]

as “Big-I-Information” is received and decoded information with meaning, and “little-i-information” is data.

Reconnecting to infons and connecting to the ontology, a particular item of information (infon \(\sigma\)) may be true or false about a given situation (\(s\)), which should be written:

\[S \models \sigma\]

This indicates that the infon \(\sigma\) is made factual by the situation \(s\) and is expressed as “\(s\) supports \(\sigma\)” [Devlin 2006_b]. The situation \(S\) is the context for the infon \(\sigma\), which in turn is the target information. The type of situation determines that one situation \(A\) provides information about another situation \(B\) by means of representations and constraints: Information can flow between. That is, “a signal \(S\) carries the information \(X\) by virtue of \(S\) being of a certain type \(T\)” [Dretske 1981 in Devlin 2006_b]. More clearly, the type of situation is something that determines that specific situation; make it special. The situation as such exists in the world, when the type of situation is in mind by means of constraints. The common feature that connects the situations to a certain type is referred to as “higher-order uniformities” [Devlin 1991].

Furthermore, objects (uniformities) in the ontology of Situation Theory include individuals, relations, spatial locations, temporal locations, situations, types and parameters [Devlin 2006_b]. To describe information flow, information must be analyzed and denoted by mathematical representations. Therefore, the ontology uses denotations for such appearances as objects: For example, Individuals is denoted by \(a, b, c, \ldots\), Relations by \(P, Q, R, \ldots\), Spatial locations by \(l, l', l'', l_0, l_1, l_2, \ldots\), Temporal locations by \(t, t', t_0, \ldots\), Situations by \(s, s', s'', s_0, \ldots\), Types by \(S, T, U, V, \ldots\), Parameters by \(\dot{a}, \dot{s}, \dot{t}, \dot{l}, \text{etc}\) [Ibid].

To exemplify this mathematical denotation, following expresses that, in the situation \(s\), the objects \(a_1, \ldots, a_n\) stand in the relation \(R\)

\[s \models R(a_1, \ldots, a_n, 1)\]

and in the situation \(s\), the objects \(a_1, \ldots, a_n\) do not stand in the relation \(R\)

\[s \models R(a_1, \ldots, a_n, 0)\]
In connecting this reasoning to information in the health care arena, this implies that

\[ s_0 \models \text{«surgery, John, Karlskrona, Appendicitis, 1»} \]
\[ s_1 \models \text{«surgery, Caroline, Lund, Congenital heart disease, 1»} \]

The higher-order uniformity is in this case that, in both situations, a surgery is performed; that is the situation-type. However, the situation \( s_0 \) and \( s_1 \) provides different contexts, involving different people, different locations and different diagnoses. This does not change the type of situation; a surgery is performed. Some basic features determine this type of situation. There must be at least one surgeon. Also there must be anaesthesiologists, a method to perform a (sterile) surgery, an operating-room, operating-room nurses and sterilized instruments etc. Consequently, some features that are common for each situation of a certain type determine that type. To return to \( s_1 \) and \( s_0 \) above, we can confirm that the type of situation is Surgery, meaning that the relation between each of the situations is surgery. Moreover, the objects are variables for each type of situation in that they further determine the context of each situation. For example, a congenital heart disease going to surgery often implies open heart surgery that requires a heart-lung machine and other operative methods than surgery on the appendix does. The surgeries must be performed at different locations as not every hospital does offer surgical services in the area of congenital heart conditions and as the individuals are living at different geographical spots. Nevertheless, it should be stated that even if objects are variable, they might not differ for every situation: If John instead lived nearby Lund, the object Karlskrona would have been Lund, as in \( s_1 \).

Situation Theory is used for detail analyses of information flow, where there are occurring needs to pinpoint certain parts that must be understood, more in detail. The formalization of a given amount of communicative data is usable for cognitive agents to carry on to other cognitive agents, software or in the end human. It should be possible to use this methodology for visualization of information and transparency into critical information structures; i.e. information critical for the ability of the patient to act. For qualitative modelling of Information Retrieval systems, Situation Theory seems to possess the right framework [Huibers et al 1996]. Situation Semantics is a framework for natural language processing that can be used in a natural language process to identify the types supported by the situation and modelling the document. Situations and types are related to documents and their content of information. "Supported information corresponds to the explicit information content (digitalized) of the document, whereas carried information corresponds to its implicit information content. Constraints are the perfect tool to represent thesaural, or any semantic or pragmatic relationships" [Ibid]. The users (mental) intention must be correctly represented which generates better retrieval. Such representations are to some extent connected to the area of Cognitive Science, certain aspects which can be formally expressed with Situation Theory [Ibid]."

This definition of how Information should be interpreted concerns the importance of awareness of the semantics in information transferring processes. This awareness is utterly important in the development of ICT for Healthcare, as transferred information must be correctly understood by the receiver. If transferred information is
misinterpreted by the receiver, Patient Safety will be jeopardized. Consequently, the correct (true) meaning of information must be understood.

Knowledge is Information in use [Devlin 2001]. Knowledge is also necessary to possess in order to transform information into Information [Ibid]. In Healthcare, there are three kinds of knowledge a physician must possess in order to utilize available information. The first is “background knowledge” which is knowledge comprising anatomy, physiology, pathology; i.e. general medical knowledge. The second type of knowledge is “case related knowledge” that is knowledge about other cases comparable to actual type of case. The third type of knowledge is “foreground knowledge” that concerns how to act in a given situation, secured in local routines and protocols. The physician must relate all three types of knowledge to the actual case s/he has to work with to be able to process new information and develop adequate case based knowledge. However, how to act in a given situation is most decisive for the outcome of a certain case. This is not only dependant on local routines or protocols such as predetermined steps of workflow (for example plans of action in case of a pulmonary edema), but also on the interpretation of communicated information and understanding about which information to be communicated. This aspect is fundamental for the collection of patient specific data. The patient and the physician must share a mutual understanding about the actual case and the information needed for the right diagnosis and treatment. In this mission, there are several pitfalls which are threatening Patient Safety. The physician must know what has happened before the visit and what prerequisites the patient possesses. The patient must also have the ability to communicate adequate information to the physician. Furthermore, the patient and the physician must understand each other and the information that flows between. Situation Theory in the form of “Info Sense”, expressed by Keith Devlin [Devlin 2001] explains the difficulty of communication, referring to the nature of information as being basically representations of information. This emphasizes the efforts that must be made to communicate the semantics of the information, not only data to be more or less freely interpreted: the intention of the sender of the information must be as close as possible to the receivers understanding of the information. Furthermore, the physician must be aware of what the patient really has experienced before the visit which depends on if the patient understands what is important to communicate. Accordingly, background knowledge is needed, not only for the physician. Today, the Patient Empowerment movement has put pressure on ordinary people to become health literate. In the next chapter (1.3) we discuss the new role of the patient, changing from being passive and receiving into active and collaborative, and the benefits of such a turn.

1.3 A Changed Role of the Patient – The Health Literate Patient
The traditional role of the Patient is to be patient. In the years of medical success, 1880-1970, modern natural science based medicine, with its positivistic approach, has been twofold. On the first hand, medicine was successful enough to control severe illness not possible to treat before this period of time. On the other hand, the patient was lost. The self evident, interactive, dialogue between the patient and the physician was superseded by technology assessing the body as measurable parameters. Simultaneously, the voice
of the patient, telling the subjective experiences of an individual, having a disease, was partially or completely lost [Häggblom & Mattsson 2007].

However, along with the Patient Empowerment movement and later efforts to overcome deficiencies in Patient Safety, the Patient has been awakened. Today, the Patient is in another position, increasingly regarded as a resource in Healthcare, not a passive receiver of care. The general use of the Internet, as a new infrastructure of the modern society, has started this trend, providing access to large amounts of medical information not available before. Health Literacy is an evolving concept, with many definitions. This definition is used in the Institute of Medicine’s report “Health Literacy: Prescription to End Confusion” [Nielsen-Bohman et al. ed. 2004] and for the project Healthy People 201025 (an agenda launched by U.S. Department of Health and Human Services in 2000 for health promotion and disease prevention):

“The degree to which individuals can obtain, process and understand the basic health information and services they need to make appropriate health decisions.” National Network of Libraries of Medicine New England Region, Shrewsbury, MA

Nutbeam [2000] describes Health Literacy in a similar way, however more in detail:

The personal, cognitive and social skills which determine the ability of individuals to gain access, to understand and use information to promote and maintain good health. Three levels of health literacy were identified:
1. basic or functional health literacy;
2. communicative or interactive health literacy; and,
3. critical health literacy

[ Nutbeam 2000]

Health Literacy is closely related to Literacy26 [Nutbeam 2008]. This implies that not every patient will have the necessary requirements to become Health Literate and that the levels of Health Literacy will be different in different individuals. Consequently, Nutbeam proposes three levels of Health Literacy in his definition [Nutbeam 2000, 2008], connected to the level of cognitive skills in an individual. The first level refers to a broad definition of Health Literacy, initially adopted to describe the concept:

“Adequate functional health literacy means being able to apply literacy skills to health related materials such as prescriptions, appointment cards, medicine labels, and directions for home health care” [Parker et al. 1995]

The second level refers to more advances cognitive and literate skills, as well as social skills, to actively process and utilize new information. The third level, the most

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26 Literacy = “The ability to identify, understand, interpret, create, communicate and compute, using printed and written materials associated with varying contexts. Literacy involves a continuum of learning to enable an individual to achieve his or her goals, to develop his or her knowledge and potential, and to participate fully in the wider society.” United Nations Educational, Scientific and Cultural Organization. International Experts Meeting. Institute for Education. (June 2003).
advanced level of Health Literacy, is the most desirable as it implies ability to control life events and situations by critical analysis and use of information. This level is most desirable, but for many individuals not achievable. The most empowered patient is those who manage the third level. Accordingly, Health Literacy is critical to Empowerment. To be empowered, considerable demands are on the patient to perform certain actions. Two approaches to Health Literacy is identified; Health Literacy as a risk factor and Health Literacy as an asset [Nutbeam 2008]. Viewed as an asset, Health Literacy concerns public health and health promotion. Health Literacy as a risk factor refers to risks with poor literacy and language skills. This approach refers to possible outcomes of clinical Healthcare related to the level of Health Literacy among patients. Paasche-Orlow and Wolf [2007] propose three critical points where health literacy influences health outcomes: 1) Healthcare 2) The interaction between patients and Healthcare professionals 3) Self-Care. The approach of Health Literacy as a risk is directly related to the three levels of literacy, where the risk is highest at level 1. This approach and, thus, the following model are obviously critical to Patient Safety and related to the direction of this thesis:

![Conceptual model of Health Literacy as a risk](image)

The critical point seems to be to increase the possibilities for patients to interact with Healthcare, in order to improve the clinical outcome (Figure 5). In this matter, it is important to note that patients are a heterogeneous group. Due to a variety of factors such as age, inadequate strength in illness, mental disorders or cognitive disabilities, not every patient is capable of achieving, or practice achieved, health literacy. The patient must often be represented by a relative or close friend, which we in this thesis sometimes will refer to by using the term “Proxy”. Today, Patient Participation is
recognized as highly important for Patient Safety, which is that the Patient is important for increased Patient Safety. In the new Patient Safety Law (January 1st 2011) in Sweden [Patientsäkerhetslagen SFS-nr: 2010:659] (Chapter 1.4), Healthcare professionals are instructed to encourage Patient Participation for increased Patient Safety. Simultaneously, Healthcare must be empowered to meet the patient at the level of Health Literacy that the patient has reached. This will be further evaluated in Chapter 1.4.

The “e-Patient” is a Health Literate patient, using the Internet to learn by information searches and communication with other patients as well as Healthcare professionals in a variety of virtual communities. This phenomenon is, among others, described by Gunther Eysenbach, MD MPH, one of the leading researchers in the field of eHealth and Internet & Medicine and founder of Journal of Medical Internet Research (JMIR). He has coined the term Apomediation, to make clear the ways in which patients learn, focusing eHealth (Web 2.0) as a phenomenon paving the way for patients to become knowledgeable and active [Eysenbach 2008]. In the next section, we will further elaborate on the implications of the e-Patient and Apomediation in Healthcare.

The Patient as Collaborator - Apomediation for Participatory Medicine

Gunther Eysenbach coined in 2008 the word Apomediation [Eysenbach 2008], to express a new phenomenon of the new, active patient style. Apomediation could be referred to as a socio-technological term, characterizing a process of disintermediation [Ibid]. This means that agents (tools and people) bypass intermediaries (middlemen, “gatekeepers”), i.e. Healthcare professionals providing in their view relevant information to patients, in order to transfer medical information to each other. Consequently, the apomediaries “stand by” in contrast to the intermediaries (professionals) who stand “in-between” [Ibid]. “Web 2.0” technologies have prepared the way for Apomediation, facilitating the growing activity in this field.

PatientsLikeMe is a typical expression for Apomediation, providing access to an online community of Patients, gaining access to information about diseases and treatment, such as medication, and communication with other patients.

“PatientsLikeMe is an online quantitative personal research platform for patients with life-changing illnesses to share their experience using patient-reported outcomes, find other patients like them matched on demographic and clinical characteristics, and learn from the aggregated data reports of others to improve their outcomes. The goal of the website is to help patients answer the question: “Given my status, what is the best outcome I can hope to achieve, and how do I get there?” [Wicks et al. 2010]

28 http://www.socialstyrelsen.se/regelverk/lagarochforordningar/patientsakerhetslag (Retrieved 2011-11-08)
29 “Gunther Eysenbach, MD (Freiburg) MPH (Harvard), is a Senior Scientist at the Centre for Global eHealth Innovation at the Toronto Research Institute/Toronto General Hospital and Division of Medical Decision Making and Health Care Research.” (Citation retrieved 100216 at http://www.ehealthinnovation.org/?q=user/51
Above Apomediation, the web site could also be used as a tool for ordinary consultations with physicians in Healthcare. For example, the site is usable as a reminder of occurring symptoms since the last consultation and for discussion about treatment such as medication and side effects to medication. To some extent, the history of occurring symptoms, the general state of health and the history of medication are visualized to the patient. This is a tool for increasing the patients Health Literacy, but also usable as a communication aid. Figure 6 and Figure 7 show the site as, by way of introduction, presented to the visitors and members.

Figure 6 - PatientsLikeMe (www.patientslikeme.com). Virtual Community for active and cooperative Patients.
ApomEDIATION should be considered an important part of what Participatory Medicine (PM), a cooperative model of Healthcare, involves. PM brings patients together with healthcare professionals; encouraging professionals to utilize patient knowledge collected not only apomediary but also by experience of their feelings of having a disease or diverse symptoms. This is also closely related to Patient-Centred Medicine (PCM) and Collaborative Patient-Centred Practise (Chapter 7.2). Tom Ferguson MD, creator of the e-Patients Scholars Working Group, later forming Society for Participatory Medicine, coined the term e-Patients [Ferguson 2007] in this matter, aiming at highlighting a new role of the, Health Literate, patient. Dr Ferguson was a visionary thinker, anticipating this paradigmatic shift in Healthcare already in the last century. He also was a member of both parties, being a Medicinae Doctor as well as a patient, suffering from a severe chronic disease ending his life a few years ago. A reflection with reference to Dr Ferguson is that professionals are sometimes in the role of being patients or they are relatives to patients, acting as proxies. This perspective could stimulate the knowledge development and collaboration in PCM (Chapter 7.2), addressing issues of varying situations of patient participation in Healthcare, if efficiently utilized.

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30 Participatory Medicine = “Participatory Medicine is a cooperative model of health care that encourages and expects active involvement by all connected parties (patients, caregivers, healthcare professionals, etc.) as integral to the full continuum of care.” (Citation retrieved 100216 at http://participatorymedicine.org/)

31 Society for Participatory Medicine = “a growing organization devoted to promoting the concept of participatory medicine by and among patients, caregivers and their medical teams and to promote clinical transparency among patients and their physicians” (Citation retrieved 100216 at http://participatorymedicine.org/about/)
Pathographies and other ways to Health Literacy

The voice of the patient is visible in the Pathography [Häggblom & Mattsson, 2007]. This is a sign of the times, occurring along with the development of “Web 2.0” technologies and the growing movement of Patient Empowerment. Pathographies express a need for visualizing personal experiences from the perspective of being a patient, to inform and guide others. As such, it can be considered to be part of the Apomediation phenomenon.

The term is not unambiguous. Merriam Webster provides the following definition:

“biography that focuses on a person's illnesses, misfortunes, or failures; also : sensational or morbid biography”

It is considered that Freud some decades ago coined the word in the book “Eine Kindheitserinnerung des Leonardo da Vinci” [Freud, 1995; Häggblom & Mattsson, 2007]. This perspective is similar to the use of the term in medicine: Pathography is an objective description of what impact illness might have on a person. Another view is brought by Hawkins in 1999 [Hawkins, 1999; Häggblom & Mattsson, 2007], reversing the traditional perspective, presenting a new angle of approach: the patients own personal experiences of illness and, in relation to that, Healthcare. This perspective is subjective, mediating the experiences to others in text form; often books. In some sense, Pathographies are related to Health Literacy; a phenomenon fueled by the development of the Internet. Pathographies, viewed in the latter perspective, are not only represented in the traditional form of printed books, but also online in digital form.

For example, “Blogs” (Web Logs) regarding severe illness, described in a very personal way by the patients themselves, attract considerable attention and large number of visitors every day. The purposes are of various meanings, but basically they are inevitably enlightening for the readers. These are gaining exclusive insight into real world situations of having a disease and how it affects the every day life of common people and their families.

Health Literacy is also obtained by memberships of varying online communities, today often referred to as Social Media. Kaplan & Haenlein [2010] define Social Media as

“…a group of Internet-based applications that build on the ideological and technological foundations of Web 2.0, and that allow the creation and exchange of user-generated content.”

For example, in Sweden there are a variety of forums not only for somatic diseases but also for psychiatric. Figure 8 shows “Aspergerforum”, a relatively large online community concerning a neuropsychiatric diagnosis “Aspergers Syndrome” that is a form of mild autism; in society often subjected to prejudices and misunderstandings [Attwood, 2008]. In this forum, the members are supporting and informing each other to cope and find strategies to function as smoothly and with as little strain as possible in the interaction with “Neurotypical”32 people. Normal social interaction, keeping a

32 “Neurotypical (NT), a term coined in the general autistic community (not Aspergerforum) describing people not being autistic, i.e. being “normal”.

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normal appearance to others (as seen from without often quite successful), is very often strenuous, resulting in total exhaustion; mental as well as physical [Ibid].

Figure 8 - Online community for Aspergers Syndrome (http://www.aspergerforum.se/ )

A variety of Patient Associations as well as Healthcare in Sweden (County Councils), 1177 (former “Sjukvårdsrådgivningen”) (Appendix 3) and the varying stakeholders of a variety of Pharmacies occurring in the last years (Appendix 3) (originally government owned Apoteket AB), provide general health related information to patients, aiming at Patient Empowerment in terms of Health Literacy and (to some extent) self-care. In particular, a noticeable turn to Facebook Communities in recent years has also attracted many Patient communities and Patient organizations to share social and medical aspects as well as issues with others and each other. For example ACHA\(^{33}\) is such a community (Figure 9):

\(^{33}\) ACHA = Adult Congenital Heart Association
https://www.facebook.com/AdultCongenitalHeartAssociation
Both aspects of Patient Safety and economical issues of Healthcare are related to the encouragement of Health Literacy among patients and the population at large. Empowerment of patients is basically a strategy for Patient Safety, where the Health Literate Patient is capable to cooperate with Healthcare towards safer diagnosing and treatment [Longtin et al. 2010, Kelley & Hafner 2011].

The Health Literate Patient should be aware of possible pitfalls in the decision making process, to have an open eye for information in relation to experienced symptoms and chosen diagnoses and treatment. E-Health has provided Patients with a wide range of strong tools for this type of cooperative tasks. One example is the web site “Wrongdiagnosis.com”. The website states that misdiagnosis is one of the most common types of medical mistakes, emphasizing the participatory role as important by stating that

“One of the first issues for a newly diagnosed patient is to consider whether the diagnosis is correct. It is important to validate a diagnosis and be certain of its accuracy. On the other hand, hoping for a misdiagnosis should not be used as a way to vacillate and avoid treatment for a serious medical problem. Nevertheless, it is prudent to attempt to confirm a diagnosis via methods such as seeking second opinions, consulting specialists, getting further medical tests, and researching information about the medical condition.”
(http://www.wrongdiagnosis.com/intro/overview.htm)

Accordingly, Wrongdiagnosis.com is a website within the Apomediation area, aiming at increasing Patient Safety by informing patients and encouraging them to be active in a voluntary validation process of decisions made for them in Healthcare. In the next chapter, we will go further into the area of Patient Safety. We will also explain the critical relation between Patient Safety and Patient Empowerment, where the Health Literate Patient is the vital point and the ability of Healthcare to meet this is decisive.
1.4 Patient Safety

In recent years in Sweden, Patient Safety has attracted much attention. However, already in the nineties Patient Safety was in the focus as the result of the report “To Err is Human - Building a Safer Health System” [Kohn, Corrigan & Donaldsson, Ed. 2000], citing the Harvard Medical Practice Study (HMPS) [Brennan, Leape & Laird et al. 1991; Leape, Brennan & Laird et al. 1991] from the eighties, which, surprisingly, in the beginning was not properly noticed. The report presented an alarmingly high number of incidents, injuries and deaths that could be connected to Healthcare activities. In Sweden, round about 100,000 patients are injured and 3000 patients die every year, caused by deficiencies in decisions and actions34 [Socialstyrelsen 2008b], which corresponds to percentages reported internationally. A relatively large amount of events threatening to Patient Safety are related to information management and communication [O’Daniel & Rosenstein 2008]. It is noticeable, that ICT implemented in Healthcare, with the aim of provide accessibility to more information, as well as more sophisticated information, obviously has not yet improved the situation [Socialstyrelsen 2008, 2008b]. Bates & Gawande [2003] stated that

“Information technology can substantially improve the safety of medical care by structuring actions, catching errors, and bringing evidence-based, patient-centered decision support to the point of care to allow necessary customization. New approaches that improve customization and gather and sift through reams of data to identify key changes in status and then notify key persons should prove to be especially important.” [Bates & Gawande 2003]

This is an attempt to articulate a need for new, more specified and goal-oriented development strategies in the area of ICT for Healthcare. For example, Bates & Gawande point at the peril of being exposed to large amounts of (unstructured and unsorted) data. Such exposure obscures important and critical Information that otherwise should be triggers to important actions.

Patient Safety literature makes a distinction between preventable and non preventable adverse advents [Wachter 2007]. When analyzing a case, it is important to be aware of the differences that the Patient Safety terminology tries to pinpoint. This increases the possibilities to find solutions for each case or conclude the possibilities of finding a solution for a certain case. Wachter [2007] uses a Venn diagram to depict the logical connection between the terms in use (Figure 10) [Ibid]:

Considering the terms used in the Patient Safety area, a definition of what “error” is must be established. Wachter [2007] refers to a common definition found in Patient Safety literature, where an error is to consider as:

“...an act of commission (doing something wrong) or omission (failing to do the right thing) leading to an undesirable outcome or significant potential for such an outcome” [Wachter 2007, p.4]

However, above the distinction between preventable and non-preventable adverse events, this diagram (Figure 10) demonstrates that not all adverse events are to consider as errors. Neither do all errors comprise adverse events: “Near misses” are errors that do not result in adverse events. Furthermore, among preventable adverse events, there are also a number of events that are the result of negligence (i.e. not to follow professional standard in care). Weingart et al. [2000] distinguish between errors of omission and errors of commission as follows:

“An error of omission is a failure of action such as a missed diagnosis, a delayed evaluation, or a failure to prescribe needed drug treatment. An error of commission is an incorrect action, such as administering the wrong drug to the wrong patient at the wrong time.” [Weingart et al. 2000]

A basic prerequisite for Patient Safety is that the diagnosing process results in a correct diagnosis and no diagnoses are missed. Unfortunately, necropsy studies have revealed that the opposite is rather common [Weingart et al. 2000]. Surprisingly high numbers of misdiagnoses and unexpected serious illness were found when necropsy reports were compared with the clinical diagnoses of the cases in the studies [Ibid].

In this thesis, we focus “Preventable adverse events”, rather than individual errors, as this perspective entails a holistic view on the organization. A systemic perspective on Healthcare provides means of increasing safety which separate punishments of individuals do not: Today, in Healthcare, there is a strong emphasis on finding sustainable solutions for Patient Safety issues. The number of injuries and deaths, with reference to the results of poor Healthcare routines and organizations, are alarmingly high. Until recently, the approach to Patient Safety has been a focus on individual responsibility (to find “scapegoats”; Chapter 4). However, the number of serious adverse advents has drawn attention to aircraft (aviation) industry and their view on air disaster investigations is now resulting in a move of the focus from an individual responsibility to a more comprehensive view of causes and prevention of repetition. A systemic perspective on incidents, injuries and deaths is today a new approach in Healthcare by means of the new “Patient Safety Law” (Patientsäkerhetslagen SFS-nr: 2010:659) [SOU 2008:117, p.35], operative in January 1st 2011, replacing the old law 1998:531 (Lagen om yrkesverksamhet på hälso- och sjukvårdens område, LYHS)35.

35 The Swedish Government Offices (Regeringskansliet), website retrieved 2010-06-23 at http://www.sweden.gov.se/sb/d/12605/a/139284
In addition, another aspect of Patient Safety seems to be salient. Besides safety in care, avoiding mistakes or misses to occur, integrity in care has attracted considerable attention. In the transition from paper based medical records to electronic medical records and intentions of transferring individual patient related medical information over varying types of networks, integrity issues have been frequently discussed. No information must leak from either medical records or healthcare personnel. In some situations, these aspects are antagonizing each other. For example, information needed at the point of care might jeopardize patient integrity. Information sent over network is never completely secure, but sometimes this has to be compromised to obtain Patient Safety in care. With reference to the questioned security aspects of NPÖ (Chapter 1.2, 7.2), the medical value of information at the point of care, unlimited by geographical positions, might be stronger than the potential risk of violence to integrity.

Today, Patient participation, as a resource towards Patient Safety, is noticed and evaluated in a number of papers and other publications. Longtin et al. [2010] stress this view by presenting a conceptual model of conceivable factors, influencing the possibilities of patients to cooperate towards increased Patient Safety by preventing errors (Figure 11):

![Conceptual model of factors that influence patient participation in preventing errors. HCW = health care worker. (Longtin et al. 2010)](image)

This direction is doubtlessly established also worldwide. WHO is currently adopting this model [Kelley & Hafner 2011] in the work with Health Literacy issues in Europe. Furthermore, another WHO Project stresses Patient Safety and Patient Rights [Virone & Tarasenko 2010] [WHO 2011] where patient understanding and active involvement to enhance care is emphasized. Consequently, the Health Literate patient is viewed as an important resource for increased Patient Safety.

In Chapter 3.2, this direction is adopted and involved directly in Research Question 2 (RQ2) and further elaborated through the results from all of them (RQ1-3). However, firstly, in the next Chapter, (Chapter 2), we will present the methodology used for the empirical work by which we were able to identify those information structures, which related to the case flows in context, in the perspective of the patient but nevertheless subtle and hidden. Such information is possible to visualize in collaboration with the patient; aided by additional Decision Making tools designed for this purpose (which we propose in Chapter 10).
Chapter 2 – Methodology

In this chapter, the methodology and methods supporting the empirical findings are presented and explained. We argue that a Qualitative approach will be necessary to address in order to catch context and causal connection of information and information breakdowns. Accordingly, the Qualitative Methodology adopted for this thesis is described and motivated. Finally, some design principles for visual communication is presented.

2. Introduction

The choice of scientific method for this thesis was based on the conviction of the importance of adopting a qualitative approach, compared to quantitative approaches mostly applied in healthcare, guiding our investigations. Accordingly, the empirical work of this thesis is foremost qualitative, using the study of cases and open-ended interviews to collect and analyze empirical data. The reason for this decision was that qualitative research allows in-depth studies of information flows in Healthcare. Revealing the context of the flow and implicit (hidden) information flows, from the perspective of the patient. This patient-centric insight would be difficult (impossible) to achieve by a, for the area of medicine more traditional, quantitative approach. One of the reasons of a qualitative direction for the studies was to be able to catch small pieces of information and study how they might influence the overall result of a certain course of disease, and treatment. The focus for the Case Study (Chapter 9) is on diseases that are serious and potentially lethal dependant on how fast the diagnosis is correctly identified and treated. The interventions professionals in Healthcare decide to choose is based on which diagnosis that initially is considered most probable. According to this perspective, our focus on increasing Patient Safety came down to identifying basically which information those decisions on interventions might be based on (the reasoning behind the decisions). Furthermore, how this information was collected and analyzed. In short, it was important to identify information, unintentionally or deliberately, left out, and how this probably affected the result (failure) of the treatment. This kind of empirical data was collected in order to be able to answer the research questions (RQ1-3) of this thesis and our proposed solution VIA (Chapter 3.2 and 11, Chapter 10).

Sociotechnical systems (STS) research specifically requires knowledge about, and addressing, context, as such systems have both technical and social viewpoints (Chapter 1.1). As this thesis focuses on STS in medicine, the choice of methodology for the research is, as indicated above, to use qualitative methods. However, there is a caveat. Using qualitative methods in research related to the area of Medicine could, to some extent, be regarded as controversial. Research within this area is strongly directed towards quantitative methodologies (preferring numbers rather than words!). The level of evidence in Medical research is very much related to measurability. This is assured by collections of large data quantities, producing statistic evidence for research
questions and hypotheses. These quantitative methods are regarded to be of high reliability and to have high validity. However, despite the traditional approach of measurability that quantitative research methods offer, qualitative methods tend to become more and more common in both medical and health service research [Curry et al. 2009] since its introduction as an alternative research methodology in Healthcare in the end of the 60ies and the 70ies [Cohen & Crabtree 2008]. For the last decade, the interest for qualitative research has grown due to the unique possibilities of studying complex social processes and for in-depth studies to understand and learn from the perspective of the participants in the study. For example, to capture the perspective of the patient might be crucial in order to identify hidden information flows, what they are, how they flow in Healthcare and its context, and their implications for Decision Making and Patient Safety. In short, the choice to base increased Patient Safety, based on assessing the needs of individual patients, calls for qualitative approaches along the lines we propose in the thesis.

On comparison, quantitative approaches are very suitable for analyzing measurements (averages, mean value, co-variance and other statistical analysis methods) that do not require (in fact avoid) any nuanced understanding of certain events or incidents, specifically certain occurrences of illness and other types of more complex Healthcare related phenomena. In fact a researcher applying quantitative methods acts as an observer while a researcher applying qualitative methods usually take an active role in the investigations. Of course qualitative or quantitative methods predefine the investigations performed and type of the findings. Usually the two methods therefore are used separately. But exceptions of different methodological combinations exist.

Quantitative research methods are not suitable to address for a holistic in-depth view on contextual aspects such as social impact on illness. If the methodology is addressed for studies of occurring medical phenomena of some certain type, with attempts to capture some kind of causal relationship between variables, they might end in statistical correlations rather than causal relations. This can be observed by the notion of frequent occurrences of contradictory facts and advices in Public Health strategies throughout the years. Furthermore, the recommendations of treatment have been repeatedly altered for Healthcare professionals; often quite contrary to what earlier was a rather self-evident “rule-of-thumb”.

One of the most recent intriguing expressions for this phenomenon is counseling of dietetic food. The conventional wisdom for decades was unchallenged as it without a doubt and was considered both reliable and valid. Rather unexpectedly, the deeply rooted, trustworthy and evidence-based, dietetic lines and recommendations are now obstructed by two conflicting recommendations, namely:

1. On the first hand, since the seventies, there is a firm conviction of avoiding fat, especially saturated fatty acids. In this view, (slow, or even fast) carbohydrates are allowed. This direction has been taught in medical education for medical workers such as nurses, physicians and dieticians, and consequently it has been the absolute guiding principle for patients by way of instructions from dieticians. Furthermore, it has been a guiding principle also for the healthy population by way of popular media (daily papers, weekly magazines, books, radio, television etc).
2. On the other hand, in the last few years LCHF (Low Carbohydrates High Fat) is recommended by pioneering critics. They claim that former research in the area was grounded in fatal assumptions of causality. A study initiated 1973 (1973-1989), the “Lipid Research Clinics (LRC) Coronary Primary Prevention Trial (CPPT)”\textsuperscript{36}, was (after a number of confusing research results) the trigger of the current general dietetic advises for avoiding cardiovascular diseases and obesity. The “Lipid Research Clinics (LRC) Coronary Primary Prevention Trial (CPPT)” was a study about pharmaceutical preparation to lower levels of cholesterol, unfortunately considered to be equivalent also with dietetically advises to confirm former research [Taubes 2001]. In this direction, saturated fatty acids are recommended and no limitations are made regarding this. Instead, regarding fat, the danger rests upon Trans-fat that is unsaturated fat with trans-isomer fatty acid(s). Trans-fat is never saturated. Furthermore, in LCHF, carbohydrates are considered to be the basic danger as they in healthy, not diabetic, individuals cause high levels of insulin secretion, resulting in increase of weight and obesity. High insulin levels are considered to be the basic reason to lesions on vessels. For diabetics, carbohydrates also cause high levels of blood glucose which requires more intense treatment with insulin injections etc. Consequently, the correlation in the first (traditional) dietetic food recommendation, both for patients with obesity and diabetic patients, is that food containing saturated fatty acids is dangerous, as people eating such food often suffer from lesions on vessels, and fatness. However, if such food also contains high levels of carbohydrates (and glucose, or trans-fats) is not in-depth considered, nor if this is the actual cause of cardiovascular diseases and fatness, and if so, why.

The choice of methodology for this thesis, interdisciplinary as it embraces both the area of Healthcare and Computer Science (the latter also most commonly influenced by quantitative scientific methods), is, as earlier stated, to adopt a qualitative approach. This choice is based on the need for knowledge about context, in order to identify and holistically understand more subtle information flows and causal relationship of breakdowns in information flows as well as missed information in the Healthcare activity.

Quantitative approaches are mainly used also in Computer Science, specifically addressing issues related to, e.g., algorithms realizing performance of computational tasks (functions). Of course, there are also areas in computer science using qualitative methods as first-hand choice, for example some sub-areas of usability in design. Other areas include aspects of interoperability, safety and security, maintenance or other constraints on the functionality of the system.

The systems we address are socio-technical which calls for attention to social factors for the system to work in, as well as supporting understanding and sharing knowledge. This focus is also of great immediate interest in eHealth today, especially concerning patient participation and Participatory Design (PD) for Patient Safety, and brought into practice by the suggestion of new (socially inspired) approaches for Software developers to work with when designing EHR-systems or (additional tools for) Clinical Decision Support Systems (CDSS) (Chapter 6.2) in the future. For example, “IT-Rond” and “MedsITtning”\textsuperscript{37} are such suggestions from the Swedish Medical Association\textsuperscript{38} and presented at Vitalis 2010\textsuperscript{39}, bringing IT-developers and Healthcare personnel more

\textsuperscript{36}https://biolincc.nhlbi.nih.gov/studies/lrccppt/
\textsuperscript{37}http://www.slf.se/it-rond
\textsuperscript{38}The Swedish Medical Association (http://www.slf.se/Info-in-English/)
\textsuperscript{39}Vitalis 2010 Conference (http://nemonet.swefair.se/templates/FlexiblePage____173817.aspx)
close together, towards a common understanding of required system behaviors. For example, “MedsITning” covers a social perspective of how the systems work in relation to workflows in the activity. Representatives for the Software developer and the local IT department at the hospital are invited to follow healthcare personnel in their work with patients for half a day, to understand how the IT-systems work in practice. This is very much comparable to methods addressed in *ethnomethodologically informed ethnography*, i.e. “doing ethnography” for information systems design, and Participatory Design. Such an approach in the design of socio-technical systems is momentous, as the chances of supporting workflow, and the activity as such, will increase by a deeper understanding of the field and its context by involving the end-users in the design process. In particular, (Participatory) Observation is a method supporting this direction. However, in the Licentiate Thesis [Ådahl 2007] this is more closely elaborated.

In short, issues and concerns related to Interoperability of Healthcare systems have gained international focus as an enabler of safe and trustworthy e-Healthcare Systems [Stroetmann et al. 2011]. As presented in the Introduction to this thesis (Chapter 1), failures of present day Healthcare support systems could most often be attributed to *interoperability failures of relevant workflows due to information breakdowns*; lost information or misinterpreted information. To gain understanding of Interoperability concerns regarding every aspect addressed, not only Technical Interoperability but also Organizational and Informational, a qualitative approach is needed. Such approach must be taken for a deep understanding of requirement elicitation, for a Social-Technical systems design of trustworthy e-Healthcare systems.

In this chapter, the main focus is not on design despite the presence of a suggested solution in Chapter 10. Instead, the focus is on the methodology for the research behind the findings and solutions presented in this thesis. Accordingly, the next section is presenting qualitative methods addressed in Computer Science, followed by the qualitative methodology adopted for the empirical work of this thesis.

### 2.1 Qualitative methods in computer science

In many scientific communities, measurability is considered a *self evident focus* addressing the positivistic spirit in science. This goes back to the efforts from 15th century to understand nature and natural phenomena. Ideas of the importance of empiric knowledge, observation and experiments to understand nature were put forward by John Locke, Isaac Newton and Galileo Galilei. Galilei also adopted and used instruments (telescope) to empower our natural senses in decoding observations. It is an understatement that advancements of models and methods and tools for empirical grounded experiments have been phenomenal successful during the last centuries to increase our understanding of the natural sciences.

Performance aspects of Computer Science, such as algorithm complexity, application performance and, to some extent, software correctness, are measurable. This entails that we have a *suitable model* of the phenomena under study as a basis for setting up and performing experiments. Formal methods, such as mathematics, are often a primary
choice for modeling. The strength, and source of reusability, of formal methods is the abstraction from context. The meaning (semantics) of the formulas and models is in the mind of the modeler.

Accordingly, mathematics and statistics are tools for explaining some measurable phenomena. However, qualitative methods aiming at formal proof-theoretical verification of theorems about models provide a supplement to statistical probabilistic reasoning (Theoretical computer science). The context dependant reasoning supporting those methods is then provided by the modeler/evaluator of the findings.

Computational models are algorithms executing on a virtual machine or implemented on a run-time computing environment. Software engineering focuses on correct implementations of correct algorithms and is outside the scope of this thesis.

It must be stressed that computer science addresses computation models at many levels; from low-level computation mechanisms (automata) to high-level cognitive computation models. Peter J. Denning [Denning 2007b] (Chapter 1.1) has proposed the following “Seven Great Principles of Computing” to support the view that computing itself is both a natural phenomena and could be implemented on artifacts:

- Communication. Data communication always takes place in a system consisting of a message source, an encoder, a channel, and a decoder.
- Coordination. A coordination system is a set of agents interacting within a finite or infinite game towards a common objective.
- Recollection. All computations take place in a storage system. Access to stored objects is controlled by dynamic bindings between names, handles, addresses, and locations.
- Automation. Physical automation maps hard computational tasks to physical systems that perform them acceptably well. Artificial intelligence maps human cognitive tasks to physical systems that perform them acceptably well.
- Evaluation. The principal tools of evaluation are modeling, simulation, experiment, and statistical analysis of data.
- Design. Design principles are conventions for planning and building correct, fast, fault tolerant, and fit software systems.

The seventh principle, Design, comprises aspects that connect to a socio technical perspective of computer systems, as in our case. Accordingly, systems that must be analyzed on a higher level: The scientific understanding and modeling of context, which in this case is to embrace the social context as part of the computer system, requires another methodology than quantitative approaches offers.

Accordingly, to understand the social context in which computer systems are implemented or will be implemented, a qualitative approach is mandatory. In the study of workflow in Healthcare, focusing on Patient Safety, it might be decisive to understand why and how information misses and breakdowns occur. If a quantitative methodology is adopted to study workflows, the method is basically to ask the participants about it (commonly by questionnaires) and analyze measurable variables given by the answers in order to derive numbers, statistics and graphical
representations. However, this will not reflect a deeper understanding of workflow in individual context. It is a notorious discrepancy between what people say they do and what they actually do [Robson 2000]. For example, deficiencies in memory or the “social desirability response bias”, i.e. “socially desirable responding” (SDR), are factors influencing the answers or descriptions, and might affect the validity of questionnaires. In the matter of workflow studies or studies of information flows, an exploratory approach is more suitable to adopt where the activity is scaled-down to a slices of reality and studied in-depth. Such slices could be authentic cases, studied by methods such as participatory observation to directly capture what actually happens in a situation or a workflow.

The next section will present the qualitative methodology adopted for this thesis, where two authentic cases are the foundation and for which a qualitative, exploratory, approach towards a more general understanding of subtle deficiencies in current Healthcare information management is addressed.

2.2 Methodology supporting the empirical work

In January 2011 a new Patient Safety law in Sweden (Chapter 1.3, 1.4, 4, 4.2, and 7.3) changed the way disastrous cases are tackled in Healthcare. A systemic perspective on fault prevention (Chapter 4.2) replaced the previous perspective on punishments of individuals (Chapter 4.1). In line with this direction, the focus of this thesis is to study information flows in problematic cases, from a systemic point of view. A qualitative methodology is chosen; to be able to perform in-depth studies of how information actually flows under the surface of rare or problematic cases; when Healthcare is not able to identify the condition in time, or at all, until it is too late. Consequently, the main empirical study for this thesis is a case study comprising two different, authentic, cases (Chapter 9). Due to a lack of crucial information, important for the differential diagnosing process (Chapter 5.2), the cases were ending in death or prolonged and more advanced care (intensive care etc.). The choice of using problematic cases was inspired by the extensive amount of cases reported to HSAN for many years, where some kind of investigation performed by HSAN experts would reveal what had gone the wrong way and whose fault it was. However, in contrast to the aim of HSAN, the aim of the study is not to pinpoint individuals that make mistakes. Instead, the case study holds a systemic perspective on disastrous cases in Healthcare in order to identify information transferring errors and important subtle information structures previously unnoticed or ignored. Accordingly, the aim of the study is to look (in-depth) into two rather representative HSAN-cases, with a focus on workflow and information flow to understand what the actual reasons to failure were and how such errors might be prevented by ICT.

As already mentioned, a qualitative approach is adopted as it is necessary to grasp context in order to understand what really happens when information misses and breakdowns occur and why they occur. The basic method adopted for the study of the cases is (in situ, participatory) observation, as it is required to understand occurring

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40 HSAN= Hälso- och Sjukvårdens Ansvarsnämnd; Eng. Medical Responsibility Board
information flows the way the physicians and the patients understand them. The patients were followed both in Healthcare and in their homes that provided vast opportunities to notice and understand occurring information flows. Unstructured, open-ended, interviews (informal as well as ethnographic) were mixed with observations, which provided in-depth understanding when there was occurring information flows of special interest. Occurring events and reflections have been noted down (field notes), sometimes also by the patients and relatives in the study (personal notes and diaries). Additionally, the medical records were ordered by the patients/relatives; to be available for the study. The medical records reflected the simultaneous perspectives on the situations; accessible for Healthcare professionals to decide on in subsequent situations. Information, relevant for the cases, was marked in both notes from the patient/relatives data collection and the professionals’ data collection. Finally, information structures appearing in the medical records were compared to information structures appearing in the interviews and the diary notes, as well as in the field observations; sometimes analyzed and discussed together with the patient/relatives. By this “triangulation” methodology, an interesting discrepancy appeared: Information misses and breakdowns, as well as hidden information structures important for the cases, however not present in the medical records or if present even ignored or missed, were revealed.

Qualitative research is sometimes criticized for a lack of rigor in terms of validity and reliability. The criticism has been heavy concerning accusations of a lack of objectivity and generalization ability [Myers 2000]. There have been different answers to these questions as it has been debated for decades. However, criteria for quality of research such as validity, as well as reliability, are basically referring to quantitative methods such as the use of tests/questionnaires and measurements of (raw) data. In qualitative research, with a complex of different methods to address, questions of validity (internal and external) and reliability, as well as objectivity, must be approached differently; as a matter of establishing trustworthiness. With reference to a proposal of Lincoln & Guba [Guba 1981; Lincoln & Guba 1985], the table in Figure 12 illustrates four alternative criteria for evaluate trustworthiness in qualitative research. (This is more deeply elaborated in the Licentiate Thesis [Ådahl 2007].) The criteria proposed are in relation to corresponding criteria in quantitative research:

<table>
<thead>
<tr>
<th>Traditional Criteria for Judging Quantitative Research</th>
<th>Alternative Criteria for Judging Qualitative Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>internal validity</td>
<td>credibility</td>
</tr>
<tr>
<td>external validity</td>
<td>transferability</td>
</tr>
<tr>
<td>reliability</td>
<td>dependability</td>
</tr>
<tr>
<td>objectivity</td>
<td>confirmability</td>
</tr>
</tbody>
</table>

**Figure 12** – Criteria for judging quantitative resp. qualitative research [Trochim 2006].

In their proposal, Internal Validity in quantitative research answers to Credibility in qualitative research. Credibility is, shortly described, confidence in the “truth” of the findings. In the Case Study in Chapter 9, the participants (patients and relatives) were
in both cases involved in the data collection and analysis of data to correct or discuss observations and interpretations of situations. The case descriptions were also verified afterwards by patients and/or relatives. Furthermore, the cases are real, _authentic_, cases. Concerning External Validity, this is related to _Transferability_, which is to be able to show that the findings have applicability in other contexts (i.e. Generalization ability).

The results from the case study should be used for awareness of the importance of subtle patient specific information and design of tools for coherent visualization of such information; to enhance information management with the aim of increasing Patient Safety. This awareness is applicable in any situation of decision-making concerning diagnosing.

Reliability corresponds to _dependability_ that is to be able to show that the findings are consistent and could be repeated. Furthermore, the instruments (tools) used for data collection must be reliable. This concern the quality of both technical equipment and the human agents addressed for data collection (observers). The case study was performed as a participatory observation where the observer (the author of this thesis) is both an experienced nurse, familiar with the field (Healthcare), as well as close to the informants in the study.

The study has been carried on as a long-term investigation, with an open-ended exploratory approach; case I for 10 years and case II for 10 months. A vast amount of data has been collected for many observation hours, initially as (ad-hoc) diary notes, eventually transformed to more structured field notes. The perspective has been mostly from the patients, but simultaneously from a professional, reflecting, point of view. The observers close contact to the informants (patients/relatives) in addition to thorough knowledge about their lives and everyday life, in addition to wide experiences as a professional in Healthcare, made a deeper understanding of both fields possible. However, this fact results in reflections on the last point in the table that is objectivity, corresponding to _confirm ability_. This is to reach a degree of neutrality or “the extent to which the findings of a study are shaped by the respondents and not researcher bias, motivation, or interest” [Qualitative Research Guidelines Project]. For the case study, a basic requirement was to observe the situations unbiased to protect objectivity. The involvement of the patients/relatives in data collection and analysis of data should prevent biases and subjective interpretation of data, as well as the observer being sensible of the risk of being subjective.

To sum up the reasoning, the _rigor and validation_ of the qualitative research for this thesis is grounded in the _authenticity of the cases_ and the “triangulated” data collection methods and the subsequent in-depth analysis of the described situations and their contexts, involving both patients and relatives. Furthermore, the cases are “HSAN-typical”, representing situations where Patient Safety is jeopardized or even defeated and where single physicians earlier could have been punished without a systemic perspective on the situations. The study provides tangible examples of how important information flows rather invisible and unnoticeable behind medical cases and how a

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41 http://www.qualres.org/HomeLinc-3684.html (Retrieved 2011-11-08)
lack of such information, remaining “unknown unknowns” (Chapter 6.4), results in disastrous situations. The study points at a need for increased awareness of such subtle information flows, and extended awareness of the context in which they appear. The cases are few, but more importantly, they are very different, occurring in different times and in different contexts. Furthermore, the patients are opposite to each other with reference to age and diseases. Depending on the qualitative approach, only two cases, that is a substantially insufficient number of participants in quantitative studies, have provided rich information of information misses and breakdowns. The cases are representative for the vast amount of HSAN-cases, which stresses the question of whether the information deficiencies occurring in the cases might reflect a basic cause of incidents, injuries or deaths in many more similar cases before and after.

2.3 Methodology for extraction of Research Questions
In Chapter 3.2 we present the following three Research Questions (RQs):

RQ1: What aspects of information misses and breakdowns in Healthcare systems have to be properly addressed to ensure interoperability?

RQ2: Which principles are crucial to ensure interoperable support and empowerment of patients?

RQ3: Which principles of healthcare systems are crucial to ensure Patient Safety and Healthcare Empowerment?

To address RQ1 we will select methodologies allowing us to pinpoint and remedy information breakdowns and misses of workflows in Healthcare. We will use the qualitative methodology described in Chapter 2.2. Our suggested solution – Chapter 10, Visual Incidence Anamneses (VIA) - to improve interoperability and Patient Safety is based on visualization of information. Visualization is a method to emphasize and utilize human visual perception. To some extent, visualization of information is related to the theories behind Gestalt psychology, which is a holistic theory. Configurationism is synonymous with this and a “theory of psychology that emphasizes the importance of configurational properties”42. Human mind tend to interpret data as patterns in a holistic context, not as discrete units. Another branch is Pattern Recognition in psychology. This is an innate ability of biological agents such as humans. However, in large amounts of data, the patterns are obscured. Furthermore, when human mind creates a pattern on discrete units of data it might be false. A variant is the human tendency to seek patterns in random data, even if there are no patterns. This phenomenon is referred to as Apophenia; in statistics referred to as Type I Error.

These theories provide an insight into how visualization of “transferred information” (the meaning of data) could help the receiver of data (representations of the information transferred) to interpret data as close to the meaning of data as possible. To create a configuration of data, such as computer graphics, should guide the mental process (gestalt creation) in the intended direction or as close to reality as possible. Visualization of information should therefore be a remedy for information

42 http://dictionary.reference.com/browse/configurationism
misunderstandings or misses. The task of grasping the basic and true meaning of data at a glance, even large amounts of data, could be supported by information visualization techniques. For example, in Healthcare, this is utilized by the development of medical imaging. To that end we address some Design principles for visual communication in Chapter 2.4, below. Those principles will also be taken into account in addressing RQ2 and RQ3.

2.4 Design Principles for Visual Communication

“Diagnosis is the identification of the nature and cause of anything. Diagnosis is used in many different disciplines with variations in the use of logics, analytics, and experience to determine the cause and effect relationships. In systems engineering and computer science, diagnosis is typically used to determine the causes of symptoms, mitigations for problems, and solutions to issues.” [Singh 2010] 43

This opening citation emphasizes the causality aspect in the diagnosing procedures. Diagnosing is basically a key to Patient Safety, as successful treatments depend on correct medical diagnoses. In DiagnoseDisease.com this is described as follows:

“Medical diagnosis refers to the process of attempting to determine and/or identify a possible disease or disorder and the opinion reached by this process. From the point of view of statistics they are classification tests. The term diagnostic criteria designate the combination of signs, symptoms, and test results that the clinician uses to attempt to determine the correct diagnosis.”

The process of diagnosing is actually the use of methods. Singh [2010] explains different diagnosing methods of as follows:

"Exhaustive method
Every possible question is asked and all possible data is collected.

Algorithmic method
The provider follows the steps of a proven strategy.

Pattern-recognition method
The provider uses experience to recognize a pattern of clinical characteristics.

Differential diagnosis
The provider uses the hypothetic-deductive method, a systematic, problem-focused method of inquiry.”

He also claims “The advanced clinician uses a combination of the pattern-recognition and hypothetic-deductive approaches” [Singh 2010]. This is crucial to our approach to Information Visualization, as it basically is related to Pattern Recognition in psychology (Chapter 2.3). In Chapter 5, we give an overview of Decision Making Principles such as Differential Diagnosing and in Chapter 6 we address some design principles of Clinical Decision Support Systems (CDSS). Our suggested tool VIA

44 http://www.diagnosedisease.com
(Chapter 10) is based on proper visualization of the current and past states of a diagnosis. Visualization of information has become a key area in design and implementation of information sharing tools and systems. A recent issue of Communications of the ACM [ACM April 2011] gives an overview of Design Principles for Visual Communication [Agrawala et al.2011].

The following three stages of design and implementation of user centric visual communication systems are identified [Agrawala et al.2011]:

1. Identify Design Principles
2. Instantiate Design Principles
3. Evaluate Design Principles

In the following verbatim citation [Ibid], we refer to findings of relevance for design, implementation and validation of our VIA tool. That is, a next generation CDSS supported by visual tools for empowerment of stakeholders in extended diagnosis supporting “what – if” reasoning and explanations:

“Visual communication via diagrams, sketches, charts, photographs, video and animation is fundamental to the process of exploring concepts and disseminating information. The most effective visualizations capitalize on the human facility for processing visual information, thereby improving comprehension, memory, and inference. Such visualizations helps analysts quickly find patterns lurking within large data sets and help audiences quickly understand complex ideas.

Key insights communicated are:

Design principles connect the visual design of the visualization with the viewer’s perception and cognition of the underlying information the visualization is meant to convey. Identifying and formulating good design principles often requires analyzing the best hand – designed visualizations, examining prior research on the perception and cognitions of visualizations, and, when necessary, conducting user studies onto how visual techniques effect perception and cognition.

Given a set of design rules and quantitative evaluation criteria, we can use procedural techniques and/or energy optimization to build automated visualization design systems.

Skilled visual designers manipulate the perception, cognition, and communicative intent of visualizations by carefully applying principles of good design. These principles explain how visual techniques can be used to either emphasize important information or de-emphasize irrelevant details; for example, the most important information in a subway map is the sequence of stops along each line and the transfer stops that allow riders to change lines. Most subway passengers do not need to know the true geographic path of each line. Based on this insight, map designer Harry Beck redesigned the map of the London Underground in 1933 using two main principles: straightening the subway lines and evenly spacing the stops to visually emphasize the sequence of stops and transfer points.

Such design principles connect the visual design of a visualization with the viewer’s perception and cognition of the underlying information the visualization is meant to convey. In the field of design, there is a long-standing debate regarding the interaction of aesthetic and functional properties of designed artifacts. We do not seek to engage in this debate here; rather, we focus on how particular design choices affect the perception and cognition of the visualization, not the aesthetic style of the visualization. Accordingly, we use the term “design principle” as a shorthand for guidelines that help improve viewers’ comprehension of visually encoded information.
Design principles are usually not strict rules, but rules of thumb that might even oppose and contradict one another. For instance, Beck did not completely straighten the subway lines; he included a few turns in them to give viewers a sense of a line’s overall spatial layout. Skilled visual designers implicitly apply the relevant design principles and balance the trade-offs between them in an iterative process of creating example designs, critiquing the examples, and improving the designs based on the critiques. Designers usually do not directly apply an explicitly defined set of design principles. The principles are a form of tacit knowledge that designers learn by creating and studying examples. It is far more common for books on visual design to contain visual examples rather than explicit design principles.” [Agrawala et al.2011]

Of specific interest for us in the VIA context is to visualize causality and causal chains. The following illustration in figure 13, from the cited article [Agrawala et al.2011], illustrates one approach: “(a) use motion arrows and frame sequences to convey the motion and interactions of the parts within a mechanical assembly. Our system analyzes a geometric model (b) of a mechanical assembly to infer the motion and interactions of the parts, then generates the motion arrows and frame sequences (c–d) necessary to depict how the assembly works.” [Agrawala et al.2011]

Figure 13 - "Hand-designed “how things work” illustrations” [Agrawala et al.2011]

The basic idea of visualization by the VIA tool is to identify casual chains of diagnosis that allows alternative explanations (Chapter 10.3). The drivers of the causal chain models correspond then to basic rules.

However, before we finally present our proposal VIA in Chapter 10 with the Conclusions in Chapter 11, we will initially, in the next chapter (Chapter 3), present the research questions for this thesis. The research questions are addressed by the methodology described in this chapter (Chapter 2), and the analysis of the cases is then presented in Chapter 9. Furthermore, in Chapter 8 we present the preparatory study, preceding the creation of the Research Questions. In Chapter 3, we present the problem area and relate previous and current research to the questions. The methodology described in this chapter is addressed.
Chapter 3 – Problem Definition

In this chapter, barriers to successful diagnoses and treatment, threatening to Patient Safety, are presented. The basic challenge is support of detection, analysis, and repair of information breakdowns. The perspective proceeds from the patient as important cooperator in a “personalized” care. Three research questions are formulated and presented to meet this, paying attention to Interoperability as a basic requirement.

3 Introduction

Healthcare as an organization is not infallible. Neither are humans. Despite best possible intentions and high ambitions, serious mistakes are made. In information intense environments as Healthcare is, information must be managed very carefully. With reference to a large number of reports to HSAN, information misses and breakdowns in Healthcare intermittently occur and, what is even worse, relatively small pieces of lost information somewhere in the course of the illness might result in serious or even lethal consequences (Study I and II, Chapter 9). Obviously, this missing information is sometimes unintentionally kept by the patient, not being aware of the importance of the information, but also sometimes it is reported and delivered to Healthcare personnel but not, for some reason, noticed, utilized and transferred into the EHR-system. The human agents acting in Healthcare (i.e. personnel) must act as “active links in the chain” to maintain an unbroken line of actions for treatment of the patient; from the diagnosing phase to the decision, delivery and follow up of treatment. These actions are based on the information available. If this information is incomplete, or even wrong, the intervention (or lack of intervention) could cause severe incidents or even deaths. Furthermore, the concept of Simplicity in the shape of Ockham’s (Occam’s) Razor, later explained more in detail in Chapter 5.4, permeates Healthcare and complicates the task of collecting critical information. Ockham’s Razor, i.e. the Law of Diagnostic Parsimony, which more trivial is expressed in the well-known medical adage “When you hear hoof beats, think Horses not Zebras”. Reports to HSAN reveal many cases where rare diagnoses (zebras) were lost as more nearby diagnoses seemed to be more probable (Appendix 2). Algorithms for clinical decision support are often based on a probabilistic ground, reflecting statistically probable diagnoses that actually stress the necessity of extreme accuracy in the input of relevant and sufficient data (i.e. patient specific information). The EHR-systems developed for the Healthcare sector generally lack functions to support the task of reconciling incomplete information structures to identify “Zebras” when they occur. As a matter of fact, we always have to deal with incomplete or irrelevant information in Healthcare! A clear overview of earlier medical histories is often insufficient or even absent, particularly evident for EHR-systems compared to the earlier paper based medical records with reference to quick overview, i.e. lucidity. Clinical Decision Support Systems (CDSS) are designed to process input of patient specific information in reflection of statistic data and evidence based medicine (EBM). However, as the collection of input is not
supported by EHR systems and much is dependant on individual human agents such as ad hoc actions of physicians, the input of data to CDSS is not secured and, as a consequence, jeopardized.

In this thesis, we basically address the Interoperability Framework (Figure 1 Chapter 1) and Decision-Maker’s Interoperability Checklist\(^{45}\), proposed by the GridWise Architecture Council (GWAC), as we consider Interoperability as a basic requirement and prerequisite for validated healthcare systems. GWAC explains the nature of Interoperability as follows:

“There are three types of Interoperability. Technical Interoperability covers the physical and communications connections between and among devices or systems (e.g. power plugs and USB ports). Informational Interoperability covers the content, semantics, and format for data or instructions flows (such as the accepted meanings of human or computer languages and common symbols). Organizational Interoperability covers the relationships between organizations and individuals and their parts of the system, including business relationships (such as contracts, ownership, and market structures) and legal relationships (e.g. regulatory structures and requirements, and protection of physical and intellectual property). All three types must be addressed to achieve effective interoperability in any system.” [GRIDWISE Architecture Council Policy Team 2007]

According to GWAC’s proposal, all three types of Interoperability must be addressed. However, in this thesis we are solely focusing the Organizational and Informational categories and selected cross-cutting issues related to Patient Safety. Further on, we will develop our apprehension of this perspective and explain its impact on the focus of our research (i.e. Research Questions).

\{3.1 Problem area\}

As explained above, Information misses as well as Information breakdowns in Healthcare is considered as highly threatening to Patient Safety. Patient Safety is jeopardized by two main types of errors: errors of omission and errors of commission, where errors of omission outnumber the latter by two to one [Weingart et al. 2000]. Accordingly, the number of errors that is missed diagnoses, misdiagnoses, delay of evaluation and treatment or wrong treatment is relatively large. Studies on necropsy reports compared to clinical diagnoses reveal findings such as unexpected severe illness in 44% of the cases and discrepancies between necropsy reports and the clinical diagnoses in 26% of the cases [Ibid]. Furthermore, these numbers has remained basically unchanged for at least four decades [Ibid].

In this thesis we focus on diagnosing as the basic element for Patient Safety in Healthcare. Relevant and correct information, presented in an unbroken flow coordinated to fit work flow, is decisive in order to identify the right diagnoses as well as the right treatment. This is clearly related to aspects of Interoperability, both referring to the Informational and to the Organizational categories. Our apprehension of the differences between information misses and information breakdowns are basically that information misses address information that is crucial for Patient Safety but not

reported, understood or transferred and therefore not used. Information breakdowns are the result of a more general collapse of information flow in relation to work flow. In a complex organization such as the Healthcare sector, in which daily activity is highly rich of information structures and information handling tasks, both misses and breakdowns in the flow tend to occur. Unfortunately, the utterly promising vision of the ICT revolution in Healthcare, both as a remedy for earlier short comings of the paper based medical records as well as the potentially usefulness of new IT features, has not completely met the expectations of an increased Patient Safety. Neither has the developing area of medical technology, today closely connected to (often embedded) ICT systems, nor the ICT systems themselves, been the complete answer to increased concerns of Patient Safety. Instead, new threats have occurred, notably in areas of information security and integrity, where others have disappeared. These threats are connected to varying aspects of Information and system management.

According to this complex of problems, we assert that insufficient Information interoperability is central for the threats to Patient Safety. This is valid for the interoperability of ICT systems, technically, but also from an organizational and informational viewpoint. Stove-pipe architectures obstruct the development towards safer information management, and work flow is not properly supported by existing protocols, with reference to the methods for collection and use of patient specific information or decision support for varying interventions. In this thesis, we focus the organizational and informational part of the interoperability aspect, trying to provide a feasible solution for the collection of patient-specific data to be used in decision support for diagnosing tasks. We claim that patient-specific information must be considered central and extremely important for any decision, as it is the key to distinguishing “Zebras” from “Horses”. As a consequence, the patient must be regarded as a first class stakeholder in Healthcare, being able to contribute with information for the specific case both passively (patient data collected by actions of human agents in Healthcare and Medical Technology/ICT) and actively (refined anamneses and protocols for collection of patient carried information). For the latter, we propose a tool for participatory medicine (VIA, Chapter 10), to support decisions in cooperation with the patient for input of relevant and critically important data to existing CDSS. The design, implementation and maintenance of the VIA tool is based on analysis of our three Research Questions in the next section.

3.2 Research Questions
The research questions (RQs) formulated for this thesis are grounded in empirical studies, experiences and conclusions, initially derived from the Preparatory Study presented in a Licentiate Thesis [Ådahl 2007] (Chapter 8). Furthermore, they have emerged from discussions in frequent seminars in our research group Societies of Computation (SoC), established 1995 at BTH. Later, in 2009, SoC become a part of the Communication and Computer Systems Research Laboratory46 (CCS-Lab). The formulation of the RQs are distilled from the discussions in these seminars, and grounded in reflections and conclusions from the earlier work performed for the

Licentiate Thesis. We have identified a number of Challenges (Requirements) related to trustworthy information sharing in groups [Ådahl, Lundberg, and Gustavsson 2009]. These Challenges were, not surprisingly, similar to rather comprehensive and basic requirements of Innovative Health information sharing Channels\(^{47}\) (IHCC) (Figure 14), a model we proposed to ensure Patient Safety in future distributed Healthcare (domiciliary care and participatory medicine approaches) systems [Ibid] (Figure 14). The IHCC model is designed to meet some of the aspects identified as threats to Patient Safety [Socialstyrelsen 2008]; that is, to align with the current ambition of Interoperability in e-Healthcare.

![Health care team](image)

**Figure 14** - Challenges and requirements of Innovative Health information sharing Channels

The requirements that kind of Healthcare Information System can be expressed as the following five Challenges:

Challenge 1 concerns **trustworthy conveying of representations of information**, by the IHCC. For this purpose, we address Situation Theory (InfoSense) [Devlin 2001] (Chapter 1.2); i.e. the concept of information and information sharing in contexts, i.e., *interpretation* of representation by human agents. Challenge 2 focuses on **support of workflows** or transactions between situations, in this thesis concerning hand-over situations in which an unbroken information flow is momentous (Chapter 9.4).

Challenge 3 involves **support of detection, analysis, and repair of breakdowns**.

Challenge 4 focuses on **support of validation** of procedures (protocols) and

Challenge 5 points at the need for **learning** in teams. Challenge 3, 4 and 5 are instrumental as they obviously should improve Patient Safety, however, for this purpose, critically dependant on Challenge 1 and 2.

\(^{47}\) Channel = “…a means of communication or expression: as (1); a path along which information (as data or music) in the form of an electrical signal passes”. Merriam Webster’s Online Dictionary. www.merriam-webster.com
Interoperability (Chapter 1), onwards constituting the base of discussion, is central for our direction in this thesis. In our perspective, we consider interoperability as crucial for safe information management in Healthcare and, accordingly, for Patient Safety. Consequently, grounded in this standpoint, the identified challenges, former conclusions [Ådahl 2007] and experiences shared at the Vitalis Conferences\(^{48}\) 2008, 2009 and 2010 in Gothenburg, Sweden, we finally formulated the following three Research Questions:

RQ1: What aspects of information misses and breakdowns in Healthcare systems have to be properly addressed to ensure interoperability?

RQ2: Which principles are crucial to ensure interoperable support and empowerment of patients?

RQ3: Which principles of healthcare systems are crucial to ensure Patient Safety and Healthcare Empowerment?

The first RQ addresses interoperability in relation to information misses and breakdowns in Healthcare. This question is answered by the presentation of aspects of such misses and breakdowns that is crucial to highlight and prevent in order to avoid defective interoperability. The Case Study (Chapter 9) will make the RQ more tangible by connecting it to Real World. Referring to the Interoperability Context setting Framework, proposed by the GWAC (Figure 1) (Chapter 1), RQ 1 is directly addressing the Informational category.

The second RQ is addressing Participatory Medicine and the Empowered Patient (Chapter 7.1 and 7.2). Basically, this RQ brings about current ambitions of Health Literacy (Chapter 1.3) important for Patient Safety (Chapter 1.4). Also, Interoperability is crucial for an adequate and unbroken information flow between the Patient and Healthcare personnel such as physicians.

Finally, the third RQ addresses the design of tools supporting Patient Safety and Healthcare Empowerment. The design must comply with the answers of RQ1 and RQ 2 to support Interoperability of Patients and Healthcare. Accordingly, two aspects of Interoperability are, with reference to the results of the Preparatory Study (Chapter 8) most decisive; Interoperability of information flowing within Healthcare and Interoperability of information flowing between Patients and Healthcare. The Preparatory study revealed commonly occurring deficiencies in such flows. Therefore, systems developed for Healthcare to support Information exchange and utilization should be developed with the aim of ensuring an unbroken flow of information. This, in turn, results in increased Patient Safety and Empowerment of Healthcare. RQ3 will be answered by our proposal in Chapter 10, the Visual Incidence Anamnesis (VIA). In the

\(^{48}\) Vitalis Conference and Fair: “Meeting place for the development of Health Care and care through IT, also the exchange of knowledge and a unique opportunity for dialog and important discussion on the future of Health Care and care, and how visions can become reality”. http://www.vitalis.nu/ (Retrieved 2011-05-26)
next section (Chapter 3.3), we will explicitly connect previous research to the current. We elaborate on the RQ by relating them to former publications. The matrix illustrates this scenario.

### 3.3 Previous and Current Research related to RQ 1-3

In this section, previous research to be regarded as a foundation for this thesis is presented. The research is represented as papers for conferences and book chapters, and the Licentiate thesis, defended in 2007. The following matrix shows this in chronological order, referring to the research questions and chapters of this thesis, with the starting point in 2001:

<table>
<thead>
<tr>
<th>Publication</th>
<th>RQ</th>
<th>Doctoral Thesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ådahl, Kerstin (2001) “Living and Learning in Virtual Health Communities on the Internet - breaking new grounds for future treatment strategies?” presented at 2nd Nordic-Baltic conference on Activity Theory and Sociocultural Research, Blekinge Institute of Technology, Ronneby, Sweden. 7-9 September 2001</td>
<td>1, 2, 3</td>
<td>Chapter 1.3, Chapter 7.1, Chapter 7.2</td>
</tr>
<tr>
<td>Kyhlbäck H, Ådahl K (2003) “Design of learning in wound care treatment by use of peer-to-peer computing and medical ontology” Paper revised for CHI2003 conference</td>
<td>1, 3</td>
<td>Chapter 1, Chapter 6</td>
</tr>
<tr>
<td>Ådahl, K. (2003) Active Care Recipients - Medical Virtual Communities supporting Learning among Laymen and Pros. Paper accepted to the IRIS26 Conference 2003</td>
<td>1, 2, 3</td>
<td>Chapter 1, Chapter 10</td>
</tr>
<tr>
<td>Ådahl K. (2006) Validation of Transparency in eHealth – Turning Information Visible through Design Paper (Keynote), accepted to the IRIS29 Conference 2006</td>
<td>1, 2, 3</td>
<td>Chapter 1, Chapter 5</td>
</tr>
<tr>
<td>Gustavsson R, Lundberg J, Rindebäck C, Ådahl K (2007) Functional versus non-functional requirements considered harmful Paper, accepted to SERP’07 (WORLDCOMP’07)</td>
<td>1, 3</td>
<td>Chapter 1, Chapter 10</td>
</tr>
<tr>
<td>Ådahl Kerstin (2007) Transparency of Critical Information for Patient Empowerment in eHealth Blekinge Institute of Technology, Licentiate Dissertation Series No. 2007:03</td>
<td>1, 2, 3</td>
<td>Chapter 1, Chapter 10</td>
</tr>
<tr>
<td>Ådahl K (2008) Approaching Humane Health Care Information Systems Paper, revised for NordICHI2008</td>
<td>1, 2, 3</td>
<td>Chapter 1, Chapter 2</td>
</tr>
<tr>
<td>Ådahl K, Lundberg J and Gustavsson R (2009) Innovative Health Care Channels - Towards Declarative Electronic Decision Support Systems focusing on patient security in proceedings of ICEIS 2009</td>
<td>1, 2, 3</td>
<td>Chapter 1, Chapter 6, Chapter 10</td>
</tr>
</tbody>
</table>
The matrix illustrates relations for each of the publications to the RQs and for each of them relations to varying chapters of the current thesis. However, the relations to the RQ are of slightly different perspectives depending on the chronological order. In 2001, we focused basically at Apomediation (Chapter 1.3), at that time a rather new phenomenon, by describing the “awakened” patient, i.e. the active patient, suddenly inhabited in Virtual (online) Health Communities on the Internet. These forums provided revolutionary new possibilities to interact and learn from peers; other patients and sometimes Healthcare Workers acting off duty at leisure time from interest in the matter. This new, altered, patient, trying to become Health Literate (Chapter 1.3), announced new directions in Healthcare to come as the patient began to act participatory. We claimed that this would affect the entire hierarchic Healthcare structure and change Healthcare in the future.

Our initial research on this aspect was for the very first time presented at a seminar on Design, Implementation, and Use of New Technologies at the 2nd Nordic-Baltic Conference on Activity Theory and Socio-cultural Research in September 2001. This presentation attracted considerable attention to the field and constituted from then on the starting point for our further research in the area. The underlying paper [Ådahl 2001] brought an early idea of Participatory Medicine in terms of Interaction as the critical point for improved Healthcare:

“But still, even if extended information about a specific disease is valuable for both care providers and care receivers, interaction seems to be even more indispensable in order to improve treatment or life quality.” [Ådahl 2001]

The paper was grounded in participatory observations of some medical patient communities and interviews. These studies resulted in a conclusion of a new fast growing trend of interaction and an aim of becoming Health Literate. Conclusively, the paper addressed the importance of information sharing (RQ1) as well as learning and empowerment of patients for the improvement of quality of care (RQ2), to empower future Healthcare. In 2001 the central point was not clearly on the interaction between patients and Healthcare. Instead, we initially focused interactive learning activities from the perspective of peers. Patients would learn from patients in online patient communities and Healthcare professionals shared experiences in their virtual settings.

However, we also brought the idea of the empowered patient as a cooperator in Healthcare (Figure 15). In this view, and regarding RQ3, we dealt with different perspectives on Healthcare Information Systems supporting information flows; for example using information sharing technologies such as peer-to-peer (P2P) to interact (file sharing) or mobile technology for home Healthcare (Figure 15).
In 2001, we also participated in the project *Alfebiite* which concerned approaches to Universal Information Ecosystems (UIE) and brought issues of trust regarding a user-friendly information society, where citizens are ensured not to be exploited, statutory and consumer rights are protected and information privacy not violated [Alfebiite 1999]. This is in some sense related to the basic Virtual (Online) Communities (VC) direction with Trust as the foundation for usability: Trust in artifacts for Information Management in Healthcare is basically an important prerequisite for usability of such artifacts as the willingness of using them depends on trust. This is evident both for patients, able to use empowerment-supporting artefacts and for Healthcare personnel, to be motivated to use for example artefacts for decision support. A deliverable for our research group (SOC) in the project was a book chapter, where the approach was elaborated in the context of Home Healthcare (Home to Health, H2H) [Gustavsson, Fredriksson, Rindebäck Kyhlbäck & Ådahl 2001].

To sum up, we concluded in 2001 that Healthcare would be affected by the empowered patient, able to suggest new treatment strategies and take part in work flow. This initial line of research, basically focusing the Apomediation phenomenon, was continued the years to come. In 2003, in a paper accepted for the IRIS26 conference [Ådahl 2003], we presented a more specified study on an online virtual community, “Parents Net” (in Swedish “Föräldranätet”, today “Allt För Föräldrar”), in a forum concerning medical information exchange about congenital heart conditions. In this study, using qualitative methods such as participatory observation, we identified methods of acquiring Health Literacy among the inhabitants of the forum. We also assumed that Health Literacy among patients obviously might influence the outcome of treatment, basically affecting}

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safety in a positive way. The members of the online community were frequently telling their stories, sharing experiences and medical treatment or strategic advises, to actively try to avoid errors to occur. In this sense, RQ 1 and RQ 2 were embraced. Regarding RQ3, the phenomenon of online communities as a resource in Healthcare was emphasized.

In 2003, we also continued with the idea of using P2P computing as information management technology. However, we were now focusing the use of the technology regarding Healthcare professionals in municipal elderly care, i.e. the use of P2P by professionals to empower Healthcare. This study concerned wound care treatment (of varicose ulcers and similar) supported by digital images of the wounds, shared in the nurses working team. To visualize information from the medical record about each of the patients’ individual wounds, digital images were created and shared. This method turned out to be successful. The wounds could be followed over time as the stages of healing could be visually compared. The paper [Kyhlbäck & Ådahl 2003], revised for CHI2003, addressed RQ1 and RQ3, however not RQ2. The benefit of (coherent) visualization of medical information, as a method for information management in Healthcare, was initially identified, avoiding misinterpretation of information and subsequent misunderstandings (information misses) to occur. In this case, the effect of treatment was visualized.

The next, for this thesis more important, “milestone” in the research process was a study on information management from a bilateral (patient – professional) perspective conducted in 2006-2007 (Chapter 8). The study was performed at the Department of Paediatric Cardiology at SUS51 Lund (Skåne University Hospital in Lund) directed to professionals in Healthcare and their apprehension and experience of Information handling issues. The study also comprised the patient perspective by involving the Swedish Heart-Childrens Association and the forum earlier addressed in 2003:

| 1 | Department of Paediatric Cardiology at the University Hospital in Lund, Sweden |
| 2 | Department of Cardiology at the University Hospital in Lund, Sweden; GUCH section = Grown-Up Congenital Heart Disease. |
| 4 | “All for Parents”52 Online forum for parents. Discussion area: Children with Functional Disorders/Heart Conditions. http://www.alltforforaldrar.se/ |

This study resulted in a paper; “Validation of Transparency in eHealth – Turning Information Visible through Design” [Ådahl 2006], accepted to the IRIS29 conference

51 SUS = Skånes Universitetssjukhus, eng. Skåne University Hospital (in Lund). Former “The University Hospital in Lund”. One of the regional hospitals in Sweden.
52 “All for Parents” is an online virtual community, with many sub communities. One discussion area is inhabited by parents to children with Congenital Heart Conditions, sometimes also by the children at greater ages. (Retrieved 2011-06-21 http://www.alltforforaldrar.se/snack2/forumdisplay.php?f=77)
2006, commended and chosen to be presented as a keynote. The paper constituted the basis for the Licentiate Thesis “Transparency of Critical Information for Patient Empowerment in eHealth” [Ådahl 2007] the year after. The basic, general, conclusion for both the paper and the thesis was that the patient, as an important information carrier, must be empowered as a collaborator by gaining insight into information in workflow (transparency if information) to be able to act when needed. A model (KIVIC) and a design suggestion, Empowerment Systems was the result [Ådahl 2006, 2007], addressing RQ1, RQ2 and RQ2.

In 2007, we also presented a paper at SERP’07 (WORLDCOMP’07): “Functional versus non-functional requirements considered harmful” [Gustavsson, Lundberg, Rindebäck & Ådahl 2007] on requirement elicitation and requirement engineering in system design, implementation, and maintenance. We addressed software intensive distributed socio-technical systems (such as trusted workflows in life-critical situations or information sharing support systems) and claimed that the division between functional and non-functional requirements is difficult and even harmful to maintain. As an alternative, we proposed a more principled and context dependant approach towards requirement engineering and high-level system validation. This corresponds to our approach to design of tools for Decision Support and related, to some extent, to RQ 1 and 3.

In 2008, a paper was submitted to NordiCHI2008: “Approaching Humane Health Care Information Systems” [Ådahl 2008]. The paper introduced “Humane Health Care Information Systems” as a design concept for what we at that time referred to as “Collaborative Healthcare”: involving both Patients and Healthcare professionals in collaboration. This paper was kind of experimental, but actually constituted the starting point for us approaching Healthcare Empowerment and the work with the current Doctoral thesis. The reflections of this paper addressed RQ1-3.

Next step towards the focus of this thesis was entered by means of the paper “Innovative Health Care Channels - Towards Declarative Electronic Decision Support Systems focusing on patient security” [Ådahl et al. 2009] presented at ICEIS 2009. The paper initiated our current direction of a focus on Decision Support in Healthcare, addressing the challenge of how to trustworthy convey and analyze the large amounts of information available in Healthcare contexts. The paper started a more explicit turn also to a professional Healthcare perspective, in contrast to the already established Patient perspective we had. Our approach in the paper was towards a context dependant information-modeling framework, supporting validated quality of information sharing in Healthcare settings. Protocols, at different system levels, were addressed as a method to design and implement intelligible information sharing structures. RQ 1-3 was addressed also in this paper.

Consequently, the paper resulted in further work on Clinical Decision Support Systems, not only as this Doctoral Thesis primarily focuses CDSS but also by means of a book chapter in 2011. The book chapter was “Decision Support by Visual Incidence Anamneses for increased Patient Safety in “Efficient Decision Support Systems:
Practice and Challenges in Biomedical-Related Domain” [Ådahl & Gustavsson 2011] published in September 2011. The book chapter is attached to this thesis, as an appendix. In this publication, the research questions (RQ1-3) are addressed most explicitly as it constitutes the heart of the dissertation, embracing the basic direction.

In the next Chapter, we will stress the turn to a systemic perspective in Patient Safety work in Healthcare. Basically, this turn is the foundation for the RQs; the aim and the research for this thesis.
Chapter 4 – Models of Improving Patients Safety. A Change of Focus.

In this chapter, we put emphasis on Patient Safety in Swedish Healthcare, accentuating the benefits of adopting a systemic perspective on faults.

4. Introduction

In Sweden, a prevailing strategy to follow up and prevent faults in Healthcare has been to “find and punish” registered individuals (such as registered nurses, physicians etc.). The main idea was to identify and punish the individual causing the identified faulty treatment. This approach of increasing Patient Safety has, however, several shortcomings. HSAN (Hälso- och Sjukvårdens AnsvarsNämnd; Eng. Medical Responsibility Board) has until 2010 received numerous cases each year to evaluate and take appropriate measures. However, a new Patient Safety Law (SFS 2010:659) came into force January 1st 2011 (Chapter 1.4). One of the consequences of this law is that Socialstyrelsen (the National Board of Health and Welfare) has shouldered the responsibility for assignments related to Patient Safety cases. Accordingly, HSAN is today a panel of lay assessors, where Kammarkollegiet\(^53\) is responsible for the administration of the HSAN cases. The role of HSAN is to test and examine the qualification of Healthcare personnel in cases where this is questioned. This is by order of Socialstyrelsen and directly related to Patient Safety cases. As a result, the Patient is no longer assigning HSAN directly. Instead, the Patient is encouraged to send any complaints\(^54\) to the Operations Manager, the medical care administration, the Health and Medical Advisory Board or the Patients’ Advisory Committee. The new law is a result of a change of perspective towards the perspective of fault prevention in the Healthcare sector, i.e. towards a “systemic perspective” on each situation. As a result, the strategy adopted is to focus on a basic change of models and methods to address shortcomings in protocols, procedures and in information management in Healthcare. Especially noticeable is that the new law also embraces the encouragement of patients and their relatives to actively participate in the Patient Safety work. This is a step forward to turn Patient Empowerment into Participatory Medicine, with legal support. Furthermore, this turn also supports Interoperability aspects in Healthcare.

4.1 Find and punish individuals causing the faults

When problems occur, people do not like to blame themselves. They will thus actively seek scapegoats onto whom we can displace our aggression. These may be out-group

\(^{53}\) “…the Agency is a modern organisation which not only exercises public authority but also operates commercial undertakings. Our tasks cover an extensive area and mainly involve activities that require qualified legal and economic expertise.” (http://www.kammarkollegiet.se/english)

\(^{54}\) http://www.socialstyrelsen.se/reportingmalpractice
individuals or even entire groups. Like bullies, we will often pick on powerless people who cannot easily resist. Scapegoating increases when people are frustrated and seeking an outlet for their anger. Once cast as a scapegoat it can be difficult to shake off the classification. The only rational for trying to establish the responsible individual causing a wrongdoing is, of course, if legal actions have to be taken. However, finding scapegoats has itself very little, if anything to do with increasing Patient Safety. Nevertheless, in cases where personnel is apparently disqualified for the task they are assigned, HSAN is still testing and examining individuals in Patient Safety cases. The critical point in Healthcare now, to fight against the large number of Patient Safety cases, is to **change the organizational perspective** which before has not been questioned, tested and examined. This is in line with how the Transport Sector for years has examined accidents. For example, the aviation industry focuses on the study of work practice, routines, and technology in cases of plane crashes. This is not a hinder for the discovery of individual incompetence and lack of qualifications. One recent example of this is Air France flight 447, which crashed into the Atlantic in 2009. However, the organizational perspective is always important also in cases where there are signs of individual faults. In the aviation industry, both perspectives are present. The recent approach in Healthcare is not to exclude the individual responsibility, but to approach a systemic view to prevent individual faults to happen.

**4.2 Find and harness flaws in work flow processes causing faults**

Since the new Patient Safety Law (SFS 2010:659) came into force January 1st 2011, the perspective on efforts to increase Patient Safety has changed. From a focus on personal responsibility when incidents, injuries and deaths occur, the focus now is on the organization; a systemic view on fault prevention. A **proactive strategy** to increase Patient Safety is to **find and harness flaws in Healthcare workflow processes**. Remedies are very context dependant and can range from education to improvements of technologies, procedures or protocols. Workflow comprises aspects of information flow. An unbroken flow of relevant information is crucial for Patient Safety. However, the central role of **information management** demands that new tools have to be in place to **monitor and identify information processing flaws**. Since important parts of this information processing is done by individuals or by teams, tools aiming at **empowerment of individuals and their cognitive abilities are central**. Consequently progress in the areas of **interoperability and visual communications** are crucial enablers for increased Patient Safety. Unfortunately, this area is still rather unexplored. Attempts have been done, related to visualization of information to support workflow. One example is ASME\textsuperscript{55} (Chapter 10.2), visualizing information from the EHR related to 3D images of the body. Another example of attempts in this area is HealthVault\textsuperscript{56} (Chapter 1.3, 7.2, 10.2), a platform where data about the personal health status can be shared with the physician.


\textsuperscript{56} Microsoft Health Vault, launched in September 2007.
Chapter 5 – Decision Making Principles.

In this chapter, we present some decision making principles such as EBM, Differential Diagnosing and The law of Diagnostic Parsimony. Such principles are all decisive for Patient Safety.

5. Introduction

Decision Making in Healthcare (Chapter 5.3) is to use general and/or specific information processing methods in order to make the right diagnoses and decide on appropriate interventions such as treatments etc. for a patient. Various types of Clinical Decision Support Systems (CDSS) (Chapter 6.2) have been developed to support this task. However, a CDSS basically make automatic processing of input data and present the results to the user. The key words here are:

- Automatic processing
- Input data
- Presentation

The strengths and weaknesses of present day CDSS are attributed to the meaning, in interoperability terms, of those concepts (Chapters 1, 1.1, 1.2). A typical CDSS session includes input of data, off-line automatic processing, and non-interactive presentation of results. The shortcoming of those tools are quite obvious and have led to our proposal of the VIA tool of Chapter 10.

The quality and role of input is a critical point in the decision support process. The selection and collection of input data to a CDSS is typically performed by a physician, initially performing an investigation of the situation at hand and potential causes. To that end, the physician performs an interview with the patient and/or relatives to the patient, resulting in an anamnesis\(^5\). Consequently, the anamnesis is a preliminary case history from the patients’ perspective. In this step, the selection and collection of patient specific data is critical for the following steps towards a diagnosis.

Both the physician and the patient must cooperate to achieve a mutual understanding of what is important for the case or not. The patient (or relative) must be able to articulate

\(^5\) Anamnesis = a preliminary case history of a medical or psychiatric patient (http://www.merriam-webster.com/medlineplus/anamnesis)
information about the actual, or former, health status and the physician must be aware of which questions that will sort out irrelevant information and focus on crucial information for further decision making. However, this decision is made in situ and should be properly tagged for later references.

The next step for the physician is to read relevant information in the (electronic) medical record. Grounded in information derived from the actual anamnesis, s/he decides what further information s/he might need to proceed with. Compared to earlier practices during the past centuries, CDSS - based information handling methods and the organization of Healthcare are very different in scope and focus in the present days. In former times, the physician firmly established the Anamnesis in the patients’ experiences, creating a complete personalized medical history. The modern society provides specialized Healthcare, assisted by advanced medical technology, but the holistic view of the human body – soul in Healthcare is mostly lost as the system is not process oriented and the patients report is marginalized. Different clinical departments further fragmentizes Healthcare, jeopardizing a continuous information flow for each individual patient involving potential information break downs between the varying units of competence. In such organization, the necessary handover situations are weakening current work flow and may cause both information misses and misinterpretations of reported information. A general lack of time for each patient will further increase the risk of mistakes.

The information elicitation process is delicate and the result depends on the physician, on a variety of variables such as competence, experience and awareness. Furthermore, regarding the patient, the level of Health Literacy (Chapter 1.3) and the ability to communicate important experiences, such as symptoms, are decisive. In addition, time available for the anamnesis phase is important. Even if such prerequisites are perfect, there are still pitfalls resulting in missed, important, information. For example, varying symptoms of a disease might occur in different ways for a long period of time, but chosen diagnoses could have been false. It might be crucial to concatenate symptoms from earlier events to more recent events, in order to find the correct diagnose. The anamnesis making process should therefore be supported by automation and visualization of data from the patients’ entire medical history, instantly visible when the patient and the physician meet. The following figures illustrate the difference between the recent traditional approach of stored separate events (incidents) (Figure 16) and the suggested alternative approach of coherent and concatenated events to the anamnesis phase (Figure 17):
Figure 16 - Separate earlier events (N-1), are randomly reported by the patient to the physician in the actual anamnesis phase (Situation N)

Figure 17 - Separate earlier events (N-1) concatenated by automation collection and processing of Anamnesis data; a visible historical feedback for the physician to consider, study and discuss with the patient in the actual anamnesis phase (Situation N)

This difference is the difference between fragmentized information flows, i.e. a number of disconnected and isolated information units on a time line, and a continuous information flow (of concatenated information units), where it is possible to observe and study earlier events due to knowledge about their existence. Figure 16 could be regarded as a model of a “hidden context”, important for the physician to be aware of in the decision making process. Figure 17 is a model of visualization of such context. Tools for proper context and user view visualizations (Chapter 2.4) are important add-ons to our VIA – tool.

Our bottom-line is that it is not a simple task to select, collect, process and communicate data for input to and output from a CDSS. The anamnesis creation is an important step in this information elicitation process as it provides the physician with patient specific information, but the method for this step is insecure. Firstly, the patient must understand, or remember to tell, what information that is important. Secondly, the physician must understand that the patient might have important information to share
and ask questions that will reveal such information. In a time-critical Healthcare, as the situation today is, this information elicitation step is hazardous. The human brain is extraordinary in its ability to sort out apparently crucial information for conclusions, but simultaneously this ability is perilous as conclusions might occur prematurely and be false if crucial information is false or missing. Accordingly, depending on context, Inductive Inference might both assist and counteract the differential diagnosing process. As a result, in Healthcare this ability might affect Patient Safety negatively despite any advanced and well designed CDSS in the traditional ways. Instead, the critical point is the whole life cycle of patient-centric information management. Figure 16 and Figure 17 are exemplifying these conditions. In Figure 16, the hidden context is not known by the physician, which is in risk of drawing premature conclusions on incomplete and deceptive information. In Figure 17, the context is visible as there are pointers to earlier incidents in the medical history, presented as a sequence. The medical history is coherent, opposed to the medical history in Figure 16.

Consequently, the basic principle of decision making is to find methods to maintain information flow in such way that the flow is unbroken, and complete or at least as complete as possible. Information is self-evidently the prerequisite for any decision and as such, information must be correct as well as correctly presented. The information in use for Healthcare interventions must be valid, relevant and individualized. A coherent presentation of a patients’ medical history, for a correct understanding of the current situation, seems to be essential.

In this chapter we will elaborate on the whole life cycle of patient-centric information management. We will describe principles and methods of decision making in Healthcare, such as differential diagnosing. However, we begin with a presentation of Evidence Based Medicine (EBM): Decisions on interventions in Healthcare must be made on a scientific basis to be safe enough. The chapter is finished with a presentation of pitfalls in the decision making process. Accordingly, we refer to Ockham’s Razor of Diagnostic Parsimony and its counter argument Hickams Dictum. This brings a focus on a need for chronologically presented patient specific information to counterbalance presumptions of probable diagnoses grounded in statistics, in order to find the correct diagnosis and to avoid misdiagnoses.

5.1 Evidence Based Medicine (EBM)

Two types of information seem to be critically important in clinical decision situations in Healthcare; individual patient data and evidence based (scientific) medical information. Patient data is needed to diagnose and maintain efficient treatment. Evidence based medical information must secure safe diagnosing and treatment, ensuring quality of care independent of location (nationally or internationally) and individual variances of the levels of physician knowledge.

Evidence Based Medicine (EBM) is a method for acquisition of information, adequate for a certain decision, in a certain situation, in Healthcare. EBM follows five steps [Dawes et al. 2005]:
1. Translation of uncertainty to an answerable question
2. Systematic retrieval of best evidence available
3. Critical appraisal of evidence for validity, clinical relevance, and applicability
4. Application of results in practice
5. Evaluation of performance

According to Dawes et al. [2005], step 4 contains a decision phase. This occurs after critical appraisal of evidence in relation to patient data and other circumstances within context. The term "evidence based medicine" (no hyphen) was coined at McMaster Medical School in Canada in the 1980’s to label this clinical learning strategy, which people at the school had been developing for over a decade” [Rosenberg 1995]. There are several attempts made to define EBM more clearly, among others:

“Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.” [Sacket et al. 1996]

This definition points out the importance of a perspective on individual patient related factors (patient data), existing in a certain context, involving external factors as well as individual variances affecting the patient within one single, comprehensive diagnose area. For example, the variances within the area of congenital heart conditions are large, resulting in different prerequisites for those sharing the same diagnose. *Truncus Arteriosus Communis types 1-4* are such diagnoses with considerable individual variations, which must be regarded holistically and by individual clinical expertise [authors conclusion]. Consequently, EBM must never result in “cook-book” medicine [Sacket et al. 1996]. Figure 18 illustrates this by visualizing three components constituting EBM; *Resources/Care provider, Evidence behind interventions and the Patient (needs, preferences).*

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58 Medical Subject Heading (MeSH) scope note, in the MEDLINE database
This demonstrates that EBM is not intended for interventions solely grounded in general conclusions on evidences. There is a context in which the patient exists, important to the outcome of every situation.

SBU\(^{59}\) defines the meaning of Evidence as “the best available scientific evidence”. This is information from research, categorized by its value in different “Levels of Evidence” (LoE). LoE varies according to varying systems developed for this purpose. In Sweden, The National Board of Health and Welfare, the Medical Products Agency and SBU have agreed upon following definition:

**Level 1**: At least two independent studies, with high values of evidence or one systematic overview of high value of evidence.

**Level 2**: A single study, with high value of evidence, and at least two studies with average value of evidence and unambiguous results.

**Level 3**: At least two studies with average value of evidence and unambiguous results.

**Level 4**: Solely studies of low values of evidence or without any study. Experts’ reports or consensus reports without explicit, systematic exposition.

A more comprehensive view on LoE, distinguishing between different aims for the evidence such as treatment, diagnosing etc., is provided by *Oxford Centre for Evidence Based Medicine*\(^{60}\), illustrated in the following table:

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\(^{59}\) SBU – “Statens Beredning för medicinsk Utvärdering. (The Swedish Council on Technology Assessment in Health Care.)

\(^{60}\) Oxford Centre for Evidence Based Medicine: http://www.cebm.net/
<table>
<thead>
<tr>
<th>Level</th>
<th>Therapy/Prevention, Aetiology/Harm</th>
<th>Prognosis</th>
<th>Diagnosis</th>
<th>Differential diagnosis/symptom prevalence study</th>
<th>Economic and decision analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>SR (with homogeneity*) of RCTs</td>
<td>SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations</td>
<td>SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres</td>
<td>SR (with homogeneity*) of prospective cohort studies</td>
<td>SR (with homogeneity*) of Level 1 economic studies</td>
</tr>
<tr>
<td>1b</td>
<td>Individual RCT (with narrow Confidence Interval)</td>
<td>Individual inception cohort study with &gt; 80% follow-up; CDR† validated in a single population</td>
<td>Validating** cohort study with good†† reference standards; or CDR† tested within one clinical centre</td>
<td>Prospective cohort study with good follow-up†††</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>1c</td>
<td>All or none§</td>
<td>All or none case-series</td>
<td>Absolute SpPins and SnNouts††</td>
<td>All or none case-series</td>
<td>Absolute better-value or worse-value analyses ††††</td>
</tr>
<tr>
<td>2a</td>
<td>SR (with homogeneity*) of cohort studies</td>
<td>SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs</td>
<td>SR (with homogeneity*) of Level &gt;2 diagnostic studies</td>
<td>SR (with homogeneity*) of 2b and better studies</td>
<td>SR (with homogeneity*) of Level &gt;2 economic studies</td>
</tr>
<tr>
<td>2b</td>
<td>Individual cohort study (including low quality RCT; e.g., &lt;80% follow-up)</td>
<td>Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§ only</td>
<td>Exploratory** cohort study with good†† reference standards; CDR† after derivation, or validated only on split-sample§§ or databases</td>
<td>Retrospective cohort study, or poor follow-up</td>
<td>Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>2c</td>
<td><em>Outcomes</em> Research; Ecological studies</td>
<td><em>Outcomes</em> Research</td>
<td>Ecological studies</td>
<td>Audit or outcomes research</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>SR (with homogeneity*) of case-control studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td></td>
</tr>
<tr>
<td>3b</td>
<td>Individual Case-Control Study</td>
<td>Non-consecutive study; or without consistently applied reference standards</td>
<td>Non-consecutive study, or very limited population</td>
<td>Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Case-series (and poor quality cohort and case-control studies§§)</td>
<td>Case-series (and poor quality prognostic cohort studies***</td>
<td>Case-control study, poor or non-independent reference standard</td>
<td>Case-series or superseded reference standards</td>
<td>Analysis with no sensitivity analysis</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
</tr>
</tbody>
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**Figure 19** – LoE in relation to aim.

“Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March 2009.”


This view supports the decision making phase by guidance towards a decision. Any intervention or informed action must rest on a decision before it is executed. In Figure
Recalling the three components of EBM, the LoE concerns only one; Evidence. Despite LoE and careful research, inconsistencies are occurring. Directions in Healthcare have been reversed, resulting in opposite standpoints. Sometimes opposite standpoints are concurrent, causing much confusion among both professionals and patients. One example is the explanation of what causes migraine symptoms and their appropriate treatment. Another example is concurrent attitudes regarding diets; saturated fat, the cholesterol content, and the danger (or benefit) of it [Knopp & Retzlaff 2004; Bryngelsson 2008; Siri-Tarino et al. 2010].

However, despite occurring inconsistencies in scientific evidence, using EBM should prevent “anecdotic medicine” to be practiced. Furthermore, EBM encourage physicians to use their tacit knowledge, experience and expertise to assess and evaluate the benefit or harm in using scientific evidence in the specific case. Last, but not least, the patient perspective is promoted, opening for patient cooperation corresponding to the current Patient Empowerment approach. Consequently, EBM opens for context awareness in Healthcare, i.e. to be aware of causal connections, now foremost incumbent on the physician to accomplish. Supporting this task by information technology is most likely as important as supporting the use of scientific evidence.

In recent years, voices are raised to broaden the concept of EBM. It is considered that Medicine directly refers to the Physician domain, requesting other to be embraced by an extended concept “Evidence Based Practise” (EBP):

“…we propose that the concept of evidence-based medicine be broadened to evidence-based practice to reflect the benefits of entire health care teams and organisations adopting a shared evidence-based approach.” [Dawes et al. 2005]

In any case, the basic action in EBM is Clinical Decision Making. In a later chapter (Chapter 5.3) this is further elaborated, followed by a description of available IT support; Clinical Decision Support Systems (CDSS) in Chapter 6.2. However, firstly we will elucidate the reasoning process behind the diagnosing task: Differential Diagnosis is a logical method used to be able to make a distinction between a misdiagnosis and a correct diagnosis.

5.2 Differential Diagnosis

The pathophysiologic explanation of occurring signs and symptoms is the actual disease, i.e. the correct diagnosis that must be identified to be able to treat. The decision making process, to find the correct diagnosis, embraces a method termed Differential Diagnosing (expressed as ΔΔ or DD). According to Merriam-Websters dictionary, the definition of DD is

“the distinguishing of a disease or condition from others presenting with similar signs and symptoms”
In addition, the Encyclopaedia Britannica describes “Formulating a Diagnosis” as follows:

“The process of formulating a diagnosis is called clinical decision making. The clinician uses the information gathered from the medical history and physical and mental examinations to develop a list of possible causes of the disorder, called the differential diagnosis.”

DD is, basically, a method used to systematically identify unknown variables; i.e. a “process of elimination”. However, the iterative process for data collection and interpretation is referred to as the hypothetico-deductive approach [Shortliffe 2006, Elstein et al. 1978, Kassirer and Gorry 1978]. The method comprises data collection and selection of a hypothesis of the most probable diagnose, iteratively repeated (refinements of hypotheses by means of additional data) until there is a hypothesis that either is considered true or the uncertainty is reduced to lowest possible level [Shortliffe 2006]. The set of active hypotheses are the differential diagnoses.

Accordingly, DD in Medicine is a logical tool by which a list of possible diagnoses is made by the physician, implicit in mind or explicit on paper, digital etc. The diagnoses (hypotheses) are, at hand, narrowed down by excluding impossible diagnoses until only one diagnosis remains. This implies that for one patient only one diagnosis, representing the symptoms, is true any other false.

Etymologically, the word Diagnosis originates from the Greek word Diagnostikein, meaning to "discern, distinguish" which is the basic aim of diagnosing: to discern the correct diagnosis from the wrong. This implies that DD in Medicine is the process of eliminating alternative diagnoses that might have some common symptoms with the true diagnosis which could mislead the physician.

In this process, Diagnostic Algorithms are used as tools for elimination. However, it must be considered that, in rare cases, two diagnoses might occur simultaneously, giving rise to almost analogous symptoms. For example, chest pain of a certain type could arise both from cardiac infarction and gastroesophageal reflux disease. Normally, after process of elimination, at least one is excluded and the correct diagnosis is identified. In another perspective, both diagnoses could simultaneously be true, where the symptoms occur reciprocally, resulting in one missed diagnosis. (In chapter 5.4, a presentation of a counter argument, “Hickam’s Dictum”, to the principle of “Ockham’s Razor” will emphasize this phenomenon.) Consequently, a defective process of elimination could result in a wrong or incomplete diagnosis, especially if not every sign or symptom is immediately available to notice. With reference to this, the importance of a complete anamnesis should be stressed.

62 In Health Care contexts, a Diagnostic Algorithm is a “mapping of the logical steps to be taken in eliminating potential diagnoses which do not match clinical signs or pathological findings and arranging possible diagnoses in order of probability” http://medical-dictionary.thefreedictionary.com/diagnostic+algorithm
To sum up, it could be concluded that both the anamnesis creation and the process of elimination is delicate, and that the need for tools to support the tasks becomes obvious. Another peril is the physicians’ memory capabilities, i.e. the ability to remember alternative diagnoses from earlier experiences and medical training (education). This ability of remembering such lists is jeopardized in situations characterized by high workload and stress, which often is reality in Healthcare of today. Therefore, IT-tools for DD are, along with the development of the Internet, available online for physicians. One such tool is DiagnosisPro63 a free self-contained web service to be used as a memorandum aid in the diagnosing task, in order to increase the quality of care and Patient Safety. This is a tool, not a Clinical Decision Support System (CDSS). However many CDSS are typically designed for DD as they basically provide Diagnosing Decision Support. To more closely be able to explain how CDSS can be beneficial to DD and Patient Safety, CDSS will more closely be described in Chapter 6.2. However, in this chapter, we will continue with a description of Clinical Decision Making.

5.3 Clinical Decision Making

As stated before, numerous decisions are continuously made every day in clinical settings within the area of Healthcare. Basically, Healthcare is built on the existence and handling of information, involving decisions to put information into practice, i.e. to use information for diagnosing, treatment and care. To understand the complexity of this action, Clinical Decision Making should be defined as follows:

“Clinical decision making is the end point of a process that includes clinical reasoning, problem solving, and awareness of patient and health care context” [Maudsley 2000]

This definition stresses the importance of context as a factor to be addressed before decisions are made. The awareness of context is a characteristic of the attending physician or other Healthcare professionals, not always evident in every situation [Dawes et al. 2005]: Decision making in Healthcare is a complex process as it requires assessment of multiple choices and decision about a course of action, among many, to adopt. Higgs et al. [2008] claims that

“Health professionals are required to make decisions with multiple foci (e.g. diagnosis, intervention, interaction and evaluation), in dynamic contexts, using a diverse knowledge base (including an increasing body of evidence-based literature), with multiple variables and individuals involved. In addition, clinical decisions are characterized by situations of uncertainty where not all the information needed to make them is, or can be, known. In this context, of clinical decision making there are seldom single decisions made from fixed choices where one decision can be isolated from others. Rather, decisions are embedded in decision-action cycles where situations evolve and where decisions and actions influence each other. [Higgs et al. 2008]

The complexity in such contexts makes great demands on the individual decision maker. Consequently, besides other variables such as time pressure and high workload at the ward, decision making is dependant on the capability of the single individual physician, as differences in skills, knowledge and experiences in medicine and Healthcare at large could potentially peril Patient Safety. Furthermore, if personal

63 http://en.diagnosispro.com/
conjectures are allowed to dominate, to varying extents, this could be even worse. Some decades ago, this course of action was more likely to occur in Healthcare: Individual care providers such as physicians and nurses grounded decisions basically in personal knowledge of unequal quality; assembled and understood through (prior or more recent) education and varying levels of clinical experience. This constituted a rigid knowledge ground, mechanically applied in situations of diagnosing, treatment and care. As a result, the quality of care was strongly dependent on the consulting physician and new discoveries in Medicine were unequally utilized.

Today, a paradigm shift has occurred, by means of IT, by the formal adoption of EBM, addressing the best scientific evidence available, in addition to individual knowledge and experience as basis for decisions. However, EBM as a term is rather new but EBM as a basic aim is not. The EBM timeline is sometimes described as starting with the Ancient era of EBM, followed by the Renaissance era of EBM in the 1700th century. The Transitional era of EBM occurred 1900-1970, when knowledge was shared more easily by the use of textbooks and, in the late part of it, peer-reviewed journals [Claridge & Fabian 2005]. The Modern era of EBM began in the 1970ies, driven by the use of modern knowledge sharing technology and, today, the large amount of medical information available. An important milestone occurred in 1972 when Professor Archibald Cochrane (Scottish epidemiologist), a well known pioneer of EBM, by the release of his book “Effectiveness and Efficiency: Random Reflections on Health Services” [Cochrane 1972], started an increasing interest for the importance of scientific evidence in Medical Practise. However, in the 1990ies the term EBM was first in use by investigators from McMaster's University, defined as a “systemic approach to analyze published research as the basis of clinical decision making.” [Claridge & Fabian 2005]. In 1996, the recent, more formally, definition was made by Sacket et al [1996], who stated that EBM was “the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients” [Claridge & Fabian 2005, Sacket et al. 1996].

Consequently, it is evident that EBM should constitute the basis for Decision Making in Healthcare. As cited above [Higgs et al. 2008], Decision Making also comprises multiple foci in Healthcare settings. Diagnosing (Chapter 5.2) is one of these, and as such it is rather important. It is momentous to find the right diagnosis. With the wrong diagnosis in the first place, any medical intervention afterwards should most likely also be wrong. An important part of diagnosing is probability. In the next section, we will highlight a well-known adage, used by physicians in Healthcare as a “rule-of-thumb”. It is Ockham’s Razor, in medicine commonly referred to as “the Zebra”. However, “a Zebra” is actually an improbable diagnosis, i.e. a rare diagnosis.

5.4 Ockham’s Razor and Hickam’s Dictum
In the area of Medicine, “the Zebra” is a rather confusing abbreviation of a well-known adage that, more closely described, is “When you hear hoof beats, think horses, not zebras”. This adage means that the simplest explanation of occurring symptoms is the most probable; i.e. a common, frequently occurring, diagnosis. Accordingly, “a Zebra” is actually an improbable and rare diagnosis. Referring to “the Zebra” when actually
referring to the adage might cause misunderstandings, which also must be stated before proceeding with this subject in this thesis. Therefore the adage will further on be referred to as the “Zebra-rule”. For example, a patient consulting Healthcare for fever, with no further distinct symptoms, the most probable diagnose might be urinary infection or “a virus”, not septicemia. This example is derived from a real case, further presented in Chapter 9 and in this case, Septicaemia was initially regarded as “a Zebra” and basically ignored. Unfortunately, finally Septicaemia turned out to be the correct diagnosis. A consequence of adopting the Zebra-rule by routine, in cases of more rare diagnoses, is time loss. For some diagnoses, a delay in diagnosing is severely threatening to Patient Safety. Accordingly, the Zebra-rule is simply a clinical “rule-of-thumb” in some stage of the differential diagnosing process. The use aims at reducing efforts and costs in unnecessary examinations and tests, but at the same time, patients affected with “Zebra-diagnoses” evidently exists. The efforts and costs, besides the humane perspective of suffering, might be even higher in case of misdiagnoses. Accordingly, a rule-of-thumb such as the Zebra-rule should not completely override other possible alternatives. To further explain and strengthen this point-of-view, we will continue with a closer description of Ockham’s Razor as a principle of simplicity.

The Zebra-rule is an interpretation of the philosophical principle “Ockham’s Razor” for Medical diagnostic situations. This principle is also expressed as “The law of parsimony”. In Healthcare, this principle is sometimes referred to as “Ockham’s Razor of Diagnostic Parsimony”. Basically, the principle is derived from the philosophical apprehension of simplicity, which has been expressed in different ways for different fields over the centuries. The idea is that simplicity is a theoretical virtue; that simpler theories should be regarded as preferable [Baker 2010]. In Healthcare, this implies that the physician must try to look for a minimum of hypotheses in the diagnosing process, to explain all of the symptoms the patient have; i.e. Diagnostic Parsimony. In order to achieve this aim, only the most probable hypotheses will be tested. What is probable to be true in this perspective is what is probable with reference to a large group of homogenous “patients”. However, if the view is that patient is not a member of a homogenous group of earlier patients, but instead a unique individual with a unique set of patient-specific data, the perspective will change. Harvey et al. [1979] expresses this as follows:

“In making the diagnosis of the cause of illness in an individual case, calculations of probability have no meaning. The pertinent question is whether the disease is present or not. Whether it is rare or common does not change the odds in a single patient. ... If the diagnosis can be made on the basis of specific criteria, then these criteria are either fulfilled or not fulfilled” [Harvey et al. 1979, p.15].

Accordingly, Ockham’s Razor of Diagnostic Parsimony has been frequently questioned. Even if the approach towards simplicity has advantages, it also brings serious disadvantages. One of the counterarguments is expressed in Hickam’s Dictum. Referring to the hypothetico-deductive approach in the diagnosing process, the principle of Hickam's dictum insists upon that, at no stage of the process, should a particular hypothesis be rejected because it does not seem to fit the principle of Ockham's razor. Hickam’s Dictum is sometimes expressed rather informal and brusque: “Patients can
have as many diseases as they damn well please”. To exemplify this statement, Saint’s triad (hiatal hernia, cholelithiasis, and diverticulosis) is often referred to. Accordingly, Saint’s triad as an example aims at affirming Hickam’s Dictum, and simultaneously questioning Ockham’s Razor as it is basically improbable with three different conditions occurring together. However, the underlying cause might be another condition resulting in those different diseases. In this perspective, simplicity as a rule for diagnosing is failing. Ockham’s Razor is further questioned by Walter Chatton’s “Anti-Razor” or the “Chatton Principle”:

“Whenever an affirmative proposition is apt to be verified for actually existing things, if two things, howsoever they are present according to arrangement and duration, cannot suffice for the verification of the proposition while another thing is lacking, then one must posit that other thing.”

[http://plato.stanford.edu/entries/walter-chatton/#ChaPri]

This could be interpreted as a diagnosis is never permanent, even if regarded as being true at some stage in the diagnosing process. Accordingly, diagnoses must be continuously questioned. The Chatton Principle also calls attention to the importance of not being precipitate in choosing a diagnosis. The context of the patient is important as there might be information that not yet has been recognised. In this perspective, the collection of information for the anamnesis is crucial.

However, in Healthcare, Rules-of-thumb might be useful for most cases and are useful in the perspective of increasing efficiency and unnecessary costs (short-term). The adoption of the Zebra-rule should be successful for most patients, as the most probable diagnose is diagnoses that statistically is most common to have in relation to the occurring symptoms. We must conclude that this is not a problem. On the other hand, there is a rather serious problem closely connected to Patient Safety and the chances to increase Patient Safety. Abrupton of the hypothetico-deductive process, prematurely, while relying too firmly at a thumb-of-rule might be disastrous: The problem is when the “Zebra” is present. Unusual or rare diagnoses exist, or even “Fascinomas” (slang). They hide in a jungle of more likely alternatives. Even more problematic are multi illness and systemic diseases. The information handling strategies in Healthcare has not been flexible enough to facilitate diagnosing of such cases. Unfortunately, the IT-boom in Healthcare has not been a remedy to these deficiencies. Consequently, it seems to be momentous to develop protocols and tools to handle atypical and complex situations, in order to prevent mistakes, information misses, injuries and deaths.

In the next Chapter, we will present some tools for Decision Making in Healthcare. This presentation constitutes a basis for further discussions on the need for additional options and tools for correct diagnosing and increased Patient Safety.
Chapter 6 – Decision Making Tools.

In this chapter, we present a number of tools aiming to support Decision Making. For example, Probabilistic Clinical Reasoning in addition to CDSS and Medical Records are described.

6. Introduction

Until today, ICT has been influencing Healthcare for decades. Nevertheless, the tools for Information Management and Decision Making are still developing and changing, in order to comply with new requirements and emerging issues related to work practises. Unfortunately, requirements have not always been in compliance with workflow as the traditional method of requirements elicitation is to interview representatives of Healthcare such as physicians, heads of clinical departments or other stakeholders. This is the first step in the software development process, which in Healthcare has resulted in usability issues and a large amount of complaints from the end-users, or even information breakdowns or breakdowns in workflow. This is seriously affecting Patient Safety. At the annual Vitalis Conference and Fair in Gothenburg, Sweden, where representatives from the IT-sector and the Healthcare sector, and politicians, meet to discuss IT in Healthcare, the participants from Healthcare give abundant evidences of this.

Regarding a basic prerequisite of acceptable Patient Safety, it is necessary to recall that Healthcare is completely dependant on Information: Without information, neither conclusions nor decisions can be made. Moreover, the information in use must be correct. It must both be true and complete. Therefore, adequate information management is momentous. The quality of general knowledge, used in Healthcare, is today controlled by the adoption of Evidence Based Medicine (EBM) (Chapter 5.1). EBM provides a guarantee of first rate quality of scientific information, used in clinical settings. As such, EBM is an important foundation for Clinical Decision Support Systems (CDSS), designed for support in diagnosing and treatment. Today, CDSS are implemented in different clinical settings, used by physicians as well as nurses. The use should preferably be “at the point of care”, i.e. at the site of patient care. With reference to the areas of Patient Empowerment (PE) and Patient Centered Medicine (PCM), further described in the next chapter (Chapter 7.1 and 7.2), every medical case is unique as every patient is an individual carrying a unique set of historical events in his/her medical history. The perspectives of the patients are utterly important: The medical history is both registered in medical records, such as Electronic Health Records (EHR) but also in the consciousness of patients and their relatives. The latter is a rich source

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64 Patient Empowerment is a concept defined as “the increasing ability of patients to actively understand, participate in and influence their health status” [Degoulet et al in Nelson & Ball 2004] (Chapter 7.1).
65 Patient Centered Medicine is a direction and model of striving for a patient-centric perspective towards a holistic patient-care (Chapter 7.2).
for both diagnosing and choice of treatment strategies, as the patient has a unique knowledge of experiencing the disease primarily, from the inside, 24 hours a day. Every single event in a medical history is important as it might be a clue to, or affect, current or future events. Neither EBM nor any EHR, or traditional CDSS, are covering such aspects on diagnosing or treatment for the patient. Nevertheless, these events are substantially important for Patient Safety as loss of such information might lead to misdiagnosing and delayed treatment. For many diseases, the time aspect is highly important for the successfulness of treatment or even survival of the patient.

In Chapter 9, we will present two different cases, with different outcomes. The first case, a longitudinal case study, going on for ten years between 1999 and 2009, is addressed to be able to observe and identify appearances of critical information and information structures over time. The second case, a rather rare case occurring during a period of ten months in 2010-2011, adds some more findings to the other and also questioned the widely adopted Ockham’s Razor of Diagnostic Parsimony (Chapter 5.4). This is important to consider, with reference to the common use of CDSS. The methodology used provided us with tools to more closely identify and study emerging, unpredictable, information breakdowns. Those breakdowns appear to be critical for the potential outcome of the different cases, however in the described situations not, or not clearly, visible in the EHR system for the physicians to observe. For each case, each new event was dependant on information from former events, sometimes carried by the patient or a relative, but not at the time of the occurrence obviously important. A successfully use of a CDSS, in order to find an accurate diagnose or treatment, requires patient data that is both true and complete. Therefore, a need for complementary tools is evident. In this respect, in Chapter 10, we propose a tool (VIA) designed to answer to some of the basic issues of incomplete information management in the diagnosing situation.

However firstly, to be able to further understand and discuss this complex of problems, we will present some tools available for Decision Making. We begin with a presentation of Artificial Intelligence in Medicine (AIM), an area related to the design of CDSS.

### 6.1 Artificial Intelligence in Medicine

As earlier stated in this thesis, Information is a prerequisite for Decisions about diagnosing and treatment. For example, patient specific data is important to collect. This is accomplished by the creation of an anamnesis, collection of body data by medical equipment and clinical medical examination of the body in different ways (palpation, percussion etc). However, Decisions also require general knowledge to connect to. To build such knowledge, scientific information of high quality is necessary. The scientific aspect is important in order to avoid conjectures and local rigid, maybe out-of-date, treatment tracks etc. Accordingly, patient specific data and general medical knowledge of high quality is the foundation for any decision about a disease.

The personal knowledge of physicians and nurses in Healthcare (in this context referred to as “human agents”) is, of course, an important part of the decision making process.
However, the knowledge bases in human agents might differ from one agent to another, as *humans are individuals*. They possess different levels or different directions in education and different former experiences, as well as more subtle tacit knowledge and differing cognitive capabilities and personalities. Together, this builds human knowledge. Due to an early apprehension of the computer as superior to the human brain, Artificial Intelligence (AI) was developed in the area of Computer Science. AI has since decades been regarded as potentially useful also in Medicine, forming a subarea: “Artificial Intelligence in Medicine (AIM) [Coiera 2003]. An early apprehension of AIM was that it would offer possibilities to create “a doctor in a box” which even could surpass the competence of a human agent; in this respect a physician [Coiera 2003, p. 331]. In more recent years, the ambitions of AIM have been more moderate, as the presumed similarity of the human brain and the computer for many years has been deeply questioned in Computer Science [Dreyfus 1992]. Instead, different applications of Knowledge Management have been addressed to complement the knowledge of Human Agents in Medicine.

As earlier mentioned, to support the decision making process in Healthcare, Clinical Decision Support Systems (CDSS) are developed for clinical practise. However, the success of CDSS is conspicuous by its absence, and the usage is still not very often established as a part of work flow. Coiera [2003] refers to some reasons for reluctance to the use of CDSS (in this case referred to as “expert systems”, further explained in Chapter 6.2):

> "Reasons for the failure of many expert systems to be used clinically include dependence on an electronic medical record system to supply their data, poor human interface design, failure to fit naturally into the routine process of care, and reluctance or computer illiteracy of some healthcare workers." [Coiera 2003, p. 344]

Above a more user friendly and intuitive design, and computer literacy training (maybe already in the education of physicians and nurses), it seems to be necessary to more deeply consider workflow and the flow of information in Healthcare, in order to develop and implement useful CDSS. Accordingly, additional tools for CDSS must be designed to repair shortcomings in protocols, procedures and information management in Healthcare. However, to be able to refine the design of information management in Healthcare, such shortcomings must be identified and analyzed. Patient Safety is an area where the results of such shortcomings are explicitly expressed, and the basic sources must therefore be understood. In this thesis, we present a Case Study and some findings pointing at this need (Chapter 9) and we also present a feasible solution for repair of information breakdowns which are jeopardizing Patient Safety (Chapter 10).

Returning to AIM, the focus is today slightly different compared to the early highflown ambitions and expectations. In 1984, Clancey and Shortliffe defined AIM as follows:

> “Medical artificial intelligence is primarily concerned with the construction of AI programs that perform diagnosis and make therapy recommendations. Unlike medical applications based on other programming methods, such as purely statistical and probabilistic methods, medical AI programs are based on symbolic models of disease entities and their relationship to patient factors and clinical manifestations.” [in Coiera 1997, 2003]
Coiera [1997] comments on this definition with “*For its day, however, the vision captured in this definition of AIM was revolutionary.*” The basic vision was apparently a machine-supported individualized direction in diagnosing, towards increased utilization of patient specific data, and the belief that AI should be able to achieve such goals. Today this vision has slightly changed. AIM is a research area comprising many aspects of Decision Making and Decision Support. In Decision Making, AIM systems should not be regarded as a (preferable and more competent) substitute to human thinking and reflection in Healthcare: They are tools to complement the human brain and the use of medical technology. *Strong AI* compared to *Weak AI* has until now proven to fail (Turing Test) [Ådahl 2007], which has changed the direction in AI towards more moderate goals.

CDSS are AIM systems, where *Expert Systems* i.e. *Knowledge Based Systems* are the most common in Healthcare settings. In the next section, we will go further into the area of AIM systems by presenting CDSS describing, briefly, different CDSS structures and use of CSDD in Healthcare.

### 6.2 Clinical Decision Support Systems (CDSS)

Clinical Decision Support Systems (CDSS) are computer systems developed to support clinicians in practice. Basically, the classification of CDSS is of two main types: Knowledge-Based and non-Knowledge-Based. As mentioned in the last section, the most frequently used type in Healthcare settings today is the Knowledge-Based CDSS, also known as “*Expert Systems*” [Coiera 2003]. The metaphorical designation “Expert” might be unfortunate as it sometimes provokes opposition about an assumed intention of the implementation of such systems; to take over the role of the physician. To avoid such interpretations, as it is not belonging to the area of Strong AI, instead emphasizing its true role as a *tool for support*, Expert Systems are today most often referred to simply as CDSS. As they also provide opportunity to pursue Evidence Based Medicine (EBM) (Chapter 5.1), to improve Patient Safety, their use is more and more commonly accepted. However, their use is still not frequent, which indicates that their role in work-flow might not be self-evident. Furthermore, non-Knowledge Based CDSS are even more rare. They belong to a subarea of Artificial Intelligence called Machine Learning and therefore they could be regarded as *Learning Systems*. We will briefly describe their design in this chapter and also explain their use in Healthcare. However, Knowledge-Based CDSS is the most common system for physicians to use in the decision making process [Coiera 2003].

Initially, we will present Knowledge-Based CDSS by design and use, and also discuss their “pros” and “cons”. In this thesis, we refer to Knowledge-Based CDSS when we discuss CDSS and additional tools for such systems. Our suggestion of an additional tool (the VIA-tool in Chapter 10) is supposed to be additional to any Knowledge-Based system for diagnosing, even if such a tool also might be useful in addition to other types of CDSS.
6.3 Knowledge Based Clinical Decision Support Systems

“Knowledge” is often referred to in Computer Science without a proper sense of the word. In the Information Management sector, this is implemented as a self-evident concept. However, the meaning of Knowledge in the subarea to Computer Science Information Management i.e. Knowledge Management is separated from the true meaning. Keith Devlin presents a definition of Knowledge [Devlin 2001] (Chapter 1.2) as follows:

“When a person internalizes information to the degree that he or she can make use of it, we call it knowledge.” [http://www.maa.org/devlin/devlin_9_99.html]

Knowledge = Internalized information + Ability to utilize the information [Devlin 2001].

Accordingly, with reference to Situation Theory, Knowledge in Information Management actually means information without a capital “I”. “Big-I-Information” is received and decoded information with meaning and “little-i-information” is data (Chapter 1.2).

With this basic understanding of Knowledge as a concept, we will proceed with the explanation of what CDSS are offering. Consequently, a Knowledge-Base is basically a Database. However, in CDSS the database is managed by AI-algorithms, constructed on Human Agents (in the sense of AIM, human experts in medicine) knowledge. The algorithms manage data input to the system and presents a result (output) that is in compliance with a result that probably would be approved of by human experts in Medicine. Accordingly, the system is interactive and dependant on Human Agents (experts in Medicine), both to construct (rules) and manage (update) it and to make adequate and correct input. Furthermore, output must be validated by Human Agents. The output must only be regarded as suggestions. This is utterly important for Patient Safety.

A Knowledge-Based CDSS consists of three parts besides a working memory: a Knowledge Base, an Inference Engine, and a Communicating Mechanism. The following Figure (20) represents the General Model of CDSS, depicting input (upper rectangle) and output data (lower rectangle) managed by the Communicating Mechanism, and with the actual system in the center [Kong et al 2008]:

![Figure 20 – General Model of CDSS](in Kong et al 2008]
The users are basically confronted with *choices of input* and *evaluation of output*. However, in Knowledge based CDSS, the knowledge (rules and data) is possible to access to be expanded, updated and maintained even if this procedure is not easily accomplished [Kong et al. 2008]. As earlier mentioned, the Knowledge Base contains data, which are large amounts of data organized and managed by a collection of rules. The rules are generally simple IF-THEN-rules, connecting some specific prerequisite data (actually data forming conditions that must be fulfilled) with a conclusion (i.e. data that implies a feasible suggestion/result). Logical or probabilistic reasoning methods are used to make conclusions, which are part of the algorithms. Furthermore, in addition to the Knowledge Base with its rules, an Inference (Reasoning) Engine is needed to connect the rules, stored in the (working) memory, to Patient Data. Accordingly, with reference to the Situation Theory [Devlin 2001] (Chapter 1.2) and its specific interpretation of data/information/Information/Knowledge, the closest comparison of what “Knowledge” in a CDSS really is, should be the conclusions of the rules, not the data/information or the rules. The rules are comparable to those procedures, or constraints, that are needed to transform information (data) into Information. This implies that the (background) knowledge of Human Agents is mirrored in the rules, based on EBM. Accordingly, *Situations*, the foundation for Situation Theory, is the occurring real world situation (in Healthcare) for which input to the system is made. In this sense, it is important to consider the actual meaning behind Knowledge as a concept, expressed in Keith Devlins statement (above) “*When a person internalizes information to the degree that he or she can make use of it*”. The Physicians (or nurses etc.), also end users of the CDSS, possesses Human Knowledge, necessary to be able to assist in the creation of new rules, refining and updating old rules and to interpret and make use of the output (Conclusions, i.e. “Knowledge”) from the system. Consequently, it is essentially important to not regard the system as a product developed in the direction of Strong AI. Human effort in input to the system and interpretation and evaluation of output is the basic challenge. The Communicating Mechanism is designed to allow input to the system (Patient Data) and presenting output (Conclusions) to the user (Figure 20). In this thesis, we call specific attention to *input*, as the output is strongly dependant on the correctness of what data is used for input. For Patient Safety, *the weak link in a CDSS is actually the choice of input*.

Diagnosis Decision Support Systems (DDSS) is a subset of CDSS. However, before we enter more deeply into “Expert Systems” for diagnosing, we will accentuate that there are also other fields in Healthcare of applications for Knowledge Based CDSS. Some of these are more successful than others and are in use more often than DDSS. For example, there are systems for *Alerts and Reminders*, *Therapy critiquing and planning*, *Prescribing*, *Information retrieval* and *Image recognition and interpretation* [Coiera 2003]. The technology has in all respects revolutionized the area of Medical Technology and contributed to increased possibilities of discover and treat a variety of conditions. The alerting systems has changed the possibilities of discovering fatal, otherwise latent or hidden, occurrences in the body very fast and in time for treatment and also to warn Healthcare personnel when treatment is inadequate, or prescribed medications are dangerous to health.
Returning to CDSS for Diagnosing (DDSS), which is our main focus for this thesis (in the other chapters are referred to simply as CDSS), it is important to consider that also various implementations of DDSS with various levels of ambition are made. A system that requires end users initiatives to generate suggestions is referred to as a Solicited-advice DSS. Consequently, systems relying on automated input of data such as patient data (body signals etc.) and not dependant on initiatives from Human Agents for acting are referred to as Unsolicited-advice DSS. DDSS can be designed as stand-alone systems or they can be integrated in EHR. When implemented in EHR, they collect input from the patient specific information in the EHR, generating suggestions for the Human Agent (physician etc.) to consider. On the other hand, Stand-Alone systems allow the Physician to make input. In both cases, the input is crucial to the result and therefore also to Patient Safety. Missing information might cause misdiagnoses, resulting in wrong treatment, prolonged treatment, injuries or deaths. Moreover, in some DDSS, rare conditions might not even be represented. Basically, for DDSS the probability of a certain diagnosis to be present is based on statistical data derived from large groups of patients. Accordingly, despite input of Patient Data to the system, this probability is not grounded in probability of a certain diagnosis for a patient in a certain personal context. This is the crucial point which we will further elaborate on, later in this thesis. For example, the tool we suggest in Chapter 10 (VIA) is grounded in the importance of individual patient-specific probability.

6.4 Probabilistic Clinical Reasoning

We will continue with a brief description of how probability, with reference to Probability Theory, is managed in Knowledge-based CDSS. The basic issue is Decision Making (choice) under Uncertainty and how this is realized in CDSS, i.e. DDSS. Uncertainty is expressed in a variety of terms to describe beliefs in a certain Diagnosis. For example, “Probable”, Likely”, Unlikely, High Probability” and “Low Probability” is often used by Healthcare professionals, but the interpretation of these words vary substantially [Shortliffe & Cimino 2006]. The basic issue is to be able to express degrees of Uncertainty. For example, “Odds” is an alternative expression. Probability, expressed mathematically (0.0-1.0), is another. The probabilistic reasoning is part of the Hypothetico-Deductive approach, i.e. the Differential Diagnosing Process. The process is iterative and, for each of the iterations, the belief in a certain Diagnosis will increase or decrease. The prior (or pretest) probability of a Disease is the degree of probability before further information is added [Ibid]. With reference to Bayes Theorem, further described in the next section, this is the basic reasoning methodology in Belief Networks which are common in many CDSS.

However, despite iterative testing, the process might be ended prematurely due to incomplete probabilistic estimation and personal belief of likelihood of a certain Diagnosis. The degree of belief for a particular diagnosis might be considered high enough, with reference to statistical evidence in large patient groups. In this sense, the impact of the principle of Ockham’s Razor is important to consider. However, missing information might corrupt or ruin the result of Bayes Theorem. The following citation
put emphasis on a basic issue in Decision Making and relates to the importance of finding the adequate patient-specific information:

There are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns – the ones we don't know we don't know.

[Statement of Former United States Secretary of Defense Donald Rumsfeld 2002]

The Unknown Unknowns (with reference to the Relevance Paradox\textsuperscript{66}) is a problematic aspect in Decision Making. Decision Theory in criticized for not considering this, instead focusing only the Known Unknowns. In Healthcare, from a physician’s point of view, the Unknown Unknowns is not part of the Anamnesis or in other sections of the EHR. It is information crucial for a correct decision that is hidden in occurrences of the past and in the minds of the patient or his/her relatives, who do not know that they know, or in the body of the patient. In addition, we want to add that there could also be Unknown Knowns; things that we don’t know that we know, i.e. we know things but do not relate them to a situation when we would. Not knowing that there is hidden but crucial information, completely changing the result of Bayes Theorem and choice of diagnosis, is potentially very dangerous. The point is how the Unknown Unknowns or Unknown Knowns will be Known Unknowns or Known Knowns, for input to a CDSS. We believe that ICT tools for increased Interoperability between Healthcare and the Patient are the key to a feasible solution for this issue. This should decrease the impact of the Relevance Paradox in Decision Making situations. Unfortunately, a lack of such tools is still the fact of the matter in such situations, which call for attention to further research focusing this aspect of Information (Knowledge) Management in Healthcare. This might be essential in order to increase Patient Safety. In Chapter 10, we present our suggestion of a solution; the VIA-tool.

In the next section, we will present a method for the implementation of Knowledge-Based CDSS and Decision Making. Consequently, Bayesian Inference and Bayesian Networks or Belief Networks is explained, whereupon we continue with a presentation of non-Knowledge Based Clinical Decision Support Systems.

\textbf{Bayesian Inference and Bayesian Networks/Belief Networks}

Bayesian inference is a statistic method to elicit knowledge for decisions about the most probable hypotheses, to be adopted in situations of uncertainty. The use of Bayes’ Theorem (in the next paragraph further explained) for algorithms in the inference process constitutes the basis. Evidence and clinical observations are important in the process of identifying the probability of the hypothesis. The underlying philosophy is \textit{probabilistic causation}\textsuperscript{67}:

\textsuperscript{66} The Relevance Paradox: “...in many significant instances across a wide range of areas, even when relevant information is readily available, the decision makers are not aware of its relevance because they don't have the information which would make its relevance clear, so they don't look for it.” [in “The Importance of Knowing the Right People.” The Guardian. 1980-03-20]

\textsuperscript{67} Causation = “Relation that holds between two temporally simultaneous or successive events when the first event (the cause) brings about the other (the effect). According to David Hume, when we say of two
“Probabilistic Causation” designates a group of theories that aim to characterize the relationship between cause and effect using the tools of probability theory. The central idea behind these theories is that causes change the probabilities of their effects.” [Stanford Encyclopedia of Philosophy http://plato.stanford.edu/entries/causation-probabilistic/]

Accordingly, it can be concluded that Causes change the probability of their effects which is the foundation of Probabilistic Causation. Thus, the importance of finding the actual cause of a disease, given the disease as being the effect, seems to be essential. In Chapter 9, Case II, we present a situation when the cause of the disease is extremely important to discover in order to prevent future events or estimate the probability of such events. Nevertheless, this perspective was not initially obvious to the physicians involved in the case. Most often, the perspective of the disease as the cause (of signs and symptoms) is in the foreground. The approach of Probabilistic Causation emphasizes uncertainty aspects in illness; that the behavior of the body is non-deterministic. However, this does not exclude the importance of finding a cause of apparently random behavior of the body. Instead, it makes this even more important in order to estimate probability and predict, as well as prevent, future pathological occurrences. Physiology is a complex topic in medicine where Pathophysiology is even more complex. Diseases and malfunctions are caused by a variety of conditions, dependant on a personal context influencing the effects.

However, returning to Probability Theory68, this is the theoretical ground for Bayesian Inference, briefly introduced in this chapter. Bayes Theorem, and its relation to Probability Theory and Bayesian Inference, is explained in Encyclopaedia Britannica as follows:

“Bayes’s theorem, in probability theory, a means for revising predictions in light of relevant evidence, also known as conditional probability or inverse probability. ... Related to the theorem is Bayesian inference, or Bayesianism, based on the assignment of some a priori distribution of a parameter under investigation. In 1854 the English logician George Boole criticized the subjective character of such assignments, and Bayesianism declined in favour of “confidence intervals” and “hypothesis tests”—now basic research methods.” [Bayes Theorem/Encyclopaedia Britannica]

Bayes Theorem (or Bayes Rule) is actually the Inference Procedure addressed in Bayesian Networks (Belief Networks) [Coiera 2003]. Conditional Probability is the basis for the reasoning. For example, referring to the study in Chapter 9, Case II, the probability for Septicaemia is expressed in relation to occurring symptoms. “What is the probability of a patient having Septicaemia, given that he/she has high fever?” expressed as Conditional Probability:

types of object or event that “X causes Y” (e.g., fire causes smoke), we mean that (i) Xs are “constantly conjoined” with Ys, (ii) Ys follow Xs and not vice versa, and (iii) there is a “necessary connection” between Xs and Ys such that whenever an X occurs, a Y must follow.” [in Encyclopaedia Britannica http://www.britannica.com/EBchecked/topic/100434/causation]

68 Probability Theory: “a branch of mathematics concerned with the analysis of random phenomena. The outcome of a random event cannot be determined before it occurs, but it may be any one of several possible outcomes. The actual outcome is considered to be determined by chance.” [Encyclopaedia Britannica]
According to Bayes Theorem, the probability of a disease given a specific clinical sign or symptom $P(D \mid S)$ is dependant on that anyone in the population has the disease, that anyone with the disease has the symptom and that anyone has the symptom but not the disease [Coiera 2003]. Bayes Theorem is expressed mathematically as follows:

$$P(D \mid S) = \frac{P(S \mid D) \times P(D)}{P(S \mid D) \times P(D) + P(S \mid \text{not } D) \times P(\text{not } D)}$$

The result of the theorem is posterior probability [Coiera 2003], opposed to the prior (that anyone in the population has the disease, $P(D)$, without any additional patient-specific information), as the patients occurring symptom is new information changing the result. When tests are used for patient-specific information collection, the probability is named pre-test probability versus post-test probability. We will not develop this further, but instead emphasize the importance of finding the adequate patient-specific information. In this thesis, we specifically stress context of the occurring symptoms and signs as important for the probability of a certain disease. Therefore, a rich anamnesis is essential for discovering context-dependant occurrences and must be developed to present more useful information.

In the next section, we will introduce non-Knowledge Based systems, another branch of AI dealing with support in Decision Making.

### 6.5 Non-Knowledge Based Clinical Decision Support Systems

Machine Learning, a sub area of AI, is the foundation for non-Knowledge Based CDSS. Two approaches are dominating the design of non-Knowledge Based CDSS: Artificial Neural Networks (ANN) and Genetic Algorithms (GA). Using Machine Learning as a strategy for Decision Making has occasionally been promising, as the ambition also is to use the technology for the creation of new “knowledge”. The human brain is not capable of creating this kind of knowledge, which is to discover, and create, new patterns in very large sets of data. Instead, the computer is very well suited for such tasks; for example, the creation of completely new unknown rules discovered to be valid in large amounts of data input. Further, machine learning has been successful for development of systems for automated interpretation of ECGs. In the following, we will present both ANN and GA before we discuss advantages and disadvantages of non-Knowledge based CDSS. However, we will not further elaborate on this topic as there is no need for deeper presentations to understand our point of view in this thesis.

#### Artificial Neural Networks (ANN)

Concerning ANN, this part of AI is a mathematical structure developed to imitate the human brain; to emulate the functions of biological neurons: Broadly described, the human brain consists of entities such as neurons, synapses and neurotransmitters; the latter transporting signals across the synapses between the neurons. In ANN, Neurodes (the word is a blend of nodes and neurones) correspond to neurons, and Weighted Connections correspond to synapses. The neurodes have multiple input signals but only
one output signal. Three layers process the signals; an input layer, a hidden layer and an output layer. The most common type of ANN, a 3-layer feedforward ANN, is described by Rounds [2002] in Figure 21:

Figure 21 - A simple 3-layer feedforward ANN [figure in Rounds 2002]

ANN’s are especially suited for finding patterns in large amounts of data sets. As ANN’s do not have a Knowledge base, ANN’s are used for analyzing patterns in patient data to find possible diagnoses. However, as Knowledge based CDSS often comprises a larger number of diagnoses, ANN’s focuses on only a few. The learning procedure of ANNs is to use examples as input that the system will “learn about”, which in other words is to “train” the network. The input must contain a wide range of examples (such as signs and symptoms related to disease). The examples provide types of patterns that the ANN will learn. For example, one method for learning in (training of) ANN is the Levenberg-Marquardt Optimization69 [Rounds 2002]. When the learning is successful, the ANN will most likely be able to find similar patterns and use them for predictions [Rounds 2002]. The use of ANN in Healthcare is varying. Some fields of application are Diagnosing of certain diseases, Prediction of certain diagnoses, Analyses of ECGs, Identification of patients predisposed to certain diseases, and to Prognosticate certain surgical operations and treatments.

Genetic Algorithms (GA)

GA is another implementation strategy for non-Knowledge based CDSS, which more closely described, is an adaptive heuristic search algorithm. Furthermore, GA belongs to the broader class Evolutionary Algorithms (EA) and is an evolutionary computing paradigm, inspired of Darwin’s evolutionary theory (Darwinism), referring to

69 Roweis paper on Levenberg-Marquardt Optimization (Retrieved 2011-09-14 at http://cs.nyu.edu/~roweis/notes/lm.pdf)
biological concepts such as Genes and Genomes, Chromosomes, Inheritance, Selection and Mutations. Basically, GA requires both a “genetic” representation of the solution domain and a “fitness” function to evaluate the solution domain. The latter is to be compared with a basic principle of the Evolutionary Theory; a function supporting “natural selection”. In Biology, this means that the best fitted individuals in a population survives and reproduces resulting in vital species. In GA, a population is a collection of chromosomes (corresponding to Individuals in Biology) where each chromosome is a complete solution. A Chromosome consists of Genes which are only parts of the complete solution. Each Chromosome has a Fitness Value that is an estimation of how good the solution is; how the solution fits into the problem area (the best design, i.e. which best meets the overall specification). Only the best Chromosomes (Individuals) are allowed to pass (to mate) in order to create (breed) better and better solutions (“offsprings”). “Survival of the fittest” in Biology is, in GA, to delete solutions that do not correspond well enough to the design goal and use those who do. Mutations occur (changes in the genes, i.e. parts of the solution) and the fitness value decides if the mutation is good or bad; if it will be deleted or used for new generations of solutions (cross-over). With this iterative process, the ambition is to optimize suggestions for solutions: For example, to create rules or “knowledge” for CDSS. Accordingly, the computer is the final designer of any solution but a crucial point is the design of the fitness function that must be correct and is performed by a human designer. If the fitness function is wrong, the solution will be wrong as the algorithm will converge wrongly or not at all. Nevertheless, despite this weak point that is the impact of human design, GA systems seems to work very well, being more accurate in diagnosing that any average clinician [Berner & La Lande 2007].

Advantages and disadvantages of non-Knowledge based CDSS

Since decades, the expectations for Machine Learning systems, such as ANN, have been great and some systems have also improved diagnosing and treatment. For example, systems in this area are able to construct new medical knowledge, where human ability is insufficient: Using pattern recognition in large amounts of raw data, the systems are able to identify and hypothesize relationships within the data. Further, as mentioned above, they are useful for the development of Knowledge bases in Expert systems, as the new knowledge can be expressed by simple rules or by decision trees [Coiera 2003]. However, the field of application in Healthcare for GA is smaller than for ANN. Furthermore, as the reasoning behind GA is not transparent, there is hesitation about using such systems (pattern recognition and machine learning) [Berner & La Lande 2007]. This seems to override the advantages of GA, in, for example, diagnosing. Accordingly, Trust concerns are an obstacle for the use.

6.6 Some identified shortcomings of CDSS

It is important to initially make clear that Clinical Decision Support Systems (CDSS) are guiding tools, not tools commanding which decisions to be made. The motivation of using CDSS is strongly related to Trust, in this matter the ability of control and visibility of the “Knowledge” in the CDSS [Berner & La Lande 2007]. This is apparent as it comes to (lack of) users confidence in non-Knowledge based CDSS, where the rules are created by the system itself [Ibid]. It is also important to maintain the CDSS in
such way that the Knowledge base is evidently supported by EBM, and updated in compliance with new research results in the Medical area. Suggestions of Diagnoses and Treatment based on out-of-date discoveries do not encourage Trust in using the CDSS and might jeopardize Patient Safety as well.

Another, more subtle, peril of CDSS is the implicit reliance on statistics in the use of such. Nevertheless, for the design of the CDSS this is very important and necessary component. However, *the use* of the CDSS and *the design* of the CDSS are different independent aspects. Ockham’s Razor is basically the reason for confusion. CDSS are grounded in probabilistic reasoning which refers to the patient as belonging to a large group of earlier patients. This notion will cover the majority of every possible cause of a symptom and most of the suggested diagnoses will probably also be true. Using a common example, the symptom “Headache” is most probably caused by muscular tension (in turn caused by nervous tension/stress) or by migraine. The first hand diagnoses, suggested by the CDSS rules, will therefore be Stress Disorder or Migraine, which might *end the hypothetico-deductive process prematurely*. Encephaloma (brain tumor) or Stroke might be considered as “Zebras” at a glance, if signs are not evidently visible or symptoms not properly reported: Signs and symptoms might have appeared over time, lost in the actual consultation by incoherent information chains or the patient inability to report properly or identify relevant information to report. In addition, it should be noticed that more than one diagnose might be true: The cause of a headache in one individual could be multiple. “Occams Razor” is fairly questioned with reference to this; i.e. the problematic cases are when the rule-of-thumb fails. For those reasons, Probabilistic thinking might limit the domain of possibilities in which a physician ventures to reason. A challenge for development of CDSS is to provide multiple decisions in case of Multiple Illness [Tan 2005]. For most CDSS, the design is to support decisions for a single disease at a time. Accordingly, this is an expression of the approach of Simplicity, i.e. Ockham’s Razor of Diagnostic Parsimony (Chapter 3 and Chapter 5.4). Furthermore, another peril concerning CDSS design using statistics, in contrast to the advantages, is that rare diagnoses sometimes are not represented at all. In this thesis, Case II is exemplifying a diagnosis not present in the Knowledge base of some CDSS: Acalculous Cholecystitis.

According to the use of CDSS, statistics might jeopardize the output as the diagnosing process might be incomplete and abrupt based on statistic probability of a certain diagnosis. To prevent such incidences to happen, more relevant data for input is needed as well as additional tools for collection of such data. Correct data and efficient information management, as a part of the work flow, is also crucial. Accordingly, *input of data to the CDSS is decisive for the correctness of its output and application in Healthcare*. However, data collection is not a simple task. Human Agents are involved to collect data, for example to manage the transducer (to position the transducer correctly for ultra-sound examinations) or to manage blood specimens [Coiera 2003]. Furthermore, Human Agents are collecting data for the anamnesis: Context of a patient is complex, and not limited to well-defined and isolated periods in life. Neither is Patient Context entirely coverable by a traditional anamnesis and the medical history in the EHR. The cases described in the Study (Chapter 9) pinpoint a need for a more
concrete time-line of events as a tool for input to existing CDSS, and evaluation of output, alerting for threatening “Zebras” if needed (Chapter 10).

Before the cases are presented in Chapter 9, and the empirical work underpinning the current is presented in Chapter 8, we will in Chapter 7 briefly present some models that the approach of this thesis is grounded in. For example, Patient Empowerment is presented as a movement encouraging the, rather recently, established Participatory Medicine concept aiming at increased interoperability between the Patient and Healthcare; on information collection for more complete anamneses and increased cooperation in treatment and prevention of further illness. Patients must participate in their own Health, in order to more safely and successfully reach increased Health.

However, first we will stress that Medical Records such as EMR managed by EHR and PHR (Chapter 10) should be regarded as Decision Making Tools. They provide information needed for most decisions in Healthcare. The next section focuses this aspect.

6.7 Medical Records as Decision Making Tools

Decision Making requires patient-specific information to ground the decisions in. Therefore, Medical Records should be regarded as tools for Decision Making, not only specifically CDSS. Many CDSS are also integrated in Electronic Health Records (EHR), sometimes referred to as Electronic Medical Records (EMR). The terminology might be confusing as there are many denominations for apparently the same tool. However, there is a difference between EMR and EHR. An EMR is the actual database holding patient data, kept and maintained only by HealthCare providers. An EHR is the system utilizing the content (data) in EMR for HealthCare professionals use in the HealthCare context [Habib 2010]. Accordingly, the EHR architecture provides different types of applications, for example Computerized Physician Order Entry (CPOE) or CDSS. For example, the importance and benefit of using CDSS is sometimes illustrated by random reports in newspapers; on incidents where supportive systems obviously would have prevented such incidents, as in Appendix 1. In CSCW (Computer Supported Cooperative Work), EHR are regarded as tools supporting workflow.

Furthermore, in Chapter 7.2, the rather new approach Connected HealthCare comprises Personal Health Records (PHR) (Chapter 10), defined by American Medical Informatics Association (AMIA) College of Medical as

> An electronic application through which individuals can access, manage, and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment. [Tang et al. 2006]

For example, Health Vault and PatientsLikeMe (Chapter 1.3) are examples of web-based PHR which are expressions of the Connected HealthCare movement. This must not be confused with EPR that actually is the same tool as EHR. PHRs are sometimes connected to EMRs (as Health Vault) which will label them also as Patient Portals. A Patient Portal is an interface allowing patients to interact and communicate with Healthcare providers and are sometimes connected to the EMR. The portals are for
patients to access, and are commonly sited at HealthCare providers’ websites. The PHR allow patients to communicate and collaborate on their Patient Specific data, and to collect their own personal medical data for the database, for example by electronic medical equipment connected to the system.

The Patient Specific data stored in the EMR is a rich source for decision making. Such data is most important for the use of CDSS. Patient Collaboration (Chapter 7.2) is decisive for the outcome of the diagnosing process as the patient holds the information necessary for the final decision. In the next chapter, we will present some models supporting increased Patient Safety by Patient collaboration. Furthermore, our proposed VIA model will both emphasize Medical Records as decision making tools and Patient collaboration as a necessary approach to Patient Safety.
Chapter 7 – Models supporting increased Patient Safety.

In this chapter, some influential models affecting the Patient Safety work today are described. Basically, the Patient Empowerment movement has been most important for this.

7. Introduction

From the given background of our thesis in Chapter 1 and Case study of Chapter 9 we propose in Chapter 10 a tool – VIA – to remedy some of identified shortcomings towards increased Patient Safety in Healthcare. The shortcomings are derived from our Case Study in Chapter 9 and assessments of current models and methods of CDSS Chapter 5 and 6. The proposed tool VIA is itself based on a needed change of focus in current practices (Chapter 4) connected to our three identified Research Questions in Chapter 3:

RQ1: What aspects of information misses and breakdowns in Healthcare systems have to be properly addressed to ensure interoperability?

RQ2: Which principles are crucial to ensure interoperable support and empowerment of patients?

RQ3: Which principles of healthcare systems are crucial to ensure Patient Safety and healthcare empowerment?

In Chapter 5, we stressed the importance of identifying, collecting and processing relevant context dependant data in the Anamnesis process. In particular, the focus is on the patient both as a *source of data* and as an *informant of the entire medical history*. The VIA tool thus has to be complemented with other tools supporting rather new directions in Healthcare;

- *Patent Empowerment (PE)*
- *Participatory Medicine (PM)*
- *Patient Centered Medicine (PCM)*

PE, PM and PCM are interrelated and all of them have bearings to the identified RQs and to the proposed design of the VIA tool.

7.1 Patient Empowerment (PE) and Participatory Medicine (PM)

The *Patient Empowerment (PE) movement* is a direction aiming at regarding the Patients as necessary resources for the outcome of care and not as an object for disciplined and supervised care. PE has developed distinctly along with the strong
attention to Patient Safety as a complementary approach. PE is contributing to Patient Safety as the empowered patient in Healthcare is regarded as a co-operator and an important brick, contributing with experience in being the one who has the “inside information” of being ill and, to a certain extent, being capable of act as such instead of passively receive care (a former, more traditional, view of the patient). PE is, among many other similar definitions, defined by Degoulet et al.[2004] as:

“…the increasing ability of patients to actively understand, participate in and influence their health status” [Degoulet et al in Nelson & Ball 2004]

The development of the Internet and activities of patients on the Internet is fundamental for the growth of PE: Unlimited access to vast amounts of medical information and communication in communities and blogs (web logs) has been both instructive and educational, and has been an important factor for the creation of “the Health Literate Patient” (Chapter 1.3). As a result, PE could be regarded as a revolution in Healthcare, dramatically changing the older previous approach, i.e. “Medical Paternalism” [Roper & Edan 2011], where the Patients were commonly regarded as passive receivers of care, intended or even hindered to have no or little knowledge in their own diseases and limited ability to influence their situations [Ådahl 2007].

In recent years, the participatory aspect of PE has been strengthened, and the underlying aspect of Health Literacy, by means of the Internet, has gained more attention to be valuable. Accordingly, PE has developed into areas such as Participatory Medicine (PM) where the patients, from the perspective of Healthcare professionals, should be regarded as potentially knowledgeable, valuable, necessary and indispensable resources, able to participate in both diagnosing and treatment. PM is defined by the Society for Participatory Medicine as:

“Participatory Medicine is a movement in which networked patients shift from being mere passengers to responsible drivers of their health, and in which providers encourage and value them as full partners.” [The Society for Participatory Medicine http://participatorymedicine.org/]

In other words, PM comprises also the perspective of Healthcare where the point of view must be to meet the empowered patients. This should be done by regarding them as co-workers; to achieve and maintain their own health, not as being obstacles or threats that could complicate diagnosing and treatment. Decision Making is focus as it comes to PM. One PM model is “Shared Decision Making” defined as “a process by which a healthcare choice is made jointly by the practitioner and the patient” [Roper & Edan 2011, Légaré et al. 2010]. As a result, this requires some kind of Patient Autonomy. However, individuals differ but with the adoption of the PE perspective there is an implicit risk of requirement; to force individuals to be Health Literate and fully capable of cooperating in any situation. This we refer to as the Patient Empowerment Paradox [Ådahl 2007]. Another angle is ethical aspects in loss of Patient Autonomy with respect to certain laws for the area of Mental Care [Roper & Edan 2011]. In this matter, proxies are important to address. Consequently, tools and methods aiming at PE and PM should also aim at elimination, or to circumvent,
identified individual shortcomings (cognitive, physical) to *comprehend and take part* in the treatment and its intended effects [Ådahl 2007].

### 7.2 Patient Centered Medicine (PCM)

*Patient Centered Medicine* (PCM) is another related line of policy, where the *perspective of care* is altered from the traditional perspective of the physicians to the perspective of the patients [Laine & Davidoff 1996]. This term should not be confused with the well known catchphrase in Healthcare that is to *place the patient in the centre of care*, which is a neither new nor controversial or, for any reasons, provoking. However, despite the frequent use of the phrase, the practical meaning of it appears to be rather obscure. A common interpretation is that Healthcare personnel should never forget why they are there; to work entirely for the patients being their “humble servants”. Of course this must be a catchphrase to adopt and with such point-of-view, the patient will be in the centre. However, with no further interpretation, the patient also might continue to be a rather passive receiver of care. Instead, the patient must not be regarded as an *object* of ultimate care (interventions and nursing) but as a *subject* in the sense that the patients’ subjective experiences of the disease should be noticed and utilized for decisions and interventions.

The adoption of PCM will also put the patient in the centre of care, but with more distinctly explained methods in order to also incorporate the patient as a collaborator; as an *active* part of a Healthcare *team*, with valuable perspectives, beliefs, wants and needs; able to influence teamwork in a positive way. Patient Activity might appear offending to some physicians as there have been fears about unrealistic requirements of the patients to fully orchestrate their own health and care [Laine & Davidoff 1996, Ådahl 2007] and fear about loss of professional control and efficiency. However, this is not the ambition. The idea is to *be aware of the patients’ point of view*. PCM is defined by Gerteis et al. [1993]:

> “Patient-Centered Care is Health Care that is closely congruent with and responsive to patients wants, needs, and preferences.” [Gerteis et al. 1993]

However, Gerteis et al. [1993] are within this definition not specific about the patients’ perspective. They include “wants”, “needs” and “preferences” with no further explanation of each point. Considering “needs”, it should be rather clear that this comprises a correct diagnosis and adequate and effective treatment. Diagnosing is the stage in the process that must be correct in order to choose the right treatment. Therefore, the process of information elicitation must be a fundamentally important. PCM comprises methodology useful for the information elicitation process of the anamnesis creation. The *Patient Centred Clinical Method* comprises six Interactive Components:

1. **Exploring both the disease and the illness experience:**
   - history, physical, lab;
   - dimensions of illness (feelings, ideas, effects on function and

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70 The Patient Centred Clinical Method http://www.med.mun.ca/getdoc/f6c338b0-71cd-4f4a-ac10-854672d06f04/Patient-Centred-Clinical-Method.aspx
expectations).

2. Understanding the whole person:
   * the person (e.g. life history, personal and developmental issues);
   * the proximal context (e.g. family, employment, social support); and
   * the distal context (e.g. culture, community, ecosystem).

3. Finding common ground:
   * problems and priorities;
   * goals of treatment and/or management; and
   * roles of patient and health care practitioner.

4. Incorporating prevention and health promotion:
   * health enhancement;
   * risk avoidance;
   * risk reduction;
   * early identification; and
   * complication reduction.

5. Enhancing the patient-health care practitioner relationship:
   * compassion;
   * power;
   * healing; and
   * self-awareness.

6. Being realistic:
   * teambuilding and teamwork

Figure 22 – The six Interactive Components of the Patient-Centred Clinical Method [from Brown 2004]

The methodology pinpoints the perspective of the patient to be the predominant. This is accomplished by interaction and collaboration; by asking the patient to describe his/her health status and to be active and ask questions [McWhinney 2003]. Point 6 establishes the fact that collaboration is decisive for the outcome: Teambuilding and teamwork is a necessary part of Patient-Centred approaches. Of course, the Patient is a self-evident part of the team. In this respect, the Patient must be encouraged to become Health Literate (Chapter 1.3) and Healthcare must provide access to medical information in order to accomplish this aim [Canadian Medical Association 2007].

Accordingly, Context is with this direction more likely to be captured, in contrast to anamnesis interviews conducted in environments of medical paternalism. Consequently, with a Patient-Centred approach, it should be more likely to also achieve a holistic perspective of the patients’ body and its actual pathophysiological status. Furthermore, it is most likely that the awareness of the Patients point of view will result in improved mental health, despite mental strain due to illness, affecting the overall well-being and life quality in a positive direction. Patient-centeredness requires tools for carrying out the approach. For example, decision support designed for PCM comprises Computerized Physician Order Entry system (CPOE), providing the prescriber of medication with patient-specific information from the EMR/EHR.

Collaborative Patient-Centred Practice
Regarding Informational and Organizational Interoperability (Chapter 1), embracing Healthcare and Patients, and their relatives, Collaboration is fundamental. I addition, Collaboration is a basic requirement for utilization and practice of PCM. As described above, point 6 in the Patient-Centred Clinical Method (Figure 22) [Brown 2004] is “to be realistic”. This implies that, in order to accomplish a Patient-Centric approach, Teamwork is essential. Teamwork is actually equal to Collaborative Practice. According to Way, Jones & Busing [2000] the definition of Collaborative Practice is:
“Collaborative Practice is an inter-professional process for communication and decision making that enables the separate and shared knowledge and skills of care providers to synergistically influence the client/patient care provided.” [Way, Jones & Busing 2000]

Way, Jones and Busing identify Collaborative Practice basically to be an inter-professional process. This implies that power is shared between members of the team, where every individual is dependent on the others knowledge and expertise. In Collaborative Patient-Centered Practice, the patient is an important member of the team. Accordingly, the patient must be viewed rather differently, not only as the focus of sympathetic as well as medically and technically advanced care but also as the important informant and as a potential collaborator in any type of care situation. Furthermore, in teams aiming at Collaborative Practice, every individual team member should provide potentially useful information, and reflections about the care situation. Simultaneously, they must be aware of the other team members’ insights and reflections and utilize the information or pass on to whom that are in the position to do so. For example, in a hierarchical organization with a traditional medical paternalistic approach, physicians might in the extreme regard nurses as servants, only there to carry out orders. They might ask questions about the patient, but not elaborate issues interactively and in-depths involving nurses (or other categories of professionals). The sense of being a knowledge-owner is strong. However, this is “dead end work” regarding Patient Safety. In Collaborative Practice, nurses’ proximity to the patient, experiences, tacit knowledge and ability to assess and evaluate is utilized to avoid information-misses; for the patients’ safety and good. Likewise, the Patient is involved in interactive dialogues.

Accordingly, Collaborative Patient-Centered Practice entails a holistic perspective on the patient comprising context. Furthermore, this patient-centric approach has pointers to another concept, in recent years more frequently occurring in Sweden; Lean Health Care. In the 60ies, ideas of efficiency in organizations by means of traditional industrial large-scale production was strongly influencing HealthCare, resulting in fragmenting units of care (such as clinical departments) that are separated in location and run separately [Berczuk 2008]. Today this system is predominant in Healthcare and implemented in most hospitals since many years, requiring special information transfer protocols to work. However, it has become quite clear that this system applied to Healthcare environments causes inefficiency such as time loss and advanced costs. Moreover, and even more seriously, such information transfer attempts, across borders (between different units), might cause loss of information; information misses and information breakdowns (Chapter 3.1 and results from the studies in Chapter 8 and 9): The more borders, the more situations are emerging in which mistakes might occur, some times deadly. However, today the holistic view on the patient as the centre of the work flow in the organization is given priority to the earlier view of work flow, comparable to an assembly production line. Lean Health Care aims at avoiding such fragmentation of Healthcare and to find ways to coordinate the patient the whole way through the care process. “Lean Thinking”, is a management strategy for improvement of processes also applicable in Healthcare. Originally, the concept was coined by a MIT research program; the “International Motor Vehicle Program” (IMVP), focusing the
automobile industry as a phenomenon in the 80ies. The program is ongoing, but resulted two decades ago in a conclusion about the efficiency of the Japanese automobile industry and the identification of Lean as an approach in contrast to western mass-production [Womack, Jones & Roos 1991]. This project resulted in a philosophical mind-set, applicable in industries and organizations such as Healthcare. The process that must be conducted to change one organization to a Lean approach is called Lean Transformation which is a challenging and time-consuming process that must be carried out within a longer period and be entirely complete [http://www.lean.org/whatslean/]. In Sweden, Lean Health Care is introduced at several hospitals, where Skåne Universitetssjukhus (SUS) (Eng. Skåne University Hospital), Lund, is one of those. These approaches are all connected to an aim of improving not only efficiency in terms of costs, but also Patient Safety regarding quality of care.

Patient-Centric and collaborative approaches require informed members of the team. As the Patient is a member of the team, the level of Health Literacy of the Patients (Chapter 1.3) [Nutbeam 2000] is highly important for successful collaboration. E-Patients (Chapter 1.3) will more likely be able to interact with professional team members, and this is a factor that also has influenced the area of Telemedicine; to develop into areas such as e-Health and Connected Healthcare. In the next section, Connected Healthcare is further elaborated to put more emphasis on the importance of the Patient as collaborator towards increased Patient Safety.

Connected Healthcare – a Topical Pathway towards Interoperability?

Behind a recent buzzword in the area, “Connected Healthcare”, there is a serious attempt to provide information to care providers and patients, irrespective of geographical location. Accordingly, Connected Healthcare (CH), or Connected Health, is an approach with its foundations in Telemedicine and Telehealth. However, CH differs from Telehealth by the adoption of some important aims. Firstly, CH comprises concerns for costs in Healthcare as well as quality and efficiency of Healthcare. Regarding these factors, chronic illness is in particular a subject of concern. Secondly, CH aims at making Healthcare Patient-Centric by providing opportunities for education and patient feedback. Thirdly, CH comprises efforts towards integration of data generated by the patient outside Healthcare settings with central EHR/EPR.

However, such an approach requires tools for collection and transfer of remote Patient generated data. A rather recent and well-known manifestation of CH is Microsofts Health Vault platform for Patients, launched in September 2007, using Microsoft Amalga71 to transfer, collect and display such data in Healthcare. Furthermore, another competing expression for this approach is Google Health launched in 2008 (however retiring in 2011-2013) and some other similar applications in other countries. The Patient-Centric aim is evidently clear, with reference to the applications. The perspective of the Patient is provided by tools for self administered collection of patient-specific data, and tools for management of such Patient-specific data. Accordingly, it realizes the patients’ new role as a collaborating resource and important team member; from the data sources of the patients’ body and mind through the central

system utilizing data and connecting it to central data (EHR) for use at the point-of-care.

In Sweden, close to the aim of Connected Healthcare, Nationell PatientÖversikt\(^{72}\) (NPÖ), part of Nationell eHälsa\(^{73}\) (former Nationell IT-strategi). NPÖ is under development. NPÖ is offering national wide access, across organizational borders, to medical records for different care providers and patients. In the end of 2012, the implementation in every county council in Sweden, initiated in Örebro 2009, will be completed. This means that the medical record (in this phase of the development only parts of the information in the EHR will be displayed) will follow the patient despite geographical location in the country at the time of falling ill. Increased mobility of the population has resulted in an extension of NPÖ; epSOS\(^{74}\). This is an EU-project concerning cross-border interoperability between EHR-Systems in Europe. Semantic interoperability is crucial in this matter.

In the next section, we will elaborate on issues such as quality of data and reasoning. For example, data must be correctly interpreted into useful and safe information whose meaning is close enough to the meaning of the data that was transferred [Devlin 2001] (Chapter 1.2). In the epSOS the challenge is foremost to develop a common ontology of medical information and the different languages in medical records of different European countries. In Healthcare as such, oral reporting protocols and methods might be crucial for how safe information will flow and if information is correctly understood. Furthermore, new protocols and methods might be needed for the discovery of known unknowns as well as unknown unknowns (Chapter 6.4) crucial for decisions about diagnoses and treatment.

7.3 Quality Assurance of Data and Reasoning

Reasoning is a part of every decision. For example, both the application of EBM and Differential Diagnosing requires reasoning strategies as well as quality assurance of addressed data for the reasoning process. In Chapter 6, we stated that there is uncertainty in information used for decisions. In the process of differential diagnosing, uncertainty is handled by the “method of elimination”. This is most often successful reasoning.

Nevertheless, wrong diagnoses occasionally occur. Human agents tend to use heuristic methods to collect data. Such methods comprise the reliance on intuitive judgments, “educated guesses”, common sense and rules of thumb. This is a perilous strategy in medicine and a critical point for Patient Safety. In the hypothetico-deductive process, the method of elimination is used to exclude hypotheses that are not probable to be true. In this process, one application of heuristic methods is the adoption of the philosophical principle Ockham’s Razor i.e. “The law of parsimony” in the shape of the well-known

\(^{72}\) NPÖ = Nationell PatientÖversikt. (National Patient Survey.) A technology allowing access to a patient’s medical record, for the occasion care is needed, irrespective of the patients’ casual geographical location in Sweden.

\(^{73}\) http://www.socialstyrelsen.se/nationellehalsa

\(^{74}\) http://www.epsos.eu/
adage: “when you hear hoof beats, think horses, not zebras” which was further described in Chapter 5.4. As described, this is a general rule-of-thumb used clinically for efficient selection of diagnose. This reasoning will most often succeed, but sometimes, for the rare cases that evidently exist, for systemic diseases and for multiple illnesses, it will fail. It is not satisfactory if such reasoning is generally adopted, as it might disregard severe illness affecting Patient Safety negatively. Therefore, an “acceptable diagnose” must always be chosen on the strength of highest possible amount of relevant patient specific information and scientifically assessed medical information (with reference to EBM). CDSS could support such a process. This is obtained by addressing a Socio-Technical approach to development of usable information management systems for Healthcare Systems, supporting workflow in design. Moreover, to adopt a PCM approach in the field of activities, as well as taking PE into consideration in the design of CDSS, would probably be favourable for Patient Safety. This requires design of additional tools for CDSS, enabling patients to collaborate in the Healthcare team.

One important aspect on quality assurance of data and reasoning for Patient Safety in Healthcare is to avoid information misses and breakdowns. For many years, different and some times very local protocols have guided oral reporting or transfer of written information between fragmented units of care or between different persons such as nurses and physicians. Healthcare is often time-critical due to treatment of acute illness or accidents, sometimes also being below strength, and these factors are all together severe threats to unbroken information chains that are necessary for sufficient Patient Safety. As a result, there are attempts to improve upon the different information management strategies in Healthcare. In the next section, we will explain this further by presenting some recent models addressed for this matter.

**Information Security Models**

As earlier mentioned (Chapter 1.4) deficiencies in communication is one of the leading causes of patient harm [Velji et al. 2008, Wallin & Thor 2008]. Accordingly, in recent years Patient Safety Models in Healthcare have been developed to remedy deficiencies in communication. Foremost two methods are recommended by the Swedish National Board of Health and Welfare\(^75\). For example, with reference to Informational and Communicational as well as Organizational Interoperability (Figure 1, Chapter 1), the method **SBAR** (Situation, Background, Assessment and Recommendation) has been developed to reduce\(^76\) the large amount of injuries that occur due to insufficient communication in Healthcare. SBAR is now in use at several Hospitals in Sweden. Especially in Emergency Care, when structured and more efficient oral reporting for hand-over situations in urgent cases is required, SBAR is addressed (SBAR in a Swedish Emergency Ward; Appendix 4). Accordingly, SBAR is a normative communication model and also part of Crew Resource Management (CRM)\(^77\) for High

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\(^75\) [http://www.socialstyrelsen.se/patientsakerhet/forbattra/kommunicera](http://www.socialstyrelsen.se/patientsakerhet/forbattra/kommunicera)

\(^76\) [http://www.skl.se/vi_arbetar_med/halsaochvard/patientsakerhet/aktuellt_2/sbar_minskar_risker_i_varden](http://www.skl.se/vi_arbetar_med/halsaochvard/patientsakerhet/aktuellt_2/sbar_minskar_risker_i_varden)

\(^77\) Crew Resource Management is a training procedure, foremost for the aviation industry, to reduce the effects of human error. "CRM training, as it is currently practiced, focuses on trainable, measurable
Reliability Organization (HRO) such as the air-craft and nuclear industry [Wallin & Thor 2008]. Healthcare is a hazardous organization but unfortunately not even close to the levels of safety achieved in HRO’s [Ibid]. Hence, the adoption of SBAR has raised expectations of increased Patient Safety. In 2006, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) addressed the importance of a new standardized method for communication which resulted in a number of new communication models of which SBAR was the most frequently used [Ibid]. SBAR contains four steps to follow in hand-over situations, which is described as follows (verbatim) by NHS Institute for Innovation and Improvement [2008]:

“S Situation:
Identify yourself the site/unit you are calling from
Identify the patient by name and the reason for your report
Describe your concern
Firstly, describe the specific situation about which you are calling, including the patient's name, consultant, patient location, code status, and vital signs.

B Background:
Give the patient's reason for admission
Explain significant medical history
You then inform the consultant of the patient's background: admitting diagnosis, date of admission, prior procedures, current medications, allergies, pertinent laboratory results and other relevant diagnostic results. For this, you need to have collected information from the patient's chart, flow sheets and progress notes.

A Assessment:
Vital signs
Contraction pattern
Clinical impressions, concerns
You need to think critically when informing the doctor of your assessment of the situation. This means that you have considered what might be the underlying reason for your patient's condition. Not only have you reviewed your findings from your assessment, you have also consolidated these with other objective indicators, such as laboratory results.

R Recommendation:
Explain what you need - be specific about request and time frame
Make suggestions
Clarify expectations
Finally, what is your recommendation? That is, what would you like to happen by the end of the conversation with the physician? Any order that is given on the phone needs to be repeated back to ensure accuracy.” [NHS Institute for Innovation and Improvement 2008]

In case of using this method, it is assumed that communication will be improved and information less likely to be lost. Research has shown that Patient Safety increases due to the adoption of SBAR [Velji et al. 2008]. However, information misses still do occur

skills crucial to successful performance outcomes. As such, the component theories of CRM are applicable to any medical domain in which effective teamwork has been shown to reduce errors and enhance patient safety.” [Baker et al. 2005] (Retrieved 2011-10-09 at www.ahrq.gov/qual/medteam)

http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvemnt_tools/sbar_-situation_-background_-assessment_-recommendation.html
as there also are other types of information flows that are not discovered or controlled by such methods. In the Case study in Chapter 9, we identify such information flows that are not clearly visible or noticed and which are broken despite implementation of SBAR. Consequently, in hand-over situations in the cases (emergency ward) information still was missed despite SBAR implementation, which was seriously affecting Patient Safety negatively. The missed information was both known information (that should have been transferred by support of SBAR) and hidden, unknown, information. To identify and control hidden information structures (Chapter 9), other additional methods or tools are required (Chapter 10). However, if properly addressed in urgent situations, SBAR is helpful to enhance communication and transfer known information between different individuals (foremost nurses and physicians) as well as care units.

Furthermore, in order to enhance Patient Safety, it is crucial to identify and analyze occurring critical situations. In other words, it is important to be aware of exactly what happened when a situation almost went wrong in order to prevent devastating results from similar future courses of events. There are some models for these purposes as well. A method which has its origin in World War II is the Critical Incident Technique (CIT)\textsuperscript{80}. The method, which is qualitative, is now used in a variety of fields and Healthcare is one of them. The CIT method was described by Chell & Pittaway [1998] as follows:

The critical incident technique is a qualitative interview procedure which facilitates the investigation of significant occurrences (events, incidents, processes, or issues) identified by the respondent, the way they are managed, and the outcomes in terms of perceived effects. The objective is to gain understanding of the incident from the perspective of the individual, taking into account cognitive, affective, and behavioral elements [Chell & Pittaway 1998].

Consequently, when a critical incident occurs, the incident must be understood in detail and depth, in order to take measures to prevent similar incidents in the future. Another method for the understanding of incidents, and decision making about actions against such incidents, is Root Cause Analysis (RCA). RCA responds to the recent aim in Healthcare; i.e. finding the basic cause of errors in a systemic perspective, rather than addressing individual faults, corresponds to the new Patient Safety Law (SFS 2010:659) in Sweden (Chapter 1.3, 1.4, 4, 4.2). RCA involves three steps towards identification of a problem\textsuperscript{81}; to determine what happened, to determine why it happened and to understand what to do in order to prevent it from happening again.

With a systemic perspective on fault prevention and identification of errors in Healthcare, it is more likely to discover information misses and breakdowns that should be able to prevent by design of ICT. However, to be able to understand how information actually flows under the surface of Healthcare, it was necessary to adopt a specially designed qualitative approach to be able to identify more subtle information streams, not immediately evident to exist. In the following chapters we will present two authentic, medical, cases which are analyzed for this thesis (Chapter 9) and the preceding research which is forming the basis for the current (Chapter 8).

\textsuperscript{80} Description of how to use CIT: http://www.usabilitybok.org/methods/p2052?section=how-to
\textsuperscript{81} http://www.safetyandquality.health.wa.gov.au/clinical_incid_man/root_cause.cfm
Chapter 8 – Preparatory Study.

In this chapter, a study performed in the field of Paediatric Cardiology in Sweden, performed 2006-2007, is presented. The study was the foundation for the Licentiate Thesis [Ådahl 2007], now serving as a preparatory basis for further research presented in this Doctoral Thesis.

8. Introduction
This thesis is principally based on two main studies. One of those is this study, used as a basis for the creation of three RQ (Chapter 3) and, accordingly, as a mean for further research. The result of the study pointed at Participatory Medicine as an important direction to follow. Information Exchange between patients and Healthcare personnel was central and the importance of this for maintenance of unbroken information flows in work practice was apparent. In the following, we present the study as it was presented in the Licentiate Thesis, occasionally, verbatim.

8.1 Preparatory Study – Information Exchange in Paediatric Cardiology
The study was performed in the area of Paediatric Cardiology 2006-2007, serving as a main study for the Licentiate Thesis with its results and conclusions presented in 2007 [Ådahl 2007]. The working title for this field study was “On (online) Information Management for Work Practise and Patient Empowerment”. In this Doctoral Thesis, the study is presented as preparatory, providing data on Participatory Medicine (Chapter 7.1) and Apomediation (Chapter 1.3), further elaborated for the following Case study, the main study of this thesis (Chapter 9). In the Preparatory Study (i.e. main study for the Licentiate thesis), the following types of participants were chosen to cover a bilateral perspective; i.e. embracing both Patients and Professionals:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Department of Paediatric Cardiology at the University Hospital in Lund, Sweden</td>
</tr>
<tr>
<td>2</td>
<td>Department of Cardiology at the University Hospital in Lund, Sweden; GUCH section = Grown-Up Congenital Heart Disease.</td>
</tr>
</tbody>
</table>

82 “All for Parents” is an online virtual community, with many sub communities. One discussion area is inhabited by parents to children with Congenital Heart Conditions, sometimes also by the children at greater ages. (Retrieved 2011-06-21 http://www.alltforforaldrar.se/snack2/forumdisplay.php?f=77)
Consequently, this bilateral study was performed on two different perspectives on a joint specialist area in Healthcare; *Congenital Heart Conditions (CHC)*. The first area is the *Professionals* (number 1 and 2 in the table), representing a “virtual community of practise” (part of an imagined Intersection of virtual communities\(^{83}\)) [Ådahl 2007]. The other area is the *Patients* (number 3 and 4 in the table), representing a “virtual community of interest/learning” i.e. Health Literacy (also part of an imagined Intersection of virtual communities) [Ibid]. The participants in the latter area are representing parents (i.e. proxies) to children with CHC, as well as Grown Ups with CHC (GUCH) participating themselves. (This bilateral perspective is still present in the Doctoral Thesis, as Participatory Medicine comprises both patients and professionals, but the focus is narrowing to the importance of patient participation.)

### 8.2 Design and Accomplishment of the Preparatory Study.

However, the initial work with the (at this time Preparatory) Study started already in November 2005: The field study *On (online) Information Management for Work Practise and Patient Empowerment*, was initialized by a request for participation to the University Hospital in Lund, Sweden (today SUS Lund), followed by a confirmation. In December 2005 the Swedish Heart Children Association published a call for participation in their periodical and on their website, directed to patients, and relatives to patients, with congenital heart conditions. In February 2006 an additional call was published on the Swedish website “All For Parents” in a discussion forum (in 2006-2007 denominated “Snack”), in the sub forum for parents to children with functional disorders/CHC. The reason to this was an attempt to recruit a larger number of participants. The study was finally started in February 24\(^{th}\) when the participants received the material, and was estimated to be in progress during approximately five weeks (until March 31).

Despite vast efforts in gathering an adequate number of participants for the study, the attempts did not result in an expected quantity. A probable explanation was that the study was considered as too time consuming and required too much effort to complete. Accordingly, the rate of participation in the professionals’ field was 5 and the rate of participation in the Patients field was 11 which could be regarded as unsatisfying low. However, the field notes (notes from a Reconnoitring Study\(^{84}\) and the material through the questionnaires from the main study) did offer a rich material for reflection and further work on the KIViC-model (KIViC = *Knowledgeable Intersection of Virtual Communities*; our model of interaction for Health Literacy towards Participatory Medicine) [Ådahl 2007] (Figure 23). Furthermore, it provided signs of needs for Transparency in health related information. The field material was used, not as evidence, but as pointers to tendencies for certain aspects of information management.

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\(^{83}\) This *intersection* is further described in the Licentiate Thesis [Ådahl 2007], but shortly presented is it a cooperative virtual area of the KIViC-model, where members of two or more online communities meet to communicate and exchange experiences and information.

\(^{84}\) The Reconnoitring Study was a qualitative study performed between 2000 and 2005. Participatory observations and interviews were made, ad hoc, to find material for scenarios and reflections. The study resulted in the description of three real world cases, taken place in Swedish Health Care and homes, used for the Licentiate thesis [Ådahl 2007].

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issues in eHealth. In this Doctoral Thesis, these pointers were reused as a basis for the formulation of the three RQ in Chapter 3.

As mentioned, the study entailed some effort for the participants. It involved a comprehensive “Questionnaire” to answer. This “Questionnaire” was actually composed of three separate parts where Part 1 comprised the scenarios, Part 2 a mock-up and Part 3 the actual questionnaire (divided in two slightly different parts to suit each community), further described later in this chapter. The whole document was initiated by a brief description of the KIViC-model [Ådahl 2007] (Figure 23).

**Figure 23 - Mathematical model of KIViC**

The KIViC model was a conceptual description of a shared space of interaction. In 2005 the model was created for development of e-health related information systems and was grounded in experiences from patients, sometimes their proxies, and professionals’ activities in an online discussion forum for parents [Ådahl 2003]. The authors own personal experiences as a “bilateral participant observer” (both in patients’ community and in professionals’ community) was the foundation for the design. The model was named KIViC (Knowledgeable Intersection of Virtual Communities) as it was a description of virtual communities, forming an intersection, due to the set theory: Each virtual community in a KIViC should be regarded as a set, and the actors within each set as elements of that set. The intersection of the sets is common for each set.

Consequently, the “Questionnaire” in the (Preparatory) Study was identical for both the targeted communities, except the part containing the actual questionnaire. It was not appropriate to use the same questions at every point of interest, as the communities have various goals for their members’ actions, despite partially shared objects for the activity, with reference to Activity Theory (Chapter 1.1). The following figures (Figure 24, 25 and 26) from the Licentiate thesis [Ådahl 2007] are demonstrating a shared object as a tool for the activity (Figure 26). With reference to the basic aim of this thesis, a potentially shared object could also be correct diagnosis with the outcome Patient Safety for the patient. The artefact (tool) should be our proposal VIA (Chapter 10) (Figure 24 and 25).
Figure 24 - KIViC as an artefact (tool) in an activity system [Ådahl 2007].

Figure 25 - Third generation of Activity Systems. [Engeström 1987] is viewed as a tertiary artefact [Wartofsky 1973] used in the activity system of a heart patient. The view is “nested” [Ådahl 2007].

Figure 26 - Third generation of Activity Systems as a tertiary artefact [Wartofsky 1973] [Ådahl 2007].
However, the study was not pure qualitative (ethnographical) in its approach. The methodology was also a kind of experimental. The reason to this approach was that there was a virtual environment that should be studied, but had not yet coming into existence and therefore could not be studied! More specific, the environment did not exist, but still it exists theoretically in a model. Instead, what could be studied were reflections and ideas on how to use this environment in practice, related to and grounded in experiences from existing situations. Consequently, reality (real world connections) had to be added to the model.

In order to analyze and understand the field of investigation, it was preferable to capture, not only the context, but also a holistic view of the research. That was the main reason to choose a bilateral perspective85 in the study for the Licentiate thesis. This approach turned out to be successful. It revealed desirability and need for cooperation in Healthcare between the both parties and the benefit of such cooperation. Information is shared between patients or their relatives/proxies and physicians, important for further diagnosing and treatment. On this foundation, the three RQ for this Doctoral Thesis were created, where the results from the study was reformulated into questions about Interoperability; information management in Healthcare and support of Participatory Medicine for increased Patient Safety (Chapter 3).

The experimental approach for the Preparatory Study was also adopted as a consequence of the situation that participatory observations were not possible to perform. This was the result of the participants being scattered over the entire country (Sweden) as well as they were working in differing services at different locations. The varying communities of practice and learning [Wenger 1999; Lave & Wenger 1991] have a “virtual part”, referring to professionals and patients varying virtual communities most commonly used today. Anyhow, they are only assumed to be seeds to the virtual communities in the model, which makes them difficult to capture: There is no physical place to enter, as the use of information occurs in so many places, different to every single participant. Consequently, the virtual surroundings that are to be studied do not yet exist! To bring order into this reasoning, and connect it further to the study, it should be helpful to start with a relatively new concept in the field of Ethnography; Virtual Ethnography86. Virtual ethnography (or Online Ethnography and Netnography) has developed during the last decade, theoretically grounded on Christine Hine earlier studies [Hine 2000, Torres et al. 2010]. Torres et al. states that “The issue of the ethnography in Internet bases on the fact that Internet is a cultural product that generates social practices, interactions and specific beliefs.” [Torres et al. 2010] In conformity with this, Bruce Mason writes that “Virtual Ethnography is an ethnography that treats Cyberspace as the ethnographic reality” [Mason 2001]. However, before making use of Virtual Ethnography, the first to be done in the Preparatory Study was to identify the ethnographic context [Ibid]. But how should it be possible to identify something that was not there? As the context does only exist in a model, this problem

85 In the Licentiate thesis [Ådahl 2007], the expression “a Bilateral Perspective” referred to the dual nature of the KIViC-model. Two perspectives were represented; the Professionals in Health Care and the Patients; to understand the need for Patient Empowerment.
86 http://en.wikipedia.org/wiki/Virtual_ethnography
was solved by the use of a mock-up, which already was created and grounded in the reconnoitering study of the Licentiate thesis [Ådahl 2007]. Consequently, the model and the virtual environments were made concrete to the participants through this mock-up and could therefore be used for imaginative reflection. Secondly, an ethnographic methodology was needed and ethnographic tools had to be generated [Ibid]. The method used for this investigation is a triangulating method, where a questionnaire (most often part of quantitative studies) is used to collect information. In this case the questionnaire could, to some extent, be regarded as an “interview in writing”, as the questions were very open-ended. The questionnaire in the study was completed with the possibility of performing follow-up interviews, written or oral, on questions where there may be a need for further explanation. As earlier described, the questionnaire was almost similar in both communities (patients and professionals) in order to find a bilateral perspective on the joint area of the investigation. The mock-up was a central focus in the questionnaire and in addition three authentic cases, i.e. scenarios, were presented to reflect on in relation to the mock-up. Also as mentioned before, the participants were introduced to the study by an initial description of the questionnaire, which was subdivided into three main parts. The first part presented the scenarios; three real world cases based on experiences from three patients with congenital heart diseases. In these scenarios, the patients’ were facing situations concerning need for information and information handling issues that entail problems possibly solvable by IT. The second part presented the Mock Up built on the KIViC-model, which initially also was briefly explained, to be used as a reflective tool in the survey: The mock-up was intended to be used in relation to the three scenarios, towards ideas about the need for information. Finally, the third part presented the questionnaire, offering both open-ended interview questions, in writing and multiple choice questions, in part referring to both scenarios and mock-up. This mix of text, graphical figures and questions of both extremes was an experiment towards some kind of qualitative instrument, to compensate for traditional ethnographic methods when they are not suitable to use. Consequently, the method was an experimental expression of a methodological transfer towards the area of Virtual Ethnography, with mock-ups, based on predefined cases, within the discipline of Participatory Design87.

8.3 Results from the Preparatory Study.

The Study in 2006-2007 captured several interesting reflections from both patients and professionals in Healthcare, due to the benefits of using a qualitative approach. Simultaneously, the study pinpointed some interesting aspects of information flow in Healthcare [Ådahl 2007].

However, this analysis from the Licentiate thesis (verbatim) turned out to be most valuable for the “future work” ongoing in the Doctoral thesis:

“Scenario 1 (Appendix 2) illustrates a problem in that the patient him-/herself gets into a situation where s/he must “transmit information”. To be forced into a role as “information carrier”, while

87 Participatory design is an approach to design that attempts to actively involve the end users in the design process to help ensure that the product designed meets their needs and is usable. 
http://en.wikipedia.org/wiki/Participatory_design
being a patient or a relative, is not secure. Not everyone can transmit information correctly and the memory can fail. One question was about experiences of patients carrying information between different units of healthcare. The patients/relatives were asked if they had been acting as information carriers in any situation. The professionals were asked if they had experienced that patients/relatives had carried information. The result of the participants’ apprehension about human agents as information carriers in health care activities, and suggested IT support is expressed in the table:

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Experiences of Human Information Transmission</th>
<th>Supportive IT alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAph</td>
<td>Yes</td>
<td>Internet account</td>
</tr>
<tr>
<td>ABph</td>
<td>Yes</td>
<td>Internet account</td>
</tr>
<tr>
<td>ACph</td>
<td>Yes</td>
<td>Other: pediatric cardiology register</td>
</tr>
<tr>
<td>AAApB</td>
<td>Yes</td>
<td>Smart Card</td>
</tr>
<tr>
<td>BAappr</td>
<td>X</td>
<td>Smart Card</td>
</tr>
<tr>
<td>BCr</td>
<td>X</td>
<td>Other: Change of behaviour before inform. storage</td>
</tr>
<tr>
<td>BDp</td>
<td>X</td>
<td>Internet account</td>
</tr>
<tr>
<td>BDr</td>
<td>X</td>
<td>Internet account</td>
</tr>
<tr>
<td>BFp</td>
<td>X</td>
<td>Internet account</td>
</tr>
<tr>
<td>BGp</td>
<td>X</td>
<td>Internet account</td>
</tr>
<tr>
<td>BHr</td>
<td>X</td>
<td>Smart Card</td>
</tr>
<tr>
<td>BPr</td>
<td>X</td>
<td>Internet account, Smart Card</td>
</tr>
<tr>
<td>BDr07</td>
<td>X</td>
<td>Internet account</td>
</tr>
<tr>
<td>BPr07r</td>
<td>X</td>
<td>Internet account, Smart Card</td>
</tr>
</tbody>
</table>

This indicates that it is a rather common activity, performed by human agents (in this case, patients/relatives) in Health Care, to carry information between different care providers and units. Also, a majority of the participants have an interest in using an “Internet Account for IT support” for information transfer activities.

However, there were some aspects in the study that emphasize the opposite. One of the physicians stresses the importance of the patient as, primarily, being a fundamental information carrier, even if s/he welcome IT support for the task:

"Yes. We can never totally avoid that patients, to some extent, carries information, but some kind of Internet access would be satisfactory."
Participant ABph

This participant stresses the importance of the patient as Information carrier (human agent) in the comments to all three scenarios, and underlines the importance of face-to-face interaction between patient and care provider. It is important to accentuate that the Mock-up was illustrating a possible implementation of a system that should support the patient and the physician or other care providers in varying situations of information handling activities. The intention is not to exterminate real world interactions. Instead, the system should support communication between care providers and care recipients.” [Ådahl 2007].

In the analysis, it is clear that patients often are acting as information carriers and that this is an important task. An Information System for Healthcare should support this, not being designed to replace the task of patients being information carriers. The reason is that input to such a system should require impossibly large quantities of adequate data and, still if this was accomplished, it would not be able to replace the patient. This task might be compared with the results of the Turing test, but even harder as the data (i.e. Information) also must be very personalized with reference to experienced levels of pain, symptoms etc.
Consequently, the further future work turned out to concern Interoperability. Firstly, Interoperability related to aspects of Information flows seemed to be crucial. Secondly, Interoperability concerning support of Patients (support of their ability to collaborate) should be decisive. The design of a system ensuring this, with reference to Empowerment of Healthcare and Patient Safety, is fundamentally important (Chapter 3). The next step towards a Doctoral thesis was to reveal subtle, hidden, information structures, i.e. causal connections in information flow, in severe cases where Patient Safety has been jeopardized. Such structures are not immediately visible or visible at all for Healthcare personnel. Neither are they clearly visible for the patients. Furthermore, they often seem to be “Unknown Unknowns” (Chapter 6.4). However, to identify such should explain why something went wrong, which would offer a possibility to design tools for prevention of such incidents. Therefore, in the next chapter we present two different case studies, wherein we, in the analysis, will go deep into occurring information structures to trace the causes of mistakes, misses or even worse, death, related to the both cases. Further on, the results of the case study and this preparatory study are elaborated, resulting in a suggestion of a tool; the Visual Incidence Anamnesis (VIA) (Chapter 10).
Chapter 9 – Case Study.

In this chapter, we present the main study for this Doctoral Thesis. The study comprises the identification and analysis of two authentic cases, illustrating the importance of a complete medical history and unbroken Information Flows in Healthcare.

9. Introduction

The main study for this Doctoral Thesis is a case study of two different authentic cases, with that in common being cases where Patient Safety was affected in a serious way. Basically, the pitfalls have been incomplete information transfer in hand-over situations where decisive information was lost or not utilized. The first case describes an underlying undiscovered condition, developing in ten years, resulting in misdiagnoses and ending fatally. The second case describes a life-threatening situation in which the patient is falling ill, but recovers from the fatal disease when the cause finally, at the last moment, is discovered. The time-factor is crucial for this disease and the situation was occasionally very critical.

Initially, in this chapter the methodology is described which is followed by a description of the cases. The chapter is completed with an analysis and with some conclusions concerning the hazard of hand-over situations in Healthcare.

9.1 Methodology of identifying and studying the cases

The methodology is qualitative which is a choice in order to identify information flow; i.e. the actual information flow behind cases in which Patient Safety has been jeopardized. A more traditional quantitative methodology, producing measurable data, should not capture the context in which information flows between individuals, wards, clinical departments or hospital (Chapter 2). Accordingly, in this study, the point is not to measure phenomena, but to explain why they occur with reference to some real world, authentic, “HSAN-typical” cases. However, neither of the cases was reported to HSAN88 or the National Board of Health and Welfare, which implies that they are part of hidden statistics not noticed in the alarming numbers of injuries and deaths reported every year [Socialstyrelsen 2008b, Kohn et al 2000] (Chapter 1). This is even more thought-provoking.

Case I, taken place in the years 1999 – 2009, i.e. for ten years, is derived from participatory observations in situ (a local hospital in Sweden) and from interviews with the relatives to the patient, and the patient (the latter until CISIT4). The observations

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88 HSAN = Hälso- och Sjukvårdens Ansvarsnämnd (Medical Responsibility Board)
are compared with the medical records from each situation, to understand what went wrong and how the information was transferred or utilized. Informal unstructured open-ended interviews with Healthcare personnel (physicians and nurses) and the patients and relatives are also performed, to understand certain aspects of the course of events. This methodology, qualitative to its nature, is specially designed for the identification of subtle information flows in Healthcare where no other methodology is suitable. In Case II, occurring 2010-2011, the same methodology is adopted. In the following, both cases are presented.

9.2 The cases - Description

Case I - Retrospective Longitudinal Case Study (situation 1-4)

This case is a retrospective longitudinal qualitative case study, which concretizes information breakdowns for one patient, occurring over a period of ten years; 1999-2009. The case study is derived from an out-patient by means of in-depth observations in-situ and interviews with the patient and her relatives, in order to capture context and identify situations of high risk threats against Patient Safety. The case is identified, described and analyzed based on the authors’ (observers) personal knowledge in the case and knowledge as a professional (nurse). Accordingly, Case I is grounded in participatory observations, interviews with the patient and her relatives and analyses of medical records. This case presents four different situations (occurring in 1999, 2002, 2008 and 2009) in which, in retrospect, hypothesis testing (i.e. hypothetico-deductive processes) seems to have failed. This is a result of incomplete and broken information flows in each of the situations. Simultaneously, it demonstrates that patient specific information, collected for a long time, might be crucial for the Differential Diagnosing task.

Case I visualizes a fatal effect in information misses and breakdowns spanning over a long time, ten years, resulting in the death of the patient. During this time, information of earlier incidents and illness, with its context, is hidden for the physicians involved. Furthermore, the physicians involved are different each time, not knowing the complete coherent and continuous history for the patient. The locations for diagnosing and interventions are also different. This affects the information flow as there is no support in the EHR system for visualizing coherent information patterns.

Consequently, the four scenarios in Case 1 will show the importance of unbroken information chains, accentuating information flow as a part of workflow throughout the entire process; from diagnostics to treatment. They will also pinpoint the importance of correct information interpretation, addressing background knowledge in critical situations, and of complete Information, visualizing the development of the medical history.
Four situations of Case I
In the following, the four situations, together constituting Case 1, are described (Figure 27).

<table>
<thead>
<tr>
<th>Situation</th>
<th>Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (CISIT1)</td>
<td>Transitory Hemiplegia (1999)</td>
</tr>
<tr>
<td>2 (CISIT2)</td>
<td>Weakness after Syncope (2002)</td>
</tr>
<tr>
<td>3 (CISIT3)</td>
<td>Hip Bone Fracture (2008)</td>
</tr>
<tr>
<td>4 (CISIT4)</td>
<td>Stroke (2009)</td>
</tr>
</tbody>
</table>

Figure 27 – The four Situations of Case I

CISIT1 in this scenario refers to the initial situation, resulting in a *misdiagnosis* which evidently was affecting the following last 10 years of the patients life and most probably resulting in the death of the patient. CISIT2 refers to the second situation, resulting in another *misdiagnosis*, further delaying the knowledge of which cause of illness that is true. CISIT3 is a situation in which the focus for attention is diverting a focus from the basic cause of the situation. Accordingly, the focus is on the most apparent medical issue, secondary consequences to the illness and concealing the alarming symptoms of the basic cause of the situation. Finally, CISIT4 is a situation in which the *true cause of the situations is revealed, but unfortunately too late*. The lethal delay of the diagnosis turns out to be a result from a lack of vital information, foremost crucial information from earlier events. With reference to the need for fast access to such (coherent) information, when diagnosing and treatment is extremely time-critical, the current design of EHR-systems is not sufficient. *A coherent pattern of relevant information seems to be needed, to react and act upon*. Case I is basically pointing at two major short-comings in current Healthcare. Firstly, a heuristic adoption of Ockham’s Razor seems to override the collection of comprehensive patient specific information. Secondly, information flows in Healthcare are apparently not supported sufficiently by ICT.

Next, the both cases (Case I and Case II) are described in italics. A short presentation before the description of Case II is, in conformity with Case I, also added.

**Situation 1 (CISIT1): Transitory Hemiplegia**
*An elderly woman, 74 years old, was in 1999 suddenly experiencing an evident weakness in the right part of her body. The relatives, present at the time for the incident, called an ambulance whereupon the woman was transported to the Emergency Ward at the local hospital. After some days of hospital treatment, the physicians were diagnosing the woman with Migraine. The hemiplegia was transitory and as she had suffered from frequent occurrences of flittering scotomas during the period of hospital treatment, in addition to a long term history (since childhood) of migraine, revealed in the anamnesis, and since she had experienced some months of increasing social stress factors, this was exclusively in focus for the physicians. One*
The CAT scan was accomplished, revealing nothing suspicious in the brain. The diagnosis Migraine was established despite the absence of the usual migraine headache and, to the patient, the newly occurring neurological symptoms of scotomas and hemiplegia. As migraine is considered rather harmless, following up visits to Primary Healthcare providers was not planned or recommended. The woman was, as many in her generation, reluctant to bother healthcare with more visits, even though the flitting scotomas continued to occur in the years to come. However, she was seriously bothered by this; in addition to the fact that she did not experience the usual symptoms of migraine by which she was spared after her menopause at the age of 58-60. Furthermore, she was since many years suffering from high blood pressure, but when she was visiting her physician for routine blood pressure controls, the information about the transitory hemiplegia was not accessible for the physician and the patient did not mention it either as she trusted the diagnose “Migrain” despite some skepticism.

**Situation 2 (CISIT2): Weakness after syncope**

A few years later, in 2002, the woman (now age 77) was found lying over her kitchen table with bilaterally very weak muscular tonus nearly unconscious. She was able to answer when spoken to but not to move her body or keep her eyes open. She told that she had, suddenly, fainted away, sitting on the chair, and after that not being able to move and still very close to fainting again. An ambulance was called and she was transported to the Emergency Ward at the local hospital.

After a few days, she was sent back home with no following up directions for the Primary Healthcare. As she, when she arrived to the ward, had some unclear fever, and earlier that day, when she experienced the syncope and general weakness, had visited the local care center for the annual vaccination against the influenza, the diagnosis this time was “Reaction against the vaccination”, after excluding Septicaemia by receiving repeated negative blood cultures. Furthermore, the general weakness disappeared within the first 24 hours. As she, after the Emergency Ward, this time was transferred to the Specialist Ward for Infectious Diseases, the physicians did not study the medical record from the Medical Ward and was not aware of the former situation (SIT1) with transitory hemiplegia. Furthermore, this time the weakness was general, occurring after syncope why the patient believed that these symptoms were dependant on the reaction of the vaccination. She also trusted the physicians’ decision about the symptoms being dependant on a reaction of the immune defense.

**Situation 3 (CISIT3): Hip bone fracture**

The following situation occurred in 2008, when the woman, now of 83, suddenly felt faintly weak and fell in her staircase, resulting in a fracture of the hip bone. For a year, she had problems with weakness, feebleness and dizziness which she thought was natural decrepitude. Not even her district medical officer did think of any other reason. She went by ambulance to the emergency ward where the physicians were puzzled by her, at this time, frequently intermittent unconsciousness: off and on she went unconscious, with a snoring breath. Furthermore, she felt very sick, by nausea and frequent vomiting.
However, they noticed that she did faint in spite of lying down in bed and having a slow pulse of 30 when it happened. She also had too low levels of oxygen (SaO2 90 at most) and therefore required oxygen supply. The ECG revealed a momentary asystolia and attacks of atrioventricular block (AV block III), not compatible with her medication: metoprololtartrat\textsuperscript{89} (beta-blocker) which immediately was removed. Furthermore, obviously by notes in her EHR, she already was diagnosed by AV-block I which was unknown by the woman herself. Accordingly, she was not in an operable condition, so she was directed to the intensive care unit for cardiology until her heart was considered stable enough.

Two days after the accident, she was transferred to the orthopedic clinic for surgical operation (hip replacement) which was a success. However, the day after she was, again, medicated by metoprololtartrat (Selokén), which obviously did not fit to her AV-block history stated at the emergency ward and the cardiology unit. In the subsequent rehabilitation on the orthopedic clinic, she fainted at least three times when trying to walk (one time in the arms of a physician) and probably, not recognized, some times lying down in bed. She felt very weak, but despite these indications, no one seemed to understand the connection between Selokén and her AV-Block and did not check her blood pressure, nor her pulse, at the moments of fainting. Instead, the dosage of metoprololtartrat was increased as the presumption was fall in blood pressure due to the operation, and her inconveniences of palpitations. The woman did not reach her habitual state, but instead she was very weak and faintly, seeming much “older” and more fragile than the last year before the accident.

Nevertheless, after a week, the orthopedic treatment programme was finished and she was about to be sent home. The daughter, being a nurse by profession, attended the care planning meeting at the ward, now gaining information about the current treatment, and according to this raised a sharp protests against the decision to move her out of hospital. She claimed that her mother was not analyzed due to the cardiac failure and that the medication was lethal, at least a considerable risk factor for further accidents. The attending nurse did not seem aware of this situation but did after all pause the meeting and informed one of the physicians of the orthopedic ward who, in turn, consulted physicians at the intensive care unit for cardiology for a new standpoint on this “new” information.

However, the intensive care unit for cardiology was also unaware of the registered attacks of AV-block III at the emergency ward, solely focusing on cardiac stability for the orthopedic surgery! As a result, Selokén was still prescribed but due to the uncertainty of the situation and special arrangements in the woman’s home, she was allowed to stay for some days more. Two days later, Selokén was suddenly removed and she was allowed to stay until she might be stable enough for short-time housing or home. An anemia was also discovered the day after the planning meeting and she was ordered a blood transfusion and iron tablets. After 2 months of recovery, partly on a

\textsuperscript{89} Contraindication for metoprololtartrat: AV-block II and III. (http://www.fass.se/)
rehabilitation clinic, she was able to go home and now the symptoms of fainting, faintness and decrepitude were also completely gone.

**Situation 4 (CISIT4): Stroke**

Seven months after the Hip Bone Fracture, in 2009, the woman, now almost 84, went to bed after a day feeling tired and feeble. In contrast to her usual active life style, she only wanted to sit in a chair, resting that last day. Some of her relatives, visiting her in the afternoon, did notice this change for the worse and her adult granddaughter decided to stay for the night as a result of a premonition of danger. After just about three hours of sleep, her granddaughter heard her calling for help and rushed into the bedroom. This time the woman, again, experienced the general weakness, difficulties in opening her eyes and felt very sick, vomiting and close to fainting. The granddaughter called an ambulance and the woman was, again, transported to the Emergency Ward at the local hospital. This time the physicians had no immediate explanation to present. They discussed if the symptoms could be caused by a stroke, but the general weakness did not clearly answered to that. The relatives was present at the ward and the daughter, being a nurse herself, asked for a CAT scan which was rejected as it was in the middle of the night.

After one hour, the woman suddenly experienced an approaching faint and called for help. She had an ECG, monitoring her heart rate, and a moment later the electric waves became straight as a result of a cardiac arrest. The daughter sounded the alarm and the personnel managed to revive her. After this occasion, the woman was transferred to the intensive care unit for cardiology for monitoring and acute treatment. The attending physician at the Emergency Ward, after consultation with the senior physician on standby duty, who did not want to order a CAT scan in the night, excluded stroke as the diagnosis, purely on clinical basis, despite suspicious signs. The patient herself, at this moment still being able to talk, posed the risk of a stroke, but got the answer it could not be. The relatives knew about new treatment methods for strokes caused by blood clots, but also that such methods must be initiated within hours after the stroke began. This made them feel very frustrated. However, the condition seemed to stabilize and the physicians were determined about it not being a stroke, so the relatives were sent home as the patient did want them to do so, to sleep and to being able to go to work in the morning.

However, in the morning, when a CAT-scan eventually was performed, it revealed escalation of thrombosis (blood clot) in the brain and brain oedema in progress. Two older infarctions were also revealed, not diagnosed before. A short while after that, the condition went worse. It was at this time too late to use any method to treat the clot (thrombolysis) and stop the stroke from proceeding. Accordingly, the woman rather quickly got an explicit paralysis in her right side (hemiplegia) and lost her ability to speak understandable (expressive aphasia). The following hours, she went worse, in the afternoon also unconscious and finally she died late in the afternoon, 17 hours after the first symptoms.
9.2 Case II

This study, in progress for a period of ten months (2010-2011), was grounded in observations, interviews with the patient and her relatives and analyses of medical records. Case II provides an example of a very rare case, where the patient, initially and too hastily, got a false opinion on it and was sent home. The “Zebra-rule” (Chapter 5.4) was in this case obviously too firm, overriding every sign of something else being in progress resulting in a fatal situation. Also in this case, as in Case I, the time-aspect was very decisive to the development, and prognosis, of the forthcoming events after the first misleading diagnose. The delay of treatment resulted in severe Acalculous Cholecystitis as well as severe Septicaemia with a fast development of Disseminated Intravascular Coagulation (DIC)\(^9\). The possibilities to survive such conditions are directly dependent on the time-aspect. In this case, the time assigned for survival has almost passed the deadline due to perfunctory reliance on the Zebra-rule. Consequently, the philosophy of simplicity in Ockham’s Razor was initially noticeable in the decision making process. Furthermore, with reference to CIISIT2, this case exemplifies a causality dilemma (“Chicken or the Egg”) for which an acceptable solution might have been decisive for prevention of any recurrences. However, information about this dilemma was not explicit in the EHR for future physicians to reflect on.

In figure 28, Case II is illustrated. The figure is followed by a description of the case and the three occurring situations.

<table>
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<th>Situation</th>
<th>Incident</th>
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<td>Missed Diagnosis: Septicaemia, DIC, Acalculous Cholecystitis</td>
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<td>2 (CIISIT2)</td>
<td>Missed Diagnosis: Recurrence of Acalculous Cholecystitis</td>
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<td>3 (CIISIT3)</td>
<td>Open heart Surgery due to CIISIT1</td>
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**Figure 28** – The three situations of Case II

**Situation 1 (CIISIT1)**

“A young woman, 24 years old, diagnosed at birth with a complicated congenital heart condition with repeated open heart surgeries since then, falls suddenly to the ground with low blood pressure (syncope). At the emergency ward the body temperature rises quickly to 40 degrees (Celsius). No other symptoms are present. The physicians are not able to find any sign of a bacterial infection so she is permitted the following day to go home, despite a rising Bilirubin in serum, however not communicated to her or the relatives. Diagnose is “virus infection – influenza” despite no other clinical influenza signs than the syncope and high fever. Her mother, being a nurse by profession, did raise a protest against the influenza diagnose as she found it strange to have an “influenza” with no other symptoms occurring. She was under apprehensions about

\(^9\) Disseminated Intravascular Coagulation (DIC) = Severe condition in which blood clots form throughout the body’s small blood vessels. These blood clots can reduce or block blood flow through the blood vessels, which can damage the body’s organs.

septicaemia, but the physician rejected this as it is a rather rare diagnose and not probable at all for the young woman to have; “she would have been in a much worse condition if so”, the physician reasoned. Accordingly, and as the fainting tendency has disappeared, the patient and her mother now were open to any other symptoms coming, pointing at “influenza”.

The next day the young woman experiences nausea and frequent vomiting in addition to pain in the stomach and a mild nose bleed when she vomits. As those symptoms might be signs of influenza (such as gastric influenza), and intense vomiting might result in nose bleed, she and her relatives do not find this very suspicious with reference to the first apparently certain diagnose. However, in the evening she starts to feel very weak and the pulse rises to the frequency of 120/min. At this point in time, two days and nights have passed since the first signs of illness. The mother did find this alarming, either as a symptom of heart failure or as a symptom of shock. After some advice from the Swedish “Sjukvårdsrådgivningen 1177”, as the young woman was reluctant to see a doctor again after the first diagnose, she was transported to the Emergency Ward. At the Emergency Ward, the examination, the blood sample, blood pressure and pulse shows that she most likely has developed severe Sepsis with a Septic Shock reaction, multiple organ failure and, basically, she was suffering from a Cholecystitis probably causing the Sepsis or vice versa.

Immediately, intra venous antibiotics are ordered, and the patient is transferred to the Intensive Care Unit for continuous supervision and treatment. However, after 12 hours at the ward, the patient is considered stable, and therefore transferred to a Surgery Ward for treatment of the Cholecystitis, a rare condition designated Acalcuolous Cholecystitis91. The physician at the Intensive Ward was told, by the mother, that the patient has a complicated congenital heart condition and that the cardiologists, both at the local hospital and at the University Hospital, where the patient has her attending cardiologist, must be consulted as she has inserted biological material by operative surgery in her heart. As a result, the risk that she develops an Endocarditis, as a complication to the Sepsis, is rather high. Furthermore, her mother tells the Intensive Care Unit physician that the Cardiologist at the University Hospital has asked for information about changed health status as she also waits for a new surgery. She finds the answer she gets as “non sequitur” and “patronizing” and despite this information from the relative, the young woman is suddenly, transferred to the Surgery Ward without further discussions and without any further supervision of the heart function. The time at the Intensive Care Unit is also questionably short. The mother, being a nurse by profession, and the supervising nurses at the Intensive Care Unit, find this odd and is worried about the situation. The mother immediately, by her own initiative, in person, contacts the Cardiology Unit at the hospital and, by e-mail and telephone, gets in contact with the cardiologists at the University Hospital. This causes an upset reaction, where the chief physician at the Cardiology Unit visits the young woman at the Surgery ward and informs her and her relatives that she now will be transferred to the Cardiology Unit for further treatment and supervision of the heart. He says, rather upset, that “he has been present at the hospital since nine a.m. and now it is six p.m.

without anyone informing him about the patients’ arrival and condition”. Further on, the status of the heart is carefully examined, to avoid Endocarditis and heart failure caused by the bacteria in the blood and the large strain by the current disease.”

Situation 2 (CIISIT2)
The patient survived the serious illness but recovered very slow, for several months. The heart condition seemed to affect her more after the disease than before, increasing the heart failure. Five months later, she suddenly experiences fatigue, diarrhea and nausea, later in the day also vomiting. As she started to feel something in the area of the liver, she contacted Sjukvårdsrådgivningen 1177 where she was directed to the “emergency care center”, a care center open until 9 p.m, receiving an appointment time. She and her mother, helping her in this situation by driving, thought the choice of healthcare center was totally wrong, but still as she was directed there, they went there first. However, the mother opened the communication with the nurse at the care center with the assumption that the patient most likely was suffering from a recurrence of the acalculous cholecystitis five months earlier, which hastened the appointment time with the attending physician to occur one hour earlier. The physician immediately redirected the patient to the emergency ward, with a letter of referral with a question at issue: “Acute Cholecystitis?”. At the emergency ward, the patient was examined by a surgeon which immediately questioned both the assumed diagnose and diagnose five months earlier based on that the symptoms (again) was atypical and that he could not find the information in the EHR at a glance. He strongly doubted the relatives repeated assurance of that this young woman actually had suffered from acalculous cholecystitis (the diagnose is rare and the woman “too young”) until the laboratory report arrives: Rising s-Bilirubin again, just as the relative said was missed before. Now the surgeon did read the entire EHR report for the medical history of the last occasion and quickly ordered antibiotics intra venously. However, an ultrasound of the biliary passage and the gall bladder should have been prescribed immediately to collect patient data for future events. The patient was transferred to the Specialist Ward for Infectious Diseases, and when arriving to the ward, the day after, some physicians again questioned the rare diagnose, suggesting a more probable explanation to the symptoms: “gastric influenza”. A physician decided to change the treatment, in the weekend, as she found it very unlikely to contract a rare disease such as acalculous cholecystitis more than once. However, the mother, being a nurse and medically trained, objected very firmly to this point of view, this time. She had found out that, despite the rare condition not likely at all to affect a young woman, of normal weight, even slightly underweighted, a state of severe heart failure might cause ischemia in the gall bladder and this is one of the causes to acalculous cholecystitis. The mother had to be very firm, both in discussions with the physician and by leaving a written report of this hypothesis. Finally, she gained a hearing. The young woman did rather quickly recover from the symptoms, and also from the soreness and swelling over the liver, by treatment for the true diagnose in a very early stage of the disease. When she later on made another visit to the clinic to control how she had recovered, she also met the doctor at the ward that treated her earlier that year, when the acalculous cholecystitis first appeared. He made a note in the medical record about paying attention to the fact that she might have this rare condition if she develops symptoms like the ones she
already had twice. In cases of such symptoms occurring, a ultrasound of the gall bladder must immediately be performed, to be able to collect unquestionable data for proof. Early treatment is crucial in cases like this.

**Situation 3 (CIISIT3)**
Two months after the recurrence of the acalculous cholecystitis, she had to undergo another open heart surgery for her heart condition as her heart failure now was severe and might have been directly life threatening. It was discovered that she had only 33 percent capacity left of the aortic valve (a biologic xenograft) that was considered destructed by the surgeon. Most probably was the initial missed diagnoses Septicaemia and acalculous cholecystitis, with the delayed treatment, a direct cause of the accelerating degeneration of the valve. Consequently, it was decisive for her survival that she received early treatment when the cholecystitis reoccurred.

**9.3 Analysis of the cases**

**Case I**
This case, spanning over a period of 10 years starting in 1999 and ending in 2009, is built on four apparently different situations. Each situation has a separate pathophysiological explanation of the occurring symptoms (i.e. diagnose), and, as a consequence, each diagnose is treated separately and not reflected by the other situations. Case I SIT 1 (CIISIT1) initiated the course of events in CIISIT4 occurring in 2009. The symptoms experienced at this time (1999) resulted in the statistically most probable diagnose **Migraine**. The reasoning towards this decision was grounded in information about the patients’ earlier medical history of severe migraine and the circumstances of increased social stress she experienced at that time. These factors were overriding the absence of other typical migraine symptoms she was used to experience; such as the headache peculiar to migraine. The patient herself did find this diagnose strange, as she did not suffer from migraine since her menopause at the age of 58-60, approximately 15 years earlier. However, as she trusted the decision and as the CAT-scan\(^{92}\) did not reveal any pathological alterations in the brain, she did not object to this diagnose. The inevitably most common cause of such symptoms is **Migraine** and in 1999 **Migraine** was the most probable diagnose which ended the DD process.

In retrospect, we should question the trust in the result of the CAT-scan in 1999. This should be done by asking if CAT-scans are quite reliable to exclude cerebral infarctions or if MRI-Scanning\(^{93}\) (Magnetic Resonance Imaging) would have revealed something else, something pathological. This imaging technique provides physicians with more detailed information, especially of the brain as it can “see through” bone (the scull).

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\(^{92}\) CAT-scan (CT-scan) = “Computerized axial tomography scan is an x-ray procedure that combines many x-ray images with the aid of a computer to generate cross-sectional views and, if needed, three-dimensional images of the internal organs and structures of the body.” (http://www.medicinenet.com/cat_scan/article.htm)

\(^{93}\) MRI = Magnetic Resonance Imaging, “radiology technique that uses magnetism, radio waves, and a computer to produce images of body structures.” (http://www.medicinenet.com/mri_scan/article.htm)
Moreover, MRI is superior to CAT-scan in imaging soft tissues (such as the brain) as it can produce images in any plane and has the ability to change the contrast of the images. However, prescribing MRI is costly. Therefore, CAT-scans are generally the first hand choice. A peril is that even if a negative result using CAT-scanning is not absolutely negative, it is still often considered as being negative. Consequently, the result must be compared with other clinical findings and tests, but also with the anamnesis. If there still are signs of pathological activity in the body, or if the anamnesis is pointing at a direction when pathological activity still must be considered, MRI scanning should be addressed. There are of course some specific situations when MRI is the first-hand choice and CAT-scan is not considered at all. For example, concerning congenital heart conditions, MRI is addressed to replace cardiac catheterization.

Returning to CISIT1, the anamnesis in 1999 pointed at a direction when cerebral infarction, or at least TIA, for this patient, was more probable than suddenly reoccurring migraine without typical symptoms; despite the negative result of the CAT-scan. Consequently, in retrospect, the differential diagnose should still have been considered and not rejected. In other words, this information should have been immediately visible for later events. Instead, the case reveals that all information about this event was lost and the following situation was completely separated from the earlier course of events. With reference to CISIT4, it is concluded that older blood cloths in the brain were identifiable by CAT-scan in 2009 which must raise questions about when (during 1999 and 2009) those were originating. Therefore, it can not be excluded that CISIT1 could have Stroke as the true cause of the symptoms. However, Migraine as the (statistically) most probable cause of the symptoms was addressed rather early in the DD process: The iterative process of a hypothetico-deductive approach [Shortliffe 2006, Elstein et al. 1978, Kassirer and Gorry 1978] to the problem was ended prematurely. No further tests were prescribed and the case was not followed up. However, the patient was referred to psychiatric consultation at the discharge, as a way to handle the unfortunate social situation which was considered to be the cause of the chosen diagnose. The patient did not enter this line of treatment as she did not feel a need for psychological aid. Instead, she was very bothered by reoccurring events of flittering scotomas and reflected much of the absence of (the migraine typical) headache.

Analyzing the course of events in CISIT1, both heuristic thinking in the DD-process and ambitions of cost-reduction might be influential to the validity of the results of the involved decision making. Background information to this situation is that an elderly patient, with high blood pressure and migraine in the anamnesis, are at increased risk for Stroke. Consequently, the occurring symptoms should have alerted for this risk. Furthermore, and unfortunately, critical information of CISIT1 was lost in the coming visits to the care center, as an outpatient (primarily the usual visits for her high blood pressure; hypertension). Limitations of (electronic) information management in Healthcare at that time (1999), and deficient routines and protocols for such information flow, was a probable cause of an information breakdown (broken information flow). The patient herself was the information carrier and therefore the
only link to the earlier CISIT1, but still convinced about the absoluteness of the diagnose migraine she did not report about the former event. Furthermore, she did not want to be a nuisance to the physician as many from her generation (acceptance of a paternalistic Healthcare).

The following situation, CISIT2, occurred unexpectedly in 2002. In retrospect, with prior knowledge about CISIT1, a reasonable hypothesis to be further tested is “Stroke”. However, as the first situation was carried only by the patient but not reported as she still trusted the first diagnose, and did not connect the new situation to the first; “Unknown Knowns” (Chapter 6.4). For the physicians, not aware of CISIT1, the fever and the fact that she had a vaccination against Influenza earlier that day did override the more serious symptoms of general neurological weakness and syncope: It was (statistically) most likely that the influenza vaccination caused the fever and the other two symptoms. The differential diagnose was Septicaemia and blood tests (blood cultures) was performed which were negative. Consequently, information from CISIT1 was not visible or easily accessible in CISIT2. Therefore, the actual (considered most probable) hypotheses this time were Reaction against the vaccination or Septicaemia (due to the vaccination). Septicaemia was excluded as the blood tests were negative and other symptoms of Septicaemia did not occur. As a result, the other symptoms were explained with reference to, a rather unusual, immune defense reaction on a vaccination. Also in CISIT2 the patient was discharged with no further follow-up. Even worse, Information from both CISIT1 and CISIT2 was invisible for physicians in the coming situations. With knowledge about these two situations, it must be considered that alternative strategies for anamnesis creation and visualization of earlier events to physicians might be necessary: Information, potentially crucial for the differential diagnosing process, was obviously lost between CISIT1 and CISIT2.

The time span between CISIT2 and CISIT3 was six years. However, during this time the patient occasionally experienced events of tiredness and feelings of weakness. This was new compared to the time before CISIT2. Furthermore, the perceptible change of personality since CISIT1, appearing suddenly as unexpected irritable mood, continued. Also, the flitting scotomas continued to bother her. In 2008 (CISIT3), she suddenly fell in the staircase and went unconscious off and on. Diagnostic radiography (“X-ray”) revealed a hipbone fracture (i.e. a colhum fracture) in addition to inability to move the leg due to pain, the fracture and tissue lesions in the area. This became the main focus of this event. Her occurring arrhythmia was also in focus, at least temporarily as it was a dangerous obstacle for operation. In CISIT3 as well as in the preceding CISIT1 and CISIT2, Ockham’s Razor of Diagnostic Parsimony is interesting to reflect upon: The Zebra-rule is identifiable in all three cases, causing premature abruption of the DD process and information break downs where need for further (important) information is not even considered. But basically, it must be emphasized that information about CISIT1 and CISIT2, occurring about nine respectively six years earlier, was not available or visible in order to be related to this event. Furthermore, additional (potentially important) information about the patients frequent occurring flittering scotomas and other occurring symptoms 1999-2008 was not either visible. The
visibility of such a “line of events” would have created a pattern strong enough for a physician to react and act upon.

Continuing with CISIT3, as described, the patient fell and broke her hip (collum fracture) in 2008. Accordingly, as the injury was rather immediately (and easily) diagnosed and required prompt action, in addition to the patients occurring heart problems which initially was hindering the surgery, the main focus was on the treatment of the fracture. However, the point in this situation is that a more comprehensive perspective would comprise the question why the patient fell. This aspect was completely lost, probably as it is rather a common phenomenon that elderly people will fall. The patient was 83 years old and many people at that age are decrepit. However, this patient was not decrepit due to her age. Basically, general state of health in relation to aging was quite good. Accordingly, it was rather unlikely for this patient that the ageing would have caused the fall. This patient specific information in relation to a coherently visualized anamnesis, revealing the two preceding situations in 1999 and 2002, could have generated a focus on why she fell. To ask “why” might be important to obtain a holistic solution, i.e. in this situation result in the creation of a new hypothesis of another diagnose, as the main cause of the others. It is conceivable that Stroke was the main pathophysiologic (and causal) explanation of the other diagnoses (Hipbone Fracture and Cardiac Arrhythmia) as she might have fallen in the stairs due to a thrombosis in the brain and the heart was affected both by the thrombosis and the physical trauma. This would have been impossible to hypothesize without knowledge about the patients’ normal state of health and earlier incidents and their symptoms.

CISIT3 is also exemplifying how life critical information rather easily is lost between wards. This is typical “hand-over” situations where the EHR system is not sufficient and must be supplemented by oral reports. This is basically an Interoperability issue: In these situations, many factors might jeopardize the hand-over act. One factor is insufficient notes in the EHR-system. Another factor is difficulties in accessing medical records from subsequent clinical departments. For example, due to integrity aspects, only physicians are (at the hospital in CISIT3) allowed access to medical records in other departments. However, laboratory reports are accessible also for nurses. A third jeopardizing factor is insufficient oral reports at the handover situation. In such a situation, the information carried by the patient might be decisive. Unfortunately, patients are unequally health literate. It is also decisive who in Healthcare they try to communicate with and how that person understands and utilizes that information. In CISIT3 it is three handover situations; the first two most critical of them all:

**Emergency Ward (EW) - Intensive Care unit For Cardiology (ICUFC) - Orthopedic Clinic (OC) -Orthopedic Rehabilitation Clinic (ORC)**

Between EW and ICUFC, information about the registered attacks of AV-block III was lost. This is rather serious as medication with metoprolol tartrat (Selokén) might be lethal in case of AV-Block III. Therefore, a serious mistake, affecting Patient Safety, occurred when the physicians at the OC prescribed Selokén again and also increased
the dosage due to vague suppositions. Moreover, no one checked the blood pressure or
the pulse when the woman repeatedly fainted at the OC. In the handover situation
between OC and ORC, a relative provided the lost information. The woman was about
to be sent home, but was allowed to stay with reference to the seriousness of that
information. However, the origin of the actual information miss between ICUFC and
OC, occurring between EW and ICUFC, was revealed when the physicians at the OC
tried to confirm the information reported by the relative. It was not registered or
reported why the woman must not be further medicated by Selokén. However, it is
obvious that the information must have been confirmed as Selokén suddenly was
discharged two days later. How that decision was made was not obvious in the medical
record, though.

Regarding handover situations in Healthcare, oral reporting is a basic necessity to make
information flow properly. However, the basic reporting methodology is dependant on
individual skills and ability to assess information. In recent years, security protocols for
handover situations are developed. One of the attempts to increase Patient Safety by
such protocols is SBAR (Situation, Background, Actual condition and Recommended
actions) (Chapter 7.3). Accordingly, this is a model for structured communication in
Healthcare. The SBAR protocol was, and still is, in use at the EW referred to in Case I.
Nevertheless, the information flow was broken probably as the EHR system did not
actively visualize important events. The human agent(s) from the EW, reporting to the
ICUFC, did not appraise some of the occurring symptoms as immediately important or
forgot to highlight such symptoms in the hand-over situation. This type of errors might
occur due to context dependant circumstances such as shortage of time, high workload
with the management of parallel patient cases etc. The result is missed vital information
causing future threats to Patient Safety. Conclusively, even if SBAR is providing a
structure of information to report, the variables (patient specific data) structured by the
SBAR protocol must still be elicited assessed and selected by human agents. This act
requires immediate access to relevant patient-specific data which put emphasis on
support of identification, collection, management and presentation of such data.

In CISIT4, occurring only a few months after CISIT3, the interrelation between the two
situations became evident in retrospect. The lethal result of CISIT4 is most probably
highly dependant on a lack of visible longitudinal coherent information, presenting
events where the symptoms basically were related (Visualization of causalities in
context, Chapter 10.3). This type of individual information should have overridden the
former assumptions of CISIT1, CISIT2 and CISIT3 grounded in Ockham’s Razor;
instead revealing the manifestation of the “Zebra”. In CISIT4, the focus was on the
heart as cardiac arrhythmia and cardiac arrest suddenly occurred at the EW. The
physicians at the EW and the ICUFC did not listen carefully to the relative (a nurse by
profession) suggesting a cerebral catastrophe. The relatives were in this case the actual
key to a coherent longitudinal medical history, revealing the true diagnose grounded in
deep knowledge about former isolated events and the actual habitual health status of the
patient, but still not considered as fully members in a “collaborative patient-centric
team”. Therefore, they could not convince the physician on duty that night to prescribe
a CAT-scan, as the more experienced physician (on stand by duty) decided not to
perform a CAT-scan at night. In this situation, he estimated the economical factors of performing a CAT-scan at emergency duty hours, by comparison with the probability of the presence of a cerebral catastrophe, more considerable. Accordingly, this decision to wait and see was made on other factors than relevant patient specific factors. The fatal decision was caused by the invisibility of such crucial information in the EHR, at the point of care and in the actual situation. In addition, the medical reports and fear of a cerebral insult presented by the relatives were not taken into serious consideration. The focus was entirely on the heart and the story about mushrooms (chanterelles) that the patient had eaten earlier that day. The symptoms were undefined (as in CISIT1, CISIT2 and CISIT3) and the nausea and attack of vomiting was primarily explained as a probable result from food poisoning, or even gastric influenza (the most probable cause of nausea statistically viewed). However, such an approach might be lethal as it delays treatment. The time aspect is sometimes very decisive in medicine and a delay might be life threatening. Stroke is one of the diagnoses when early treatment is decisive. For Stroke by Thrombosis (the true diagnose in CISIT4, unfortunately revealed too late) treatment must begin very early. Thrombolytic drugs must be used immediately within hours to minimize the injury of the brain. Accordingly, in this last situation, when the CAT-scan finally was performed, it was too late for such treatment.

Heuristic thinking in the form of rules-of-thumbs is common for human agents, but in Healthcare, other strategies may be needed. Healthcare personnel are often working under pressure due to cost-reduction ambitions in Healthcare. For example, relevant for the actual Swedish hospital in CISIT4, only one physician for each clinical department is at duty in the night-time. The physician is responsible for decisions at each ward and, in addition, the emergency ward and the intensive care unit (for cases related to the department). The physicians in duty at night and in week ends are often less experienced (assistant physicians/housemen) but they can call a more experienced physician if required. Accordingly, s/he must simultaneously handle parallel multiple cases at the different wards and also make decisions about diagnosing and treatment or decide to consult the experienced “physician on stand by duty”. Even in daytime, the pressure is severe and physicians often experience a lack of time for each patient. Therefore, a solution for such insufficient routines and protocols must not be time consuming in itself. Instead, it must release time at the same time as it increases Patient Safety by providing a more holistic view of the patient and his/her entire medical history. The ambition must be to compensate for mistakes and misses dependant on hidden important and/or life-critical information, but not to aggravate the situation by occupying more time. In CISIT4, the more experienced physician was at home, not available to listen directly to the relatives. The less experienced physician at the EW/ICUFC did not entirely grasp the situation and missed to report decisive information when consulting the experienced physician by telephone (a type of “hand-over” situation). A decision support tool, additional to available CDSS and EHRs, visualizing events over time (CISIT1- CISIT3), could have confirmed the importance of the information reported by the relatives in CISIT4; resulting in further examinations of the patient (Chapter 10).
Case II
This case study is divided in three situations (CIISIT1 CIISIT2 and CIISIT3), at a glance, or from the perspective of Healthcare, rather different with no clear interrelationship. However, with deep knowledge about context, analyzing the hidden information structures of the case, it is possible to reveal several alarming deficiencies in both information handling routines and the decision making process.

The analysis of the first situation points at abruption of the differential diagnosing process prematurely, i.e. the hypothetico-deductive process. In the beginning phase of this situation, the signs of adopting the “Zebra-rule” are strong as the physicians did not suspect early symptons of neither Acalculous Cholecystitis nor Septicaemia. The most (statistically) probable diagnosis was “Influenza”, despite any visible symptoms except the high fever. For at least two reasons, the time aspect was very decisive in this situation. Firstly, the hypothetico-deductive process was abrupt prematurely, before the blood tests did reveal a severe bacterial infection. Initially, such infections show rather low levels of blood activity pointing at a virus infective activity. Simultaneously, and secondly, the prognosis of such severe bacterial infections is very dependant on early treatment strategies, foremost treatment with antibiotics. The earlier treatment, the less damage to the body with lower mortality rate as a result. CIISIT1 shows the opposite as the Zebra-rule (Chapter 5.4) was overriding the suspicious information and the information that the relative brought. There were at least four aspects announcing for a risk of lethal development of an infection not being “Influenza”:

1. The patient suddenly falling ill (fainting with no other symptoms than intermittent high fever).
2. A slightly pathologically high s-Bilirubin.
3. The relative worrying about Septicaemia and the information about the patients’ earlier and habitual health status she brought.
4. The very early consulting (time aspect).

These aspects should have motivated prolonged monitoring in hospital with new blood tests. Instead, there was no hesitance in the information to the patient and the relative about the diagnosis chosen (Influenza) and both the patient and the relative were convinced at the discharge. This is an example of the difference between statistical probability and individual (patient specific) probability. The latter is probability in relation to individual information, i.e. causalities in context (Chapter 10.3).

In the continuation of CIISIT1, there were also (as in Case study 1) occasions of information losses in hand-over situations; for example, when the patient was discharged from the hospital in the situation above or transferred between wards. In these hand-over situations, both crucial information of the current period of care and potentially crucial information about the previous medical history were lost. The probable reasons for this are dependant on a variety of actions. For example, information in the EHR is noted down by human agents (if not embedded software take care of certain data coding and registration), with individual apprehensions of the value
of patient specific data, and important data is not clearly visualized for the physician, or understood, at the point of care. Moreover, and even more serious, the relatives were not considered as important collaborators in a patient-centric team (Chapter 7.2) in the situation. The information brought by the patient (or its proxy) should serve as a tool for further decisions as this information might point at crucial information in the EHR or being additional to the current information, collected in the actual situation.

One of the first identifiable losses of information in a hand-over situation within the hospital occurred in the situation when the patient suddenly was transferred to the Surgery Ward (SW), from the Intensive Care Unit Ward (ICUW). However, there were other information losses before, such as a substantially fall in blood pressure (to roundabout 48/24) after a morphine injection (she had severe pains) at the Emergency Ward (EW) before. The fall in blood pressure occurred when the nurse had left the room and resulted in unconsciousness. The blood pressure was automatically tracked by the patient monitoring system, displayed on a medical monitor and noticed by the relative (calling for help), but not registered in the medical records (by the EHR). This information was afterwards carried orally by the relative throughout the hospitalization period.

It was later proved that the patient, above severe Septicaemia with Disseminated Intravascular Coagulation (DIC), causing multiple organ failure, also suffered from the rare condition Acalculous Cholecystitis. However, as she was considered stable from the point of view of a senior physician at the ICUW (where she was situated after the EW), she was transferred to the SW for further treatment of this condition. In this situation the information loss was concerning her complicated congenital heart condition comprising implants of biological material. There is a considerable risk of developing Endocarditis in case of bacteria’s in the blood (Septicaemia), which in case of heart conditions with implants is increased. In her case, such an infection would destroy the biologic valves of the xenograft (aortic valves) that she had or the conduit (a homograft) from the right chamber to the pulmonary arteries (pulmonary valves and artery). Just before the transfer to the SW, the mother tried to discuss this risk with the senior physician. She also reported what the patients’ attendant cardiologist had told her; to report to him every health related incident or change of health status as the patient was awaiting another surgery; to change the xenograft that was leaking too much. The senior physician did not listen to her at all and, instead, decided that the health status was enough stable to stop the intensive supervision at the ICUW. This situation occurred only twelve hours after the origin of the septic shock at the Emergency Ward (EW). In this situation, the mother acted as information carrier as she, very upset and in despair, went to the Intensive Care unit For Cardiology (ICUFC) and reported that the patient was out of supervision with the entirely focus on the Acalculous Cholecystitis on a SW with no monitoring or supervision of her heart. As the senior physician was reluctant to do so, the relative also contacted the attendant

\[94\] Endocarditis = a serious infection of one of the four heart valves. [http://www.medicinenet.com/endocarditis/article.htm](http://www.medicinenet.com/endocarditis/article.htm)

The information changed the direction of care and the patient was transferred from the SW to the ICUFC for further monitoring, with the physicians at the SW as consultants. The patient was monitored and treated for Septicaemia and DIC as well as Acalculous Cholecystitis. Furthermore, her heart was carefully monitored to discover any changes in function or signs of Endocarditis. For example, the DIC resulted in general oedema due to malfunctioning kidneys, with an increasing body weight up to 9 kg (approx. 19.8 pounds) above the normal 55 kg (121 pounds). The Hb count decreased to levels below 80 which, in addition to the oedema, also put severe strain on the heart. Medical examinations of the valves (UCG⁹⁶) were performed to discover growth of bacteria (vegetations) of the heart valves. In order to prevent complications or even lethal result of chosen decisions, a need for a holistic view of the body is evident with reference to this example. The information about the heart was decisive as the congenital heart condition was fundamentally important for the prognosis. This case also points at the importance of using patient carried information, i.e. listen to the patient. The senior physician at the ICUW had an unresponsive attitude to the information that the mother carried (paternalistic approach, not patient-centered, Chapter 7.2), which might have affected the outcome of the treatment severely if the mother had not acted on behalf of her own decision.

After a very slow recovery, comprising several reverses and finally an infection with Clostridium Difficile⁹⁷, the patient was discharged after six weeks at hospital. However, she was in the following months not fully recovered, suffering from after-effects (related to the CIISIT1) described later in this section.

Interestingly, a causality dilemma was arising when the true diagnoses were decided. It could not be concluded if the Acalculous Cholecystitis was the cause of the sepsis or vice versa. The most probable hypothesis was the first assumption. However, the strain of bacteria found in the blood test (culture) was not a bacteria normally expected to be found in the biliary passage. Therefore, the probability of the Acalculous Cholecystitis as the cause of the sepsis was low. Instead the strain of bacteria was a rather common bacteria normally found the respiratory passages; Haemophilus parainfluenzae. Even more intriguing was that Acalculous Cholecystitis is a very rare condition and the patient was not at all the statistically typical patient in danger for such a condition. Most patients affected with this infection are elderly, seriously ill patients or trauma patients at the intensive care unit. On the contrary, this patient was a young woman; hastily and totally unexpectedly falling ill at work with no preceding warnings. Beyond her heart condition, with some inconvenience with a heart failure, she was completely healthy. The physicians did not find it necessary to answer the question “Why” as they thought is was rather impossible to do so.

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⁹⁷ Clostridium Difficile Colitis = an infection of the colon caused by C. difficile that occurs primarily among individuals who have been using antibiotics. http://www.medicinenet.com/clostridium_difficile_colitis/article.htm
However, it should sometimes be of importance to also identify the cause of the diagnosis, not only the diagnosis as a cause of the symptoms. In this case, it seems to be decisive! Acalculous cholecystitis is a life-threatening condition with a high mortality rate. Severe sepsis with DIC and multiple organ failure is also extremely serious. For both conditions, the time aspect is critical for the possibilities to survive. Consequently, causation is very important for the development of further events such as recurrences. Therefore, following points could be hypothesized:

1. The sepsis is a result of the Acalculous cholecystitis.
2. The Acalculous cholecystitis is a result of the strain of the sepsis.
3. The sepsis and the Acalculous cholecystitis are separate, independent conditions, randomly appearing simultaneously.
4. Due to the strain of a heart failure, the sepsis is a result of some undetected infection in the throat or respiratory passages.
5. The Acalculous cholecystitis in CIISIT1 is caused both by the strain of the sepsis and a potential ischemia in the gall bladder due to a heart failure.
6. The Acalculous cholecystitis in CIICIT2 is caused by an increasing heart failure and a potential ischemia in the gall bladder.

Lack of time and high workload, unfortunately often evident in Swedish Healthcare, prevent physicians from hypothesis testing aiming at finding a causal explanation in context for the origin of the diagnose itself. Nevertheless, such testing might decrease the number of recurrences or further illness. In this case, the most probable hypotheses for this particular patient, with reference to hidden patient data, should be no. (2), 4, 5 and 6. However no. 1 and even no. 3 was the hypotheses in focus for the physicians, but only occasionally. The different perspectives are dependant on presence or absence of critical patient data. In this case, the physicians in case II had not a holistic context related view of the situation for the patient, which the relatives and the patient had. Accordingly, visualization of information (i.e. visualization of causalities) in context (Chapter 10.3) supporting a holistic view might change the perspective and provide possibilities of treatment to prevent recurrences. This is why “The Why” is important.

Returning to the initial and decisive situation in this case (CIICIT1), the physicians were apparently adopting the principle of Ockham’s Razor interpreted in the shape of the proverb; referred to as the “Zebra-rule” (Chapter 5.4). They decided to choose a very common, and therefore also statistically probable, diagnose: Influenza due to a virus. However, they both neglected and missed important information in this phase: The actual disease started with a syncope and suddenly high fever (ague) that declined to the next day. Interviews with the patient afterwards reveal senses of confusion during the night at hospital and inability to communicate this experience clearly to the personnel. The explanation must be that the communication between the personnel at the ward and the physicians was incomplete or even none existing (information- and communication deficiencies [Socialstyrelsen 2008]). Furthermore, the patient was also exhausted when she was discharged the day after. Nevertheless, in the medical record are notes about the patient “being in good condition” when discharged from the
hospital. However, in reality she was not capable of walking and had to borrow a wheelchair to be able to make it to her mothers’ car. This information had unfortunately also been lost and the physicians were not aware of it.

The personnel were not informed about the differential diagnosing procedure actual for this case, or did not have the knowledge about the differential diagnoses, and could not act on deviations from the decision. Unfortunately, the time aspect was crucial for a true diagnose to be found in this case. The blood tests were performed too early in the process and not repeated the next day. Therefore, the CRP-test (C-Reactive Protein) was rather low, pointing at a virus infection, and also the level of white blood cells was not alarmingly high. With reference to this, neglecting a rising Bilirubin in serum, and with a (false) apprehension of the patients apparently good condition, the hypothetico-deductive process was prematurely ended and a simple and common virus diagnose chosen. However, with a continued process, with repeated tests before a decision, a fast rising CRP and level of white blood cells, in addition to Thrombocytopenia (decreased number of platelets in the blood) and increasing stomach pains would have lead the physicians to another conclusion. Furthermore, more attention to patient specific data reported from the patient and the relatives would probably have diverted the physicians’ from attending to the “Zebra-rule”, instead trying to extend the hypothetico-deductive process a little more until there was certainty.

In CIISIT2, an even more problematic dilemma was arising. When the patient recognized the symptoms of arising Acalculous Cholecystitis from the abdomen, she quickly consulted Healthcare for early treatment. However, the physicians were very unequally willing to listen to the information brought by the patient and her mother. As the information about CIISIT1 was not immediately visible for the physician at the emergency ward, the patient had to convince him to search for it in the EHR. He was certain about the impossibility of the former diagnose being Acalculous Cholecystitis, as it is a rare condition and even impossible for a young and apparently healthy girl to be affected with. Consequently, he was initially very reluctant to spend time to search for earlier information in the EHR. Not until the laboratory report of a rising s-Bilirubin arrived, he was willing to do this. When finding information about CIISIT1, he was convinced and immediately ordered antibiotics intravenous. This example shows that it could be hard for patients and relatives to be regarded as reliable information carriers, even if they are Healthcare professionals themselves (as the mother in this case was). To save time and increase the possibilities for patients of being taken seriously, the EHR must immediately present a relevant medical history in chronological order (coherent medical history) to physicians trying to decide on a diagnosis. In CIISIT2, the patient herself and her mother had to inform the physician about their apprehension of the current symptoms and how they related to the symptoms occurring in CIISIT1. This physician finally trusted this information and started to search for more information in the EHR, resulting in early treatment of the illness (intravenous administered antibiotics). Furthermore, palpation revealed that the area of the liver was swollen and sore. The patient was transferred from the EW to the Specialist Ward for Infectious Diseases (SWFID) but also in this hand-over situation, information about the initial decision and treatment at the EW in CIISIT2 was lost. The information transferred by
the EHR was incomplete and not clearly visible as some crucial information about the choice of treatment was lost. Therefore, the day after at the SWFID, the treatment and diagnose was questioned again (as it is a statistically rare condition). Again the principle of the “Zebra-rule” was addressed and the physician at the new ward insisted on the pathophysiological explanation “Gastric Influenza” for the occurring symptoms, as that is the most statistically probable cause of such illness for a young woman. The physicians’ apprehension was that being diagnosed once with the very rare condition Acalculous Cholecystitis decreased the probability of being affected twice. They did not consider the role of the individual medical context; the heart condition as being the basic cause to it. The burden of proof was on the patient and the relatives which is not a preferable or safe situation in Healthcare. Not until a physician, present at CIISIT1 and clearly remembering the patient, was on duty at the SWFID the information was utilized: The increased risk of developing Acalculous Cholecystitis and future strategies to meet this was confirmed as an “alerting note” in the EHR.

Finally, CIISIT3 was a result of CIISIT1 and the underlying problem of the patients Congenital Heart Condition. CIISIT1 was most probably causing the increasing Heart Failure that motivated another Heart Surgery seven months later. The aortic valve was, by the surgeon, considered destructed. This increases the individual (patient related) probability of developing Acalculous Cholecystitis, as a state of severe heart failure might cause ischemia in the gall bladder which is preparing for infections to grow. Furthermore, a state of lingering moderate heart failure should probably be considered as a potential risk. This example points at the difference between statistical probability and individual, patient related, probability. Patient specific information must always be reconsidered before any adoption of “the Zebra-rule” (Chapter 5.4, 10, 11). Case II is a typical example of this, when “the Zebra is more probable than the Horse”. Accordingly, the context of “the hoof beats” is decisive.

9.4 Conclusions of the analysis
A “line of events” represented in chronological (coherent) order, in retrospect forming a pattern of “pathological developments” in a complete historical perspective, was missing in both Case I and Case II. In order to perceive such pattern, intensive review of medical records and interviews are required which is time-consuming and probably not prioritized or even considered. In this perspective, Ockham’s Razor is an obstacle to the true diagnosis as the simplest and “most probable” explanation tends to be addressed if the symptoms in broad outline seem to fit the explanation: Nevertheless, context of the symptoms, i.e. earlier symptoms and events and other patient specific variables might change the validity of the chosen diagnose.

Case II presents occurrence of a typical “Zebra”, a “Fascionoma”, where the diagnosis is preposterous in relation to probability. The context of this diagnosis is the underlying Congenital Heart Condition. To be aware of this context is crucial; to diagnose, to explain the illness and to prevent further illness. The case shows the need for a quick visualization of the medical record; for exposition of earlier events (visualization of causalities in context, Chapter 10.3). In CIISIT2, the patient and her mother should not have to convince the physicians to search in the EHR for a specific earlier occasion and
diagnose to confirm the current most probable cause of the symptoms. Each hand-over situation in a case of illness is hazardous as crucial information could be lost, but also the periods between the cases of illness are hazardous for the same reason.

In addition, demonstrably both evident in Case I and in Case II, prematurely abrupt hypothetico-deductive processes were noticeable. A potential cause of those abruptions was heuristic thinking and an apprehension of probability in relation to certain, in these cases misleading, variables. Such variables were simple data about immediate circumstances and data about the patient-type such as age etc. Simultaneously, crucial and more complex information was missing. In Case I, the crucial point is invisibility of earlier events and also the potential importance of earlier events. The possible relation between those events is also hidden to the physicians. To be able to discern such relations, the line of events must be exposed. In Case II, the initial invisibility of evidently important earlier events was directly jeopardizing Patient Safety as the absence of such information was affecting the hypothetico-deductive process, in a time critical situation. Interestingly, the collaborative roles of patients and relatives were essential for both cases. They proved to be important for the prognosis of the cases. However, even if patients always are important in the care process and always must carry patient specific information [Ådahl 2007], this must not be a single-handed task of the kind that the patients’ survival is directly dependant on it. Accordingly, it should not depend on if, or what, the patient or relatives might report from the former medical history. Such tasks should also to some extent be automated, as a foundation for further interactive discussions with the patient (Chapter 10.5).

Case I and II: Exemplifying the hazard of Hand-Over Situations
Case I and II basically presents a number of hand-over situations in which information is lost. It is a well-known problem in Healthcare that communication is at the peril of being insufficient, jeopardizing Patient Safety [Socialstyrelsen 2008]. The elements of risk are multiple. For example, information might be missing, misinterpreted, ignored or not utilized.

Furthermore, the sources of relevant information might be hidden, neglected or not found (Chapter 6.4). The acquisition of information might also be difficult or time-consuming when the sources of information are hard to access: Medical records or the human body might be sources of information, but also human agents. The latter are often the patients themselves, or those who know the patient well such as relatives. However, human agents are also Healthcare Personnel. Hand-over situations are situations when information must be passed over; from a sender to a receiver, rather often orally. Since many years, in hospital care, hand-over situations such as change of work shifts (gangs) is solved both viva voce and in writing. For example, the change from day shift (actually evening shift) to night shift is performed by oral reporting from the nurse in charge for the work team leaving. S/he reports, by virtue of the written notes made during the shift, the present situation; important immediate occurrences and planned actions for the night. This procedure will visualize the information connecting the work flow in the former shift to the coming. The same procedure is repeated by the night nurse, reporting the same way in the morning to the day shift. Furthermore, the
morning shifts reports likewise to the evening shifts. Doing this procedure appears to be necessary and self-evident. However, the procedure poses a risk for information deficiencies to occur.

In another perspective, hand-over situations also occur when inpatients are changing wards, or when a patient is discharged; in the future being an out-patient, consulting different physicians in non-institutional care etc. However, visualization of important information for an unbroken work flow is not part of standard procedures. On the contrary, due to factors such as size of span after completed treatment programmes, and changes of care providers or clinical departments, crucial information connecting pieces of workflow to form a whole is most likely lost. The actual workflow in Healthcare is fragmented, interrupted by time and changes. Interoperability, i.e. in this matter forming an unbroken flow of relevant information despite such discontinuances, might be crucial for the possibilities to perform a correct differential diagnosing; a complete hypothetico-deductive process resulting in a correct diagnosis. Basically, the prognosis of any treatment is dependent on the correctness of the diagnosis.

To realize a patient (individual) centered workflow, and attain Interoperability, the patient must, in a way, sometimes enter the role of nurses at the wards who are reporting between different work shifts to maintain workflow in healthcare. The patient is the key to information, hidden from current personnel, which might concatenate those “islands of workflow”. Accordingly, the patients must deliver information about what has happened before the current situation and in the current situation. This task, which is a hand-over situation, is traditionally carried out by virtue of the physician, drawing up an anamnesis. However, the traditional anamnesis creation taking place at the initial contact with a physician is perhaps not sufficient for a patient centered workflow. The anamnesis creation should instead be updated along the time when the patient is under diagnosing and treatment. Furthermore, the anamnesis should also be updated between such consultations. The challenge is to develop ICT tools supporting this, for the EHR.

Consequently, in the task of such anamnesis creation, the patient must act as a collaborator, i.e. “coworker” in a team (Chapter 7.2). However, to know exactly what the doctor needs to know is hard (Chapter 6.4). The task is delicate, both for the patient and the physician. The crucial point is how the physician is able to elicit crucial information from the patients s/he encounters. In order to elicit information and create an anamnesis, the physician must ask the right questions which might be impossible if there are details in a hidden context that is invisible for the physician and neglected (or not even noticed) by the patient: Maintaining workflow depends on coherent knowledge about the medical history, involving context of the occurring symptoms i.e. various reactions of the body, in different situations, occurring over time. In this perspective, a visualization of such knowledge, supporting the anamnesis creation and decisions about diagnosis and treatment or other interventions, seems to be needed (Chapter 10).
The span while a patient is diagnosed and treated (in this perspective regarding inpatients as well as outpatients) is in this thesis named *Period of Healthcare Interventions* (PHI), as the terminology for such obviously is limited. PHI embraces diagnosing, treatment, general care etc. for the current illness, which is close to the meaning of the term *Hospitalization*. However, PHI is much wider in its purport as it also comprises non-institutional healthcare (primary healthcare). Consequently, PHI embraces patients’ first consultation and the following interventions until the chosen treatment programme is finished and the patient is considered recovered to normalcy. The following figures (Figure 29 and Figure 30) describe workflow in relation to PHIs and illustrate where hand-over situations might occur. The arrows are representing hand-over actions, where hazardous junctures in work flow might occur.

![Figure 29](image)

*Figure 29* - A Period of Healthcare Interventions (PHI) containing hazardous hand-over situations.

Typically, one PHI (the large exterior box in Figure 29) contains 1-n Sub-PHI (the smaller boxes in the large box in Figure 29). The sub-PHIs are interrelated interventions for the illness in the PHI. For example, it could be treatment in other clinical departments or non-institutional care etc. Figure 29 also points out the weak connections between those sub-PHI, i.e. the “overlapping” workflow connecting different sub-PHI within a PHI (arrows). The weakness consists of deficiencies in information flow in the work flow. *Hand-over situations are risk situations regarding missed information or abrupt information flows.* Accordingly, there are many occasions where information could be lost, which depends on reporting routines in Healthcare, misjudgment of the value of certain information, information not visible at the point of care etc.

In a coherent, chronological, perspective, there is often a chain of PHI (each of them also containing chains of Sub-PHI) but with occasionally, from the perspective of Healthcare personnel, invisible relations in-between the links (between the PHI) (figure 30). Accordingly, the links are connected but the relation is not clear or the links are not always even visible in the EHR at the time of a new consultation.

![Figure 30](image)

*Figure 30* – A Chain of PHI: Multiple Periods of Healthcare Interventions (PHI) with hazardous hand-over situations within and between.

Consequently, the relations (overlapping workflow) between PHIs with their Sub-PHIs (Figure 30) are even weaker; inter alia because impact of the time-factor and accessibility factors. In Case I and Case II, to exemplify this reasoning, the different situations in each of the cases are equal to one PHI and the Cases are chains of PHIs with very week connections in-between.
For example, workflow in both Case I and Case II (Figure 31) is abrupt between the different situations (PHI) as the connection between each is not obvious until the case is closed (Figure 32). In CISIT1/CIISIT1, there is no plan for actions in the next CISIT2/CIISIT2 or other related incidents, which is a consequence of the actual misdiagnosis. The same condition exists in CISIT2 and CISIT3. Each of the situations is equally unexpected and, as a result, appears as self-contained cases of illness.

As each situation appears to be separated from any other incident in the medical history, the connections to the previous situations are very weak. There is no possibility or motivation to backtrack in the EHR to find a coherent line of events. Absence of coherent information in the EHR is, with reference to Case I and II, hindering a correct diagnosis to be revealed. In each of the situations CISIT2, CISIT3 and CISIT4, there is no coherent relation to what has happened before or if previous incidents are related (from a logical point of view) to the current. Accordingly, crucial coherent (chronological) data decisive for a successful differential diagnosing process is hidden in the EHR and/or carried by the patients’ relatives, however not always obviously important enough to be reported. Case I shows that with visualization of case critical data, and backward reasoning (backward chaining) on such data as a decision support method, the correct diagnosis might have appeared before it was too late for treatment.

Consequently, such fundamental data should serve as a basis for further data collection, discussion, anamnesis creation and decision making in cooperation with the patient. Interestingly, the method of backward chaining is opposite to the method used for expert systems (decision support) where forward chaining is implemented by inference rules (if-then) to collect new information to add to the data. However, backward reasoning in such cases as Case I and II should be performed by human agents (Healthcare personnel and patients). Clinical Decision Support Systems (CDSS) is the basic tool but human reasoning must form the basis for data collection for input to such systems. In this perspective, a tool for such data collection, facilitating the backward reasoning, is necessary. In the next chapter (Chapter 10) we propose such a tool; Visual Incidence Anamneses (VIA) (Chapter 10.5).
Chapter 10 – Visual Incidence Anamneses (VIA).

In this Chapter we outline some aspects of our proposed Decision Support Tool VIA. The chapter is a synthesis of discussions in Chapter 4 and Chapter 7. The design is intended to implement our findings of our stated Research Questions in Chapter 3. Our analysis of Case studies in Chapter 9 is a validation of our approach.

10. Introduction

Recalling the ideas, and drawbacks, behind the use of Ockham’s Razor (Chapter 5.4), we argue that determining the status of a patient in decision making situations in Healthcare should be based on the unique individual s/he is. More precisely, this means that the probability of a certain specific diagnosis should not only depend on what diagnoses earlier patients as a group statistically had, but also on what kind of critical individual information the unique patient represents as a result of his/her earlier medical history. The sum of the symptoms recorded from a patient during the entire medical history must be considered as potentially coherent. That is, basically caused by one and the same disease. Assessing atypical occurrences of symptoms, rare, or complex medical states such as systemic diseases where vague symptoms occur over a (longer) period could be very hard. We have found that CDSS as such, based on probabilistic algorithms, might not be sufficient, or even inappropriate in those cases (Chapter 6).

However, current methodologies and tools do not support healthcare personnel to compose a comprehensive patient medical history ranging over a longer period of time. That is, supporting “what-if” reasoning and alternative history context dependant analysis. To remedy some of those shortcomings, we propose an additional tool, Visual Incidence Anamneses (VIA), to assist Healthcare professionals to supplementary use of available CDSS towards individualized care and increased Patient Safety. The VIA tool collects the actual medical history of a patient, that enables reassessments of earlier diagnosis towards a more reliable patient-centric grounded healthcare. The VIA should be available as the initiating point in a patient (individual) centered workflow, quickly visualizing vital information such as symptoms, signs, incidents and diagnoses, occurring earlier in the medical history as a basis for vital decisions.

Modern Personal Health Record (PHR), following the “Connected HealthCare” approach (Chapter 7.2), are typically (web-based) electronic device-based systems maintained by the Patients, not by HealthCare authorities as EHR-systems typically are (Chapter 6.7). Examples of such systems are: HealthVault and PatientsLikeMe (Chapter 1.3, 4.2, 7.2) exemplifying web-based PHR-solutions of Connected
HealthCare. Design, implementation and maintenance of such systems are in recent focus of international R&D.

A recent issue of *IEEE Internet Computing* (July/August 2011, Volume 15, Number 4)\(^98\) gives an overview of relevant issues and technologies. Our VIA tool could be seen as a complementary tool to different PHR health platforms such as Lifestrong\(^99\) and TrialX\(^100\) mentioned in the issue. Those PHR examples illustrate the use of web technologies to implement suitable PHR architectures. PHR let individuals monitor and share their healthcare information with healthcare providers as well as third party health and wellness providers.

Whereas only healthcare providers can keep and maintain *Electronic Health Records (EHR)*, PHR record systems, on the other hand, are typically controlled by the patients. The PHR platforms could radically move the locus of control over health information to the patient (consumer).

Our intention with the VIA tool is to support both the healthcare professionals and the patient, in collaboration with each other. *Access control* has therefore to be carefully designed and implemented to allow both *proper information sharing and protect concerns related to security and privacy as well as accountability*.

Mechanisms based on *rule based access control and credentials* have therefore to be designed, implemented and enforced. Those issues and concerns are however not in the focus of the thesis.

In Figure 33, the *E-health scenario* illustrates some challenges related to exchange of health information between patients and health professionals. In this scenario, rather typical for the confusing terminology in the area (Chapter 6.7), Electronic Medical Records stands for EHR and Electronic Health Records for PHR. The *accessibility challenges of the VIA tool* is highlighted by the accountability question mark. Furthermore, it put emphasis on questions of *Health Information Interoperability* regarding issues of *Information Security and Patient Privacy* (integrity). The figure is from “*Sharing with Care. An Information Accountability Perspective*” [Gajanayake et al. 2011].


\(^{99}\) Home page: http://www.livestrong.com/

\(^{100}\) Home page: http://trialx.com/
10.1 Visualization of Information in Health Care

The following definition of Visualization is useful for our investigations:

*Visualization* is a human, internal, cognitive activity performed to gain insight and understanding about something [Spence 2001, p.1].

The visualization activity results in mental models or internal models of something experienced, for example occurring symptoms or specific information. The models are recalled (i.e. visualized) mentally, to be re-experienced (memory). Information overload is substantially an obstacle for such activity as too much data will obscure patterns of meaning within data and the mental process of pattern recognition will be disturbed or hindered (Chapter 2.3). Pattern recognition in psychology is utilized by experienced physicians, along with the differential diagnosing method, in order to decide on a correct diagnosis (Chapter 2.4).

However, due to the current design and development of EHR, a comprehensive picture of the patients’ entire and coherent medical history is very hard to grasp based on those tools. From the seven Great Principles of Computing (Chapter 1.1, 2.1), we note that Design principles are conventions for planning and building correct, fast, fault tolerant, and fit software systems. Since visualization is a mechanisms supporting all the other six principles of computing it is an important part of the design and implementation of the VIA tools as well. In short, visualization is a method to abstract large amounts of
data into units of data that are easily comprehensible for the human brain. Visualization is thus a core technology to meet the requirements of VIA derived from our Research Questions in Chapter 3 and our analysis of Cases in Chapter 9. To that end, *Design Principles for Visual Communication* [Agrawala et al.2011] was referred to in Chapter 2.4.

In Healthcare, large quantities of patient related data are produced every day. However, the underlying meaning or semantics of that data is not unmistakable due to circumstances elaborated in Chapter 5 and Chapter 6. In short, due to lack of interoperability of healthcare systems! Moreover, the amount of data makes the interpretation task both difficult and perilous from a Patient Safety perspective. Referring to Devlin [2001] (Chapter 1.2), data is the representation of information which meaning must be interpreted by the receiver, using supporting cognitive tools to perform that task. The more data to be interpreted related to different tasks and involving different competencies, the harder this task becomes.

There are many attempts to manage content complexities related to data. In one field, Information Visualization (InfoVis), a sub field to HCI, the focus is on the suitable representation of information. The basic idea is that large amounts of (abstract) data are hard to textually interpret, for which reason graphical visualization representations are used. Card [1999, 2007] defines Information Visualization, as follows:

"The use of Computer-supported, interactive, visual representation of data to amplify cognition” [Card 1999, p.6]

"Information visualization is a set of technologies that use visual computing to amplify human cognition with abstract information.” [Card, 2007, p. 542]

Design Principles for visual communication have been elaborated in a recent paper in *Communications of the ACM* [Agrawala et al. 2011] (Chapter 2.4). The following summary is guidelines for our design and implementation of the VIA tool (Chapter 2.4, 10.4, 10.5):

- Design principles connect the visual design of a visualization with the viewer’s perception and cognition of the underlying information the visualization is meant to convey
- Identifying and formulating good design principles often requires analyzing the best hand-designed visualizations, examining prior research on the perception and cognition of visualizations, and, when necessary, conducting user studies into how visual techniques affect perception and cognition
- Given a set of design rules and quantitative criteria, we can use procedural techniques and/or energy optimizations to build automated visualization design systems

For our VIA tool techniques supporting analyzing of patient history (Figure 13) are of particular importance. This includes a common set of documents across time flows.

### 10.2 Using 3D Visualization in Supporting Diagnosis

On September 26th 2007, researchers at IBM's Zurich Research Lab unveiled a prototype of a visualizing EHR-system, denominated ASME (Anatomic and Symbolic
Mapper Engine). The technology is basically similar to the technology addressed for game development in using a game engine with a rendering engine for 2D/3D graphics. Interestingly, the design of ASME corresponds very well to the basic ideas of our suggested mockup for the Licentiate Thesis [Ådahl 2007] which was initially developed in 2004-2005 and finally used in 2006 for the preparatory study (Chapter 8). Our design suggestion, demonstrated in practice by the mockup, was also in line with the ideas of the current Connected HealthCare trend and specifically Microsoft’s HealthVault, also launched in September 2007 (Chapter 1.3, 7.2, 4.2). We basically suggested a visualizing PHR with interoperable connections to EHR, however with respect to issues of Patient Integrity and System Security [Ådahl 2007]. The data elicited by using our hand-designed visualizing mockup for the preparatory study (Chapter 8) corresponds to the design principles for visual communication [Agrawala et al. 2011] we refer to in Chapter 2.4 and Chapter 10.1. Accordingly, for the design of the VIA tool, we also address those parts of the findings in this preparatory study that answer to questions of human visualization, and the use of information visualizing tools in HealthCare [Chapter 3.5 in Licentiate thesis Ådahl 2007].

The ASME-project is today in progress, most often referred to as the Medical Information Hub (MIH); by cooperation between IBM and Thy-Mors Hospital in Denmark on future 3D–based medical records. The aim of developing ASME/MIH is twofold [Rudin 2008]:

- exploring and defining the components of a next-generation browser for electronic medical/health records
- redesigning access to medical information to lower the barrier of IT acceptance in healthcare organizations.

Rudin [2008] describes the result as “a comfortable, intuitive and inviting interface” and adds that Andre Elisseeff, one of the lead researchers, has compared the system to a "Google Earth for the body". The large amount of medical data in HealthCare and the problems of managing and utilizing such amounts of data is a well known issue for HealthCare providers and other stakeholders. As mentioned, visualization of data is a successful method to grasp the meaning behind overloads of data. Within this area, ASME/MIH is one direction to enter. Rudin [2008] describes the basic functionality of ASME/MIH as follows:

“The result of the ASME project is making interaction with medical data as simple and as convenient as possible. If, for example, the doctor were to click on the spine, the system would display the available medical history, including text entries, lab results and medical images such as radiographs or MRIs. While the system is already extraordinarily attractive, work continues to make it still better. One idea is to include speech technology to ease record keeping.” [Rudin 2008]

Furthermore, in a first test at a Danish hospital ASME/MIH has proved both practical and valuable. This demonstrates that the use of Visualization technologies should

guide the receiver of information, providing structures to find the desired information and to understand the information in context. The 3D-representation (or even a 2D-representation) should be valuable as a guide to the medical history, but an abstracted guide to a visual chronological representation (coherent medical history) is missing with respect to this. In order to pinpoint causalities, a coherent visualized representation of the medical history should be considered indispensable. In the next section, we discuss visualization of causalities, a basic aim of our VIA tool.

10.3 Visualization of Causalities

One of the most difficult problems in the area of Information Visualization is Visualization of Causality [Miao 2008]: Efficient Communication of Causality is one of the “top ten unsolved problems” in the area of Information Visualization [Chen 2005, Miao 2008] wherein visualizing causality in context is particularly intriguing to address [Miao 2008]. Accordingly, visualizing causal relations using existing representations (referred to as Causal overlays by Miao [2008]) must be further explored [Miao 2008]. An interesting example to reflect on is here the “3D Avatar” in ASME/MIH developed by IBM, and in use as prototype at Thy-Mors Hospital in Denmark (Chapter 10.2): In two demos on YouTube we can as users discuss and explore 3D views on the human body. However, so far, there is no support tool for investigation and supported discussions of causalities. Chen [2005] states that

“The core challenge is to derive highly sensitive and selective algorithms that can resolve conflicting evidence and suppress background noises. Complex network analysis and link analysis are expected to continue to play an important role in this direction. Because of the exploratory and decision-making nature of such tasks, users need to freely interact with raw data as well as its visualizations to find causality. Techniques such as multiple coordinated views will enhance the discovery process. Features that facilitate users in finding what-ifs and test their hypotheses should be provided.” [Chen 2005]

Furthermore, Chen [2005] emphasizes a basic need of Information Visualization by referring to Knowledge Domain Visualization (KDViz) as a holistic driving problem. Large amounts of data are hard or impossible to grasp (Chapter 2.3) without guiding visual representations of data. He emphasizes that

“The greatest advantage of information visualization is its ability to show the amounts of information that are beyond the capacity of textual display. Interacting with information visualization can be more than retrieving individual items of information. The entire body of domain knowledge is subject to the rendering of KDViz.” [Chen 2005]

In a paper on an earlier colloquium, Chen [2004] also concludes that

“a search for intellectual turning points can be narrowed down to visually salient nodes in the visualized network. The method provides a promising way to simplify otherwise cognitively demanding tasks to a search for landmarks, pivots, and hubs.” [Chen 2004]

103The following YouTube links describes the ASME/MIH-project, illustrating future 3D enabled patient centric medical records: http://www.youtube.com/watch?v=VAwYdmUd59A&feature=related
http://www.youtube.com/watch?v=G5Zk-sJAOxk
In the thesis on *Visualizing Causality in Context using Animation*, by Miao Yao from Simon Fraser University, Canada, referred to above [Miao 2008], some findings along those lines are reported [Ibid]. The thesis suggests the approach of *Visual Causal Vector* (VCV) that holds a promise as a perceptually efficient *causal overlay technique*; how to elicit and avoid causal impression and how to represent the strength of causal effect. The thesis reports results from four experiments that demonstrate that the use of *vector animation to produce flow of causality and node animation to convey the strength of caused influence* can be a basis for a set of principled guidelines for designing causal overlay visualizations. Considering VCV as a method to convey and visualize the time-dimension (coherence) in large amounts of data from individual medical histories, applied on visualizations of the human body, is rather intriguing to consider. However, other directions in design are also applicable for such tasks. Chen [2004, 2005] considers the use of *visually salient nodes*.

We find the ability to use visually salient nodes, for decisions on further information retrieval in a medical history, decisive. Such use should provide an abstraction of a coherent medical history and call attention to important occurrences and events, which would simplify search for more information. The visualization is then a tool for cognition, triggering “intellectual turning points” in differential diagnosing processes. In the next sections (10.4 and 10.5), we present our proposal of a tool supporting cognitive visualization and decisions on coherent medical events; Visual Incidence Anamneses (VIA).

**10.4 Core Principles of VIA design**

Based on earlier discussions in this Thesis and derived from the results of the Research Questions (Chapter 3, Chapter 11), the design and implementation of the VIA tool is grounded in three main principles:

**Core Principle 1**: Clinical decisions in Healthcare must be grounded in a sufficient amount of relevant and (potentially) important patient specific information.

**Core Principle 2**: Information of importance for decisions must be easy to comprehend; visualized at the point of care in the anamnesis process.

**Core Principle 3**: Clinical Decision Support Systems and additional tools to complement such systems (such as the VIA) to support diagnosis must be part of the workflow and not unduly time-consuming for the work or of doubtful value for the task.

Regarding the first principle, a sufficient amount of relevant information is equal to individual medical histories where *no vital information is missing or can be missed*. The information must be presented coherently, in chronological order, with (causal) relations between important events along a “time-line”. Accordingly, a design focus on visualization of Patient-specific information in this perspective is counterbalance to potentially unfettered and routine-like use of Ockham’s Razor in Healthcare. It should be emphasized that *Participatory Medicine*, utilizing the possibilities of collaborating
with the patient (Chapter 1.3, 7.1, 7.2), must be addressed in order to collect and classify relevant and important Patient-Specific information. For example, in the anamnesis phase of the medical examination, certain input to and output from the VIA-system must be performed interactively with the patient.

The second principle is the principle of Visualization. Information is considered more comprehensible for a team and for individuals if it is graphically expressed along the principles outlined in Chapter 10.1. In Chapter 10.3, Visualization of Causalities emphasizes the basic challenge in our design; the challenge of presenting a visual coherent medical history, providing support to “what-if states” in diagnosing processes. The rationale for the third principle is discussed in Chapter 7.

The third principle concerns usability and emphasizes the importance of ICT to be part of workflow. For this design task, for requirements elicitation, ethnomethodologically informed ethnography should preferably be addressed.

In the next section (10.5), we present an abstracted outline of a contemplated VIA-system. We deliberately will not provide detailed design suggestions, as the design at this stage of research must be conceptual. Further research is required before more sophisticated design solutions are possible to present (Chapter 10.7).

10.5 Visual Incidence Anamneses (VIA)

Patients are sources of valuable individual information for diagnosing, generally being capable of collaborating with Healthcare. Patient Empowerment (PE) and its further development to Participatory Medicine, related to Patient Centered Medicine (PCM) (Chapter 7.1, 7.2), is the basic foundation for awareness of an increasing need for tools supporting Information elicitation and Patient Collaboration. Our proposal Visual Incidence Anamneses (VIA) is a result of the findings in the Case Study (Chapter 9) and the Preparatory Study (Chapter 8) [Ådahl 2007] where input to the basic requirements for the design was collected by qualitative in-depth analyses of authentic cases (Chapter 2, 9.3).

In the licentiate thesis “Transparency of Critical Information for Patient Empowerment in eHealth” [Ådahl 2007], we suggested Empowerment Systems (Figure 34) (Chapter 1.1, Figure 4) that are systems supporting the basic requirements of Patient Empowerment. In the thesis [Ibid], architecture and design of Empowerment Systems, specifically supporting teams, were in focus. Figure 34 captures a comprehensive design context of such systems. It might be worthwhile to survey in order to grasp the idea of Empowerment Systems.
The picture (Figure 34) captures some concepts, important for the design of an Empowerment System. The main supporting components are Foundations, which is grounded in the collaborative aspect of PE, and Functions in context that emphasizes visibility of crucial information. The latter includes Activity theory, based on ethnographic studies, while Foundations focus on issues related to interaction and semantics (collaborative aspects). Furthermore, it involves some design aspects, considered important for the functionality in such a system [Ådahl 2007].

From this base, our design proposal VIA is developed. Empowerment Systems were exemplified as prototypes in the Licentiate thesis [Ådahl 2007] and, for this thesis, the data collected from the evaluation of those prototypes (mock-ups) was to some extent utilized for design of the VIA. However, a VIA Empowerment System has a slightly more directed design goal: Towards Empowerment of Healthcare. Patient Empowerment needs to be met by empowered professionals in Healthcare which is professionals and patients in collaboration. Empowerment of Professionals could be to support physicians in their information elicitation task in the hypothetico-deductive process. Simultaneously, the Patients need support to be able to report important information for this process.

Our design proposal grounded in the conclusions of this thesis is VIA. However, VIA needs a refined and specifically directed architecture and design for implementation. Figure 35 outlines the basic idea of a VIA tool in diagnosing decision processes, not a complete system architecture. Such architecture is a basic goal for the Future Work (Chapter 10.7) as further and more directed studies on workflow is needed.
Figure 35 describes the main types of information needed for the hypothetico-deductive process, and the application of VIA to that information. The general medical knowledge is the foundation stone; knowledge which must be grounded in Evidence Based Medicine (EBM) (Chapter 5.1). This is a prerequisite for any decision on diagnosis or subsequent treatment. Consequently, EBM is addressed in current CDSS. Furthermore, above the need for general medical knowledge, Patient Specific information is needed for the use of CDSS (input) (Chapter 5, 6.2). On the top, our VIA is situated providing pointers to potentially crucial (former) information; indicated by visually salient and coherent nodes.

VIA is independent of the fragmenting of Healthcare with separate specialist knowledge divisions or any change-over from institutional care to non-institutional care. It should visualize information across borders and chronologically. Interoperability concerns are important to address when designing and implementing such a tool. Today, technical interoperability of current EHR-systems is a major concern for stakeholders and software engineers. Furthermore, the design of current EHR seems to confuse the users as the possibilities to survey the content in the EHR for each patient is small, even smaller than for the former paper based medical records. The ASME/MIH project provides a solution for the latter, however obviously without any visualization of causality in context. In contrast to that, this is provided by VIA. It is also important to stress that VIA is a tool for Collaborative Medicine. It must be used in
collaboration with the patient, as more information of the preceding medical history might be revealed in using VIA as a shared artifact with shared meanings (referring to Social constructionism, a sociological theory of knowledge). The role of the physician is to act as an intellectual sparring-partner, in order to find the true patho-physiological explanation of the occurring symptoms and signs. The physician uses the patients’ knowledge of his/her own body in the differential diagnosing process. The basis for the discussion is the visualizations of the medical history.

We will motivate the need for VIA by calling attention to how Patient Specific data is collected: There are a variety of current methods for elicitation of Patient Specific data, and along with the fast and sophisticated development of Medical Technology and MIDS (Medical Information Data Systems\textsuperscript{104}), such data collection (of body generated data) for diagnosing is refined and still in progress. In addition, the patient can provide urine specimen and Healthcare personnel can take blood tests of varying kinds. There are also simple methods for the physician to initially address, for the identification of signs of disease or absence of such. For example, such methods are Inspection, Palpation, Auscultation and Percussion. Furthermore, to be able to initially grasp the overall medical history, the context of the patient and identify symptoms reported, an Anamnesis is created. This is a situation that might result in very unequal quality of the information gathered, in contrast to the other methods addressed for collection of body data that are more precise, and easily controlled by the Healthcare provider. The measurable information stored in the body is concrete and “tangible”, but the information stored in the mind of the patient and in fragmented and incoherent sections of EHR-systems, gathered at different positions on an imagined time axis, is difficult to capture and display. Therefore, the usefulness of the anamnesis is today unequally sufficient depending on the ability of the patient to report, the time available for the physician to ask questions or reflect on crucial questions for valuable answers or the actual presence of “unknown unknowns” (Chapter 6.4). Therefore, using a CDSS or adopting diagnosing methods such as Pattern Recognition in addition to the Differential Diagnosing process (Chapter 5.2) could lead to a misdiagnosis or to a missed diagnosis if not Patient Specific Information is coherent and complete.

Consequently, a juncture in a Healthcare consultation is obviously the anamnesis-phase. We have concluded that the subsequent course of events is influenced by what information the anamnesis holds (Chapter 9.3, 9.4). This is critical with reference to the anamnesis as being an important initiating point for decisions on further examinations of the body. Although there are routines for standard tests, for example initially equal for all hospitalized patients, such tests do not reveal every state of ill-health. Furthermore, such tests are sometimes ad hoc for patients consulting District Health Services. Therefore, and based on our findings of the Case Study in Chapter 9, we conclude that ICT support for anamnesis creation and visualized information of a coherent anamnesis seems to be a basic requirement for increased Patient Safety.

\textsuperscript{104} http://www.mtf.nu/MIDS_Rapport_Eng_2008_web.pdf
Proposal for VIA

To sum up, considering the counter arguments to the use of Ockham’s Razor (Chapter 5.4), we argue that the probability of a certain diagnosis should not only depend on general statistic probability of a certain diagnose, but also on critical individual differences; i.e. individual information the unique patient holds as a result of his/her earlier medical history. The sum of the symptoms experienced by a patient during the entire medical history must be considered as potentially reciprocal, caused by a common disease. Furthermore, occurring symptom could be caused by more than one disease simultaneously. Inter alia, we base this statement in our findings of the Cases (Chapter 9). Regarding atypical occurrences of symptoms, rare, or complex medical states such as systemic diseases where vague symptoms occur over a (longer) period, we have found that CDSS as such, based on probabilistic algorithms, i.e., average values in a population, might not be sufficient, or even inappropriate in diagnosing an individual patient.

To remedy some of those shortcomings, we propose an additional tool, Visual Incidence Anamneses (VIA), to support Healthcare professionals in using available CDSS towards individualized care and increased Patient Safety. The VIA visualizes the entire medical history of a patient, enabling reassessments of earlier diagnosis towards a more reliable Patient-Centric grounded Healthcare (Figure 35) (Chapter 7.2). The VIA should be available as an (individual) Patient Centered Workflow, quickly visualizing vital information such as symptoms, incidents and diagnoses, occurring earlier in the medical history, at different times, to make further vital decisions Patient- and Context-centric. Basically, Visualization of Causalities in Context is the basic concept influencing design.

In effect this entails that the VIA enabled Empowerment System should be configurable from selected components and tools rather than a fixed client–server system. For example, the users could use IPads with selected Apps configured using Memory Sticks to ensure flexibility and information security. An example of such experimental environment is given in [Stahl et al. 2010]. Furthermore, some of the input information to the entire VIA system could be provided by proper sensor networks [Lundberg & Gustavsson 2011]. However, the VIA is basically an Information Visualizing tool, presenting valuable data graphically (visually salient nodes), in chronological order, for the physician and the patient to discuss in collaboration.

10.6 Discussion. Pros and Cons of VIA

Our proposal for VIA is grounded in our conclusions from in-depth analyses of authentic cases in Healthcare, where Patient Safety has been jeopardized due to identifiable information handling deficiencies and information breakdowns in the care process (Chapter 9). The basis for our proposal is therefore information handling issues that actually occur in the Healthcare context. VIA should be an additional tool to the EHR, which also could be regarded as a decision support tool, and an additional tool to traditional CDSS. The advantages of using VIA are visualization of subtle or hidden (not visible or known to the physician) information flows if used as an artefact for
common understanding and discussion. VIA also visualizes information not easily or self-evidently accessed in EHR, but crucial for a correct diagnosis to be made or the correct diagnosis to be made in time. If VIA are designed participatory with the end-users, the use should be a part of work-flow, reminding the decision maker of information that should be considered before decision. Fewer information misses and mistakes, caused by lack of decisive information, increases Patient Safety as the opportunity of correct diagnoses early in the decision process increases by immediate and correct information at the point-of-care.

However, if not developed and implemented to fit workflow, in a Sociotechnical systems approach, the system might be regarded as hindering and time-consuming. With inadequate understanding of which type of information that must be visualized, there is also a risk of the system to be time consuming or to require physicians to make extra labour intensive steps in the decision process. These factors would not encourage the use of the system. Furthermore, with such insufficient design and implementation, there is a risk that VIA provides too much information, resulting in information overload which paradoxically would make relevant information invisible.

Therefore, system development based on the VIA model must comprise the users of the system (addressing participatory design) and preferably also be grounded in in-depth studies of the activity in which the VIA is intended to be implemented. Furthermore, it is utterly important to use VIA as a discussion tool in collaboration with the patient, and not as a freestanding guide. To only rely on the abstract visualizations of the former medical history is not sufficient and the VIA must only be regarded as a pointer to indications of earlier potentially important events. The patient is the important information carrier and the key to a correct diagnosis if patient participation is utilized for Patient Safety. By using the VIA as a guide to Patient Collaboration and as a pointer to areas in the EHR to be reopened and further studied, the aim of increasing Patient Safety could be properly addressed.

To meet some of the challenges related to design, implementation and validation of the VIA tool we have in Chapter 7 outlined some important models, That is,

- Patient Empowerment (PE)
- Patient Centered Medicine (PCM)
- Quality Assurance of Data and Reasoning

Validation of interoperability – from requirements to systems – should be an integrated part of the VIA life cycle. We argue that our approach of setting up and analysing cases assure validation of our Research Questions and Chapter 10.4.

10.7 Future Work

The next steps include an elaboration and further development of the proposed VIA model, in addition to setting up, as well as validation of, VIA pilots. Preferably, further studies addressing Ethnomethodologically Informed Ethnography (Chapter 2) should be carried out in Healthcare settings. Hopefully this can be utilized in cooperation with
other Healthcare teams from academia and Healthcare producers. We also need to address issues related to interoperability and accountability in more depth. An interesting direction in health informatics is openEHR\textsuperscript{105}, which we are addressing as an approach for further research in our future work.

\textsuperscript{105} http://www.openehr.org/home.html
Chapter 11 – Conclusions and Final Thoughts

In this chapter, we give a summary of earlier chapters of relevance to the Research Questions, RQ 1-3, derived from the findings of the Main Study (the Case Study in Chapter 9). Furthermore, we outline the rationale behind our suggested visualization tool Visual Incident Anamnesis (VIA) aiming at ensuring increased Patient Safety due to support of interoperability and alignment of patient-centric workflows.

11. Introduction

The task of ensuring Patient Safety is, more than ever, central in Healthcare (Chapter 1.4). The report “To Err is Human” [Kohn et al. 2000], was revealing alarming numbers of incidents, injuries and deaths caused by deficiencies in Healthcare activities. The book attracted considerable international public attention and resulted in a starting point for assessment and change of healthcare methods and procedures. In addition, numerous reports to Swedish HSAN (Medical Responsibility Board) have shown a high rate of information and communication deficiencies in Healthcare has a direct or indirect cause of incidents, injuries and deaths [Socialstyrelsen 2008]. Despite numerous of new sophisticated tools for information management in recent years, e.g., tools such as Electronic Health Records (EHR) and Clinical Decision Support Systems (CDSS), the threats to Patient Safety have not been redeemed. Rather to the contrary. Underlying reasons for this paradox are twofold. Firstly, advancements in diagnosing techniques have given rise to increasing volumes of data at the same time as the number of patients has increased due to demographic changes and advancements in treatments. Secondly, the information processing systems are far from aligned to related workflow processes. In short, we do not at present have interoperability in our healthcare systems.

In this doctoral dissertation, we present an in-depth analysis of two different “HSAN-typical” cases, where Patient Safety was jeopardized by incomplete information flows and/or information breakdowns (Chapter 9). The cases are mirroring the apprehension of Simplicity, that is, Occam’s Razor of Diagnostic Parsimony. A well-known protocol used in Healthcare and implemented in most (knowledge based) CDSS. This rule of thumb is the foundation for the well-known adage: “when you hear hoof beats, think horses, not zebras”. Hickam’s Dictum is one well known objection to the simplifications of Occam’s Razor stating "Patients can have as many diseases as they damn well please". Of course, this Dictum is harder to implement effectively! In the thesis we suggest a visualization tool Visual Incidence Anamnesis (VIA) to provide middle out compromise between Occam and Hickham but providing means to increase Patient Safety.
Our analysis of the cases reveals alarming information breakdowns due to prematurely abrupt hypothetico-deductive processes (diagnosing) (Chapter 9). A challenge in diagnosing is to have mechanisms that support necessary complements to the Diagnostic Parsimony (Chapter 5 and Chapter 6)! Setting this scene we identified three Research Questions to be addressed in the thesis (Chapter 3) and identified qualitative methodologies to support our investigations (Chapter 2, Chapter 4 and Chapter 7).

Supporting technologies to design, implement and evaluate our proposed VIA tool is given in Chapter 10. Accordingly, the tool supports configuring context sensitive environments thus enabling increased Patient Safety.

The findings of our Study for the thesis have resulted in a number of Aspects and Principles as well as Core-principles for future CDSS design, That is, tools and methodologies that will support designing and validating Interoperability of Healthcare systems across patient-centric workflows. Present day R&D, on Interoperability of Healthcare systems, is mainly focusing on the necessary, but not sufficient, issues related to Technical (Syntax) interoperability. In our analysis and design proposal of the VIA tool we will also address Organizational and Semantic aspects of Interoperability. The VIA tool should be used as the initiating point in a patient (individual) centered workflow, quickly visualizing vital information such as symptoms, incidents and diagnoses, occurring earlier in the medical history, at different times, to ground further vital decisions on. The visualization will enable analysis of timelines and earlier diagnoses of the patient, using visually salient nodes for visualization of causalities in context. Furthermore, support for customization of the tool to the views of stakeholders, members of healthcare teams and empowerments of the patient, is crucial.

The Research Questions were formulated as follows (Chapter 3):

RQ1: What aspects of information misses and breakdowns in Healthcare systems have to be properly addressed to ensure Interoperability?

RQ2: Which principles are crucial to ensure interoperable support and empowerment of patients?

RQ3: Which principles of healthcare systems are crucial to ensure Patient Safety and Healthcare empowerment?

11.1 Conclusions
In both our cases we were able to identify context dependent causal connections occurring in subtle (hidden) information flows. The analysis resulted in identification of information misses, broken information flows and signs of incomplete causality models, seriously jeopardizing Patient Safety. With reference to the findings of the study, we conclude that supporting ICT systems in e-Healthcare should not only aid
elicitation of individual health related data but also aid pattern recognition within, and
semantic interpretation of, such data, coherently visualizing important information
structures to act on. The patient as a collaborator (co-evaluator) in this task is crucial as
the patient knows some relevant Patient Specific data.

The systemic approach of assessing the case study for this thesis also revealed that in
similar earlier cases, where individuals were identified and hold accountable for misses
in patient security identified a Scapegoat but not all causes. That is, this view of fault
prevention did usually not prevent related cases from happening! The earlier mentioned
changed focus towards rather identifying systemic causes and views on disastrous cases
is a more promising way to increase Patient Safety. This kind of analysis is typically
leading to changes of routines, organizational issues and proper design, implementation
and maintenance of ICT support as means to increase patient security. Our motivation
and design of the VIA tool fits very well into this view.

In order to manage the vast amount of information flowing on different levels, visible
or hidden. Information is the foundation of Healthcare and a prerequisite for correct
decisions and correct Information Management is decisively important and a
prerequisite for Patient Safety.

We have addressed the Research Questions in order, from RQ1 to RQ3 with the
following findings:

**RQ1: What aspects of information misses and breakdowns in Healthcare systems
have to be properly addressed to ensure Interoperability?**

*Firstly*, we have found that much of the subtle information behind cases, such as those
in the study (Chapter 9), is crucial to identify and address for a successful diagnosing
process. Such important information is of the type we refer to as “unknown unknowns”
as well as the more noticed “known unknowns” (Chapter 6.4). Consequently,
“Unknown unknowns” must be “known unknowns” at least by the awareness of the
existence of “unknown unknowns”. Furthermore, we add “Unknown Knowns” to this
reasoning (Chapter 6.5, 9). This nuanced perspective on patient specific Information is
basically the first aspect that must be addressed and this was clearly identifiable in both
Case I and Case II (Chapter 9).

*Secondly*, an aspect that normally is not gaining enough attention is that it always, to
some extent, occur information misses and breakdowns that potentially might affect any
decision or intervention in Healthcare negatively. The cause is the fragmentation of
Healthcare (Chapter 7.2). Consequently, the information flow in Healthcare workflows
is not continuous. Instead it is divided into discrete parts, interrupted by changes of
locations, personnel at duty, time spans between occurrences of illness and care,
deficiencies in different information systems and machine-to-machine communication
etc. (Chapter 9.4). Both Case I and II revealed a number of safety threatening
occurrences caused by incomplete information chains.
As a result, with reference to both aspects, it must be noticed that wariness in the termination of the hypothetico-deductive process is necessary and cooperation with the patient must continue also when a diagnosis finally is decided. Addressing these two aspects should ensure Interoperability as they emphasise the importance of Interoperability between the patient and care providers in teams to avoid information misses and information breakdowns.

**Aspect 1:** Potentially, subsequent, appearances of subtle information, not known but important for the identification of a correct diagnosis, must be addressed. That is awareness of the existence of information that at present is not known to exist.

**Aspect 2:** Information misses and breakdown do always occur due to the fragmented nature of Healthcare and of ad hoc, context dependent, communication.

**RQ2: Which principles are crucial to ensure interoperable support and empowerment of patients?**

Continuing with RQ2, we found that the first principle to adopt should be to consider the patient as the primary source of information. Basically, the patient specific information is of two kinds: Firstly, it is physically generated data identifiable by the varying examination methods addressed in Healthcare. For example, such data is possible to gather by physical examination such as palpation, percussion, auscultation, inspection, medical imaging, blood tests, specimen of urine etc, in order to find signs of illness. Secondly, the patient experiences symptoms that might be immediate or occasional, sometimes occurring over time. Consequently, the second principle is that much information is in the minds of the patients, which must be elicited. This is a challenge that must be in focus, not hastily overlooked or disregarded. With reference to Case I and II in the study, such information might be decisive for the result of the diagnosing process and treatment. The physician holds deep background knowledge, however without regarding the patient as the central source of absolutely essential information (the first principle), also over time, and not basically as a target for care, and try to elicit such information (the second principle), the medical knowledge cannot be fully utilized.

Therefore, the health literate patient cannot be too highly praised: The health literate patient increases the possibilities of turning unknown unknowns, know unknowns and unknown knowns into known knowns (Chapter 6.4, 1.3). The third principle is therefore that Health literacy should be both encouraged and supported by physicians and other Health professionals. This is important, as crucial information, otherwise hidden and invisible in the mind of the patients, can be communicated (the first two principles) if the patient is able to understand how the physician reasons and what information is potentially important to communicate (the third principle).
**Principle 1:** The Patient is the primary source of Information.

**Principle 2:** Much of the most crucial information is in the mind if the patient. Elicitation of that information is decisive for correct diagnosis.

**Principle 3:** Health Literacy among Patients must be encouraged and supported by Healthcare professionals in order to improve upon communication with the patient.

**RQ3:** *Which principles of healthcare systems are crucial to ensure Patient Safety and Healthcare empowerment?*

RQ 3 brings a focus on ICT systems in Healthcare as tools for increased Patient Safety and for empowerment of Healthcare. To design systems for such purposes, the first principle must be to *design for participatory medicine* as this direction comprises empowerment of both patients and Healthcare professionals. Patient Centered Medicine emphasizes shared knowledge and collaboration in teams, wherein the patient must participate as a fully member (Chapter 7.2). Participatory Medicine also emphasizes the Empowered Patient as a collaborator in Healthcare. Accordingly, Participatory Medicine aims at empowering Healthcare. ICT systems should therefore strongly support workflow and allow input of occurring patient specific, or patient reported, information in such way that it becomes visible for physicians independent of location or time. The second principle is therefore to *visualize information* in such way that the risk of missing crucial information decreases.

**Principle 1:** Design ICT for Healthcare to support collaboration with the patient and between Healthcare professionals in teams.

**Principle 2:** Design Decision Support Systems with a focus on individualized care, coherently visualizing Patient Specific data patterns supporting decision making, collaboration (PCM) and further patient data elicitation.

In addition, we will repeat our core principles of software design for Decision Support in Healthcare, first appearing in *Decision Support by Visual Incidence Anamneses for increased Patient Safety* in “Efficient Decision Support Systems: Practice and Challenges in Biomedical-Related Domain” [Adahl & Gustavsson 2011], slightly revised and presented for this thesis in Chapter 10.4:

**Core Principle 1:** Clinical decisions in Healthcare must be grounded in a sufficient amount of relevant and (potentially) important patient specific information.

**Core Principle 2:** Information of importance for decisions must be easy to comprehend; visualized at the point of care in the anamnesis process.

**Core Principle 3:** Clinical Decision Support Systems and additional tools to complement such systems (such as the VIA) to support diagnosis must be part of the
The Core Principles are constructed on the aspects and principles (RQ1-3) identified in the Studies for this thesis and therefore we argue that the principles should guide in design of decision support by ICT in Healthcare. The Principles and Aspects derived by the RQ, and the Core principles for CDSS design, are suitable to address also for further research on Socio-Technical systems.

Socio-Technical systems are computer systems including social systems, in social contexts, and with Human Agents as actors. Healthcare Information Systems (ICT for Healthcare) are Socio-Technical systems, comprising the end-users as important actors (Human Agents) for Interoperability at different levels of the system (Chapter 1) and between systems. Interoperability is supported by Collaborative Patient-Centered Care. Patient Empowerment and Participatory Medicine are important ideas, encouraging collaboration between Healthcare Professionals as well as between Healthcare and the Patients. Information elicitation for Anamnesis collection is based on initial exploratory interviews with the patient (sometimes structured by predetermined standard questions) and the way such interviews are performed (structured or more open-ended and ad hoc) might affect the result of diagnosing and treatment with impact on Patient Safety. Traditional methods, in addition medical paternalism, will not embrace context of the patient as the questions tend to be more standardized for streamlining of situations. For example, inexperienced physicians tend to, more often, adopt such structured interviews.

Dysfunctions of the normal physiology of the body (pathophysiologial occurrences) are the basic problems that have to be solved by decision making for correct diagnoses and treatment or other interventions. The patient has knowledge about those dysfunctions by the experience of their manifestations and simply by having the actual body. Consequently, data from the body and *the mind of the patient* are the basic keys to a solution of a large amount of information misses and threats to Patient Safety. The challenge is develop tools that help elicit mentally stored data and information, i.e. information that is hidden and labeled as unknown unknowns. Furthermore, ICT must support unbroken flows of information in a fragmented organization of Healthcare. These are basically the most important Interoperability issues we address, based on the findings of the cases (Chapter 9).

11.2 Final thoughts
Support systems in Healthcare aiming at increasing quality of healthcare for an aging population and with budget constraints are a daunting task.

In our investigation we have focused on aspects of Patient Safety. Our investigation has been limited to a few (two) real cases and is based on qualitative reasoning. However, we argue that;
• Information processing systems will play an increasing important role. However, those systems much be aligned to and inoperability supporting individual workflows

• Patients must be empowered to take as active part as possible in establishing the necessary context to support trustworthy diagnosis and treatment.

Our investigations behind and suggestions of our Visual Incidence Anamnesis (IVA) tool indicate some fruitful R&D directions towards those ends. But, much remains to be done!


Mason B (2001) Issues in Virtual Ethnography Cardiff University and Memorial University of Newfoundland Published in: Ethnographic Studies in Real and Virtual Environments: Inhabited Information Spaces and Connected Communities. Ed. K.


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Decision Support by Visual Incidence Anamneses for increased Patient Safety

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1. Introduction

1.1 How to get the right information?
Decision support in Health Care is based on proper collection and evaluation of relevant information related to the patient and her/his medical history. In the process of Anamnesis the patient will provide individual testimony regarding her/his status in a dialogue with the physician. The diagnosis will then be conducted by complementing this information with written information from (electronic) Health Records (EHR) followed by clinical examination, laboratory testing and imaging.

The quality and relevance of the information from Anamnesis is strongly dependant on the format and focus of the dialogue at hand. The dialogue itself is partly derived from analysing the patients EHR. As we know, the information found in EHRs is based on treatment of the patient by different hospital specialist departments. This structure of the EHR hampers the understanding of the treatment processes and their relevance in preparing the dialogue with the patient in the Anamnesis process.

We argue in this chapter that tools supporting the Anamnesis Process, such as the Visual Incidence Anamneses (VIA), have potential to improve decision support and process transparency in diagnosing patients and hence increasing patient safety. The following two figures capture our main ideas. Figure 1 illustrates information collected by the physician at two separate anamnesis events. Situation N is the present situation. Situation N-1 refers to

Fig. 1. Separate earlier events (N-1), randomly reported by the patient to the physician in the actual anamnesis phase (Situation N).
an earlier event (which could also be multiple earlier events). The inbound arrows denote different important aspects to consider in the anamnesis. The outbound arrow denotes the selected diagnosis and treatment.

In Figure 2 we illustrate a tool offering feedback to earlier anamneses allowing the physician to take these into account during the current anamnesis in Situation N. Specifically, it illustrates that the selected diagnosis and treatment might differ due to an enhanced patient-centric greater context.

Fig. 2. Separate events (in situation/s N-1) concatenated by automation of data; a visible historical feedback for the physician to consider, study and discuss with the patient in the actual anamnesis phase (Situation N).

In this chapter we will take a closer look at decision support tools and processes related to anamneses in the remaining part of this section. In Section 1.2 Patient Safety we shortly refer to the current alarming situation worldwide and the need for improved tools and methods (such as VIA) collecting and analysing patient information to improve Patient Safety. Section 2 Artificial Intelligence in Medicine gives a short overview of tools supporting decision making in medicine such as 2.1 Differential Diagnosing and 2.2 Clinical Decision Support Systems (CDSS). Issues related to decision making under incomplete and/or uncertain conditions are discussed in Section 2.3 Safety Assessment. The two complementary decision models “Find simplest cause” and “What if ..” are discussed in Section 3 Ockham’s Razor vs. Hickham’s Dictum. In Section 3.1 The rare cases and the probable we stress that the concepts of “rare” and “probable” are highly context dependant. A “rare” cause can be highly propable due to more patient-process centric contexts such as enabled by, e.g., the VIA model and method. In Section 4 Case studies we motify exemplifies our VIA model as a mean to increase the quality of medical diagnosis. Our proposal is described in Section 7 Visual Incidence Anamnesis (VIA). The chapter ends with Section 8 Conclusions and Section 9 References.

Various types of Clinical Decision Support Systems (CDSS) have been developed to support the tasks to make the right diagnoses and decide on appropriate interventions such as treatments etc. However, a CDSS requires an input that is a critical point in the decision support process. In order to collect data for input to the system, the physician must initially perform an investigation of the situation and what might have lead up to it. The traditional action, even before any CDSS were available, is that the physician performs an interview with the patient and/or relatives to the patient, resulting in an anamnesis. Consequently, the anamnesis is a preliminary case history from the patients’ perspective. In this step, the collection of patient specific data is vulnerable. Both the physician and the patient must
cooperate towards a mutual understanding of what is important for the case or not. The patient (or relative) must be able to articulate information about the actual, or former, health status and the physician must be aware of which questions will sort out crucial information, valuable for further decision making.

The next step for the physician is to read relevant information in the (electronic) medical record. Grounded in information derived from the actual anamnesis, s/he decides what further information s/he might need to proceed with. Compared to earlier centuries, the information handling methods and the organization of Health Care are very different. In former times, the physician was reduced to use a complete medical history of the patients’ experiences in order to make decisions. The modern society provides specialized Health Care, assisted by advanced medical technology, but the holistic view of the human body is mostly lost as the system is not process oriented and the patients report is marginalized. The current situation, dividing up Health Care (institutional care and primary care) into different clinical departments, is fragmenting. This jeopardizes a continuous information flow for each individual patient involving potential information breakdowns between the varying units of competence. A general lack of time for each patient will further increase the risk of mistakes.

The information elicitation process is delicate and the result depends on a variety of variables such as competence and observation of the physician, ability to communicate important experiences by the patient and time available for the anamnesis phase. Even if the prerequisites are perfect, there are still pitfalls resulting in missed, decisive, information. For example, varying symptoms of a disease might occur for a long period of time but earlier diagnoses could have been false. To concatenate symptoms from earlier events to more recent events might be crucial in order to find the true diagnosis. The anamnesis making process should therefore be supported by automation of data from the patients’ medical history, instantly visible when the patient and the physician meet (Figure 2).

The difference between fragmented information flows, i.e. a number of disconnected and isolated information units on a time line, and a continuous information flow (of concatenated information units), where it is possible to observe and study earlier events due to knowledge about their existence, is vital. Figure 1 could be regarded as a model of a “hidden context”, important for the physician to be aware of in the decision making process. Figure 2 is a model of visualization of such context.

It might be emphasized that it is not a simple task to collect data for input to a CDSS. The anamnesis is an important step in this information elicitation process as it provides the physician with patient specific information, but the method for this step is rather ad-hoc and insecure: The human brain is extraordinary in its ability to sort out apparently crucial information for conclusions, but simultaneously this ability is perilous as conclusions might occur prematurely and be false if vital information is missing. Consequently, in Health Care this defectiveness might affect Patient Safety despite any advanced and well-designed CDSS. The critical issue is collection of relevant data.

1.2 Patient safety

Due to alarming numbers of incidents, injuries and deaths in Health Care caused by deficiencies in the field of activities, Patient Safety has attracted considerable attention in the last decade. Declaring that every year in USA, approximately 44 000 to 98 000 deaths occur related to deficiencies in Patient Safety, the report “To Err is Human” (Kohn et al. 2000), is still frequently cited and regarded as significant in the western world. Therefore, it has
caused far-reaching attention to the seriousness of the situation and constituted a starting point for appropriate actions. Furthermore, the findings in the report have been confirmed in other, more recent, reports in other western countries such as Sweden. Consequently, for the last decade, in Sweden, as in the European Union, an increasing interest in Patient Safety is noticeable. Various efforts in order to manage the critical situation in Health Care are already in place and the efforts towards models and methods assuring improved Patient Safety have high priority.

In this Section 1 and Section 7 we propose Visual Incidence Anamneses (VIA) as a model and method to increase patient safety. Our proposal is underpinned by an analysis of two case studies illustrating some shortcoming of present methods and tools such as Differential Diagnosing (DD) and Clinical Decision Support Systems (CDSS).

However, first we must return to an outline of the present situation for Health Care, in relation to Patient Safety. In Sweden, a prevailing strategy to follow up and prevent faults in Health Care has been to “punish” registered individuals (such as registered nurses, physicians etc.). HSAN (Hälso- och Sjukvårdens AnsvarsNämnd; Eng. Medical Responsibility Board) has until 2010 received numerous cases each year to evaluate and take measures against. Today, the National Board of Health and Welfare has shouldered the responsibility for assignments related to Patient Safety cases. However, the perspective on action plans for a safer Health Care has radically changed towards the perspective of fault prevention in the transport sector, i.e. towards a “systemic perspective” on each situation. As a result, the tendency forward is to adopt a basic change of models and methods to address shortcomings in protocols, procedures and in information management in Health Care. For example, among other contributions, to the area, a new Patient Safety Law (SFS 2010:659) came into force January 1st 2011. Especially noticeable for this matter is that the law also embraces the encouragement of patients and their relatives to participate in the Patient Safety work. This is in line with the development of the Patient Empowerment (PE) movement, appearing more distinctly along with the strong attention to Patient Safety as a complementary approach. PE is contributing to Patient Safety as the empowered patient in Health Care is regarded as a co-operator and an important piece of the puzzle, contributing with experience in being the one who has the “inside information” of being ill and, to a certain extent, being capable of act as such instead of passively receive care (a former, more traditional, view of the patient). Patient Centered Medicine (PCM) is another related line of policy, where a holistic view on the patient is given priority over the earlier, most common, industrial inspired view of work flow in Health Care as comparable to an assembly production line. PCM aims to avoid fragmentation of Health Care and to find ways to coordinate the patient the whole way through the care process. A related perspective is “Lean Thinking”, a management strategy for improvement of processes also applicable in Health Care. Accordingly, “Lean Health Care” is introduced at several hospitals in Sweden where Skåne Universitetssjukhus (SUS) (Eng. Skåne University Hospital), Lund, is one of those. These approaches are all connected to an aim of improving not only efficiency but also Patient Safety.

Returning to a very basic principle of Patient Safety, we must consider that Health Care is built on Information. Without information there will be neither conclusions nor decisions. Furthermore, the information in use must be correct. It must both be true and complete. Regarding the quality of knowledge used in Health Care, Evidence Based Medicine (EBM) is adopted as a guarantee of first rate quality of scientific information, used in clinical settings. As such, EBM is an important foundation for Clinical Decision Support Systems (CDSS),
used for support in situations of diagnosing and treatment. Today, CDSS are used in different clinical settings, preferably at the point of care, by physicians as well as by nurses. However, referring to the areas of Patient Empowerment and Patient Centered Medicine, briefly described above, every medical case is unique as every patient is an individual carrying a unique set of historical events in his/her medical history. This medical history is both documented in medical records, such as Electronic Health Records (EHR) and in the consciousness of patients and their relatives. Every single event in a medical history is important as it might be a clue to, or affect, current or future events. Neither EBM nor EHR and traditional CDSS are completely or clearly covering such aspects on diagnosing or treatment for the patient. Nevertheless, these events are substantially important for Patient Safety as loss of such information might lead to wrong diagnoses and delayed treatment. For many diseases, the time aspect is highly important for the successfulness of treatment. To be able to observe and identify appearances of critical information and information structures over time, a longitudinal case study, going on for ten years between 1999 and 2009, has been addressed. Moreover, a rather rare case occurring during a period of six months in 2010 added some more findings to the other and also questioned the widely adopted Ockham’s Razor of Diagnostic Parsimony. This seemed to be important with reference to the common use of CDSS. A qualitative methodology was chosen (including participatory observation, interviews and the study of medical records) which made it possible to more closely identify and study occurring, unpredictable, information breakdowns. Those breakdowns appeared to be critical for the outcome of the different cases, however not, or not clearly, visible in the EHR system for the physicians to observe. For each case, each new event was dependent on information from former events, sometimes carried by the patient or a relative, but not evident to be important at the time of the occurrence. To successfully use CDSS in order to find an accurate diagnosis or treatment requires patient data that is both true and complete. Figure 1 and 2 illustrate this aspect. In this chapter, we focus on incomplete causality models in Health Care. We suggest a feasible solution by utilizing graphical visualization of chronological information in EHR-systems. This information structure is suggested to complement the widely adopted rule-based Decision Support architectures. The rule bases can be regarded as isolated islands of knowledge while our graphical visualization ties together those patient specific events.

2. *Artificial intelligence in medicine (AIM)*

Health Care is basically built on Information. Without Information, decisions about investigations, diagnoses and treatment would be impossible to make. For example, patient specific data is important to collect. This is accomplished by the creation of an anamnese, collection of body data by medical equipment and clinical medical examination of the body in different ways (palpation, percussion etc). Decisions also require general knowledge to connect to. To build such knowledge, scientific information of high quality is necessary. Patient data and general medical knowledge is the foundation for any decision about a disease; deciding to choose diagnosis and the best practise of treatment. The knowledge of physicians and nurses in Health Care (in this context referred to as “human agents”) is evident to be part of the decision making process. However, the knowledge bases in human agents might differ from one agent to another as humans are individual; different levels or different directions in education and different former experiences, as well as more subtle tacit knowledge, build human knowledge. Artificial Intelligence (AI) has since decades been
regarded as potentially useful in Medicine, forming a sub-area: “Artificial Intelligence in Medicine (AIM). An early apprehension of AIM was that it would offer possibilities to create “a doctor in a box” which even could surpass the competence of a human agent; a physician (Coiera 2003, p. 331). In more recent years, the ambitions have been more moderate. Instead, different applications of Knowledge Management have been addressed to complement the knowledge of human agents in this area. To support the decision making process in Health Care, Clinical Decision Support Systems (CDSS) are developed for clinical practise. However, the success of CDSS is conspicuous by its absence and the usage still not very often established as a part of work flow. Coiera (2003) refers to some reasons for reluctance to use CDSS:

“Reasons for the failure of many expert systems to be used clinically include dependence on an electronic medical record system to supply their data, poor human interface design, failure to fit naturally into the routine process of care, and reluctance or computer illiteracy of some healthcare workers.”(Coiera 2003, p. 344)

Above a more user friendly and intuitive design, it seems to be necessary to more deeply consider work flow and the flow of information in Health Care, in order to develop and implement useful CDSS. Furthermore, additional tools for CDSS must be designed to repair shortcomings in protocols, procedures and information management in Health Care. However, to be able to do that, such shortcomings must be identified and analyzed. Patient Safety is an area where the results of such shortcomings are explicitly expressed. In this chapter, we will present a case study and some findings pointing at this need and we will also present a feasible solution for repair of information breakdowns which are jeopardizing Patient Safety. However, first we will deepen the reasoning about CDSS by presenting a logical method termed Differential Diagnosing.

2.1 Differential diagnosing

Symptoms might be caused by a great variety of causes. For example, fever is such a symptom. To pinpoint the true cause of occurring symptoms, i.e. the pathophysiologic explanation of the symptoms which is the actual disease, the decision making process embraces a method termed Differential Diagnosing. Referring to Merriam-Websters dictionary, the definition of Differential Diagnosis (ΔΔ or DD) is “the distinguishing of a disease or condition from others presenting with similar signs and symptoms”.

Accordingly, DD is, basically, a method used to systematically identify unknown variables; i.e. a “process of elimination”. This is a logical tool by which a list of possible diagnoses is made by the physician, implicit in mind or explicit on paper, digital etc. The diagnoses are, at hand, narrowed down by excluding impossible diagnoses until only one diagnosis remains. This implies that for one patient only one diagnosis, representing the symptoms, is true any other false. The word Diagnosis\(^1\) originates from the Greek word Διαγνωσκειν, meaning to "discern, distinguish" which is the basic aim of diagnosing: to discern the right diagnosis from the wrong. Consequently, DD in Medicine are the process of eliminating alternative diagnoses that might have some common symptoms with the true diagnosis and which could mislead the physician. In this process, Diagnostic Algorithms are used as tools for elimination. However, in rare cases, two conditions might occur simultaneously, giving

rise to one similar symptom. For example, chest pain could arise both from cardiac infarction and gastroesophageal reflux disease. Normally, after process of elimination, at least one is excluded; but both could be true, resulting in one missed diagnosis. (Later in this chapter, “Hickam’s Dictum” in relation to “Ockhams Razor” will emphasize this phenomenon.) Consequently, a defective process of elimination could result in a wrong or incomplete diagnosis, especially if not every sign or symptom is available to notice. In this matter, the importance of a complete anamnesis should be stressed. Accordingly, it could be concluded that the process of elimination is delicate.

Another peril is the physicians’ memory capabilities, necessary to be adequate, especially in situations characterized by high workload and stress. Therefore, IT-tools for DD are, along with the development of the Internet, available for physicians, for example DiagnosisPro\(^2\), a free self-contained web service to be used as a memorandum aid in the diagnosing task, in order to increase the quality of care and patient safety. This is a tool, not a Clinical Decision Support System (CDSS); however many CDSS are typically designed for DD as they basically provide Diagnosing Decision Support. To more closely be able to explain how CDSS can be beneficial to DD and Patient Safety, CDSS will more closely be described in the next section.

### 2.2 Clinical Decision Support Systems (CDSS)

Clinical Decision Support Systems (CDSS) are computer systems dedicated to the decision making task, i.e. to support clinicians in practice. Typically, CDSS are of two main types: Knowledge-Based and non-Knowledge-Based. The most frequently used type in Health Care settings today is the Knowledge-Based CDSS, also known as “Expert Systems” [Coiera 2003]. However, the metaphorical designation “Expert” might be unfortunate as it could provoke opposition about the sometimes assumed intention of the implementation of such systems; to take over the role of the physician. To avoid such interpretations and emphasize its true role, Expert Systems are today most often referred to simply as CDSS. Their use is more and more commonly accepted as they also provide opportunity to pursue Evidence Based Medicine (EBM), to improve Patient Safety. More infrequently occurring in Health Care settings are non-Knowledge Based CDSS. They could also be regarded as Learning Systems as they belong to a sub-area of Artificial Intelligence called Machine Learning.

In this chapter, we will focus only the Knowledge-Based CDSS as it is the most common system for physicians to use in the decision making process (Coiera 2003). Furthermore, we will only focus decisions about Diagnosing as this action actually forms the basis for any further decision about interventions, such as treatment etc. However, the diagnostic types of CDSS (sometimes referred to as Diagnostic Decision Support Systems, DDSS) are considered not as successful in clinical practice as Prescribing Decision Support Systems or other much smaller systems. In the Cases, later presented in this chapter, the diagnosing phase of the decision process turned out to be deficient and threatening to Patient Safety and provided an indication of a need for additional decision supporting tools. However, in this section we will now continue with a brief description of the typical CDSS.

Human agents possess knowledge. Knowledge-Based CDSS also possess knowledge. Without presenting any in-depth analyzes, we will stress that there is a basic difference between human knowledge and the types of knowledge referred to in the area of AI. The

\(^2\)http://www.diagnosispro.com/
knowledge in a Knowledge-Based CDSS is typically represented by a set of rules (i.e. Rule-Based systems). Furthermore, such CDSS also consists of an inference engine and a communicating mechanism. A working memory is necessary to store data and conclusions. Patient specific data will be combined with the knowledge in the rule-base by the inference engine while the communicating mechanism allows both input of such data and provides output of the results, from the CDSS. This architecture offers extended possibilities to store large amounts of scientific information, supporting Evidence Based Medicine (EBM).

Nevertheless, a CDSS, despite the metaphor of an expert system, is not to compare with a human expert. Human agents are capable of reaching a different, and far more complex, level of thinking that is not possible to implement by AI. Instead, it is necessary for the human agent to interact with the CDSS in a way that will optimize the functions available. For example, it is necessary to provide the CDSS with patient data that is crucial for the task and to interpret and assess output from the system. Some parts of this task can be automated, but not entirely. In the next section we will further explain this and point at difficulties and perils of information management for CDSS.

2.3 Safety assessment

There is always uncertainty in the knowledge that underlies a decision. With reference to the assessment of risks to human health posed by chemicals, an uncertainty factor is used to compensate for a deficiency in knowledge and create margins-of-safety. On the other hand, in differential diagnosing, the uncertainty is handled by the “method of elimination”. Nevertheless, wrong diagnoses occasionally occur. It might be concluded that there are no margins-of-safety to use as an imagined diagnostic value has only two states; true or false. Consequently, in the diagnosing process, the uncertainty is delicate. How can it be assured that the pathophysiologic explanation of the symptoms is true? If it turns out to be false, the consequences might be lethal. Due to clinical data that is imperfect and treatment that is not a guarantee for remedy, human agents in Health Care must deal with decision making under uncertainty. Probabilistic Medical Reasoning is an approach to this problem (Shortliffe 2006). Instead of expressing that diagnoses are either true or false, the human agents might express the assessment of diagnoses in terms of “probable” or “highly likely” (Ibid). In medical decisions requires strategies and one is to employ an iterative process for data collection and interpretation referred to as the hypothetico deductive approach (Shortliffe 2006, Elstein et al. 1978, Kassirer and Gorry 1978). The method comprises data collection and selection of a hypothesis of the most probable diagnosis, iteratively repeated (refinements of hypotheses by means of additional data) until there is a hypothesis that either is considered true or the uncertainty is reduced to lowest possible level (Shortliffe 2006). The set of active hypotheses are the differential diagnoses.

Human agents tend to use heuristic methods to collect data. This is perilous in medicine and a critical point for Patient Safety. In the process, the method of elimination is used to exclude hypotheses that are not probable to be true. This method is related to the use of a philosophical principle named “Ockham’s Razor” i.e. “The law of parsimony”. A clinical application of this principle in medicine might be jeopardizing to Patient Safety if the interpretation is close to the well-known adage: “when you hear hoof beats, think horses, not zebras”, a rule-of-thumb for selection of diagnosis. Safety assessment in Health Care, concerning the diagnosing task, should be a process that results in an “acceptable diagnosis” chosen on the strength of highest possible amount of relevant patient specific information and scientifically assessed medical information (with reference to EBM). With a Socio-
Technical approach to development of usable information management systems for Health Care, CDSS could support such a process. Systems, supporting workflow, are more likely to be used and to be usable for the task. Moreover, to adopt a PCM approach in the field of activities, as well as taking PE into consideration in the design of CDSS, or additional tools for information acquirement for CDSS, would probably be favourable for Patient Safety. CDSS requires input of patient specific data and to elicit relevant data concerning the patient is both challenging and decisive. Referring to figure 2 in Section 1, it might be of vital importance to gain a comprehensive picture of earlier events. The next section will further relate to this angle of reflection as events occurring over time might oppose rules-of-thumbs such as Ockham’s Razor.

3. Ockham’s (Occam’s) razor vs. Hickam’s dictum

In the area of Medicine, “the Zebra” is most often familiar to everybody. More closely described, this refers to the adage: “When you hear hoof beats, think horses, not zebras”. For example, a patient consulting Health Care for fever, with no further distinct symptoms, the most probable diagnosis might be urinary infection or “a virus”, not septicaemia. In this case, septicaemia is regarded as “the Zebra”. The adage is simply a clinical “rule-of-thumb” in some stage of the differential diagnosing process. This aims at reducing efforts and costs in unnecessary examinations and tests, but at the same time, patients affected with “Zebra-diagnoses” evidently exist. Accordingly, a rule-of-thumb should not completely override other possible alternatives. To further explain and strengthen this point-of-view, we will continue with a closer description of Ockham’s Razor as a principle of simplicity.

As concluded, “The Zebra” is an interpretation of the philosophical principle “Ockham’s Razor” i.e. “The law of parsimony”. In Health Care, this principle is also referred to as “Ockham’s Razor of Diagnostic Parsimony”. The principle is derived from the philosophical apprehension of simplicity, which have been expressed in different ways for different fields over the centuries. Basically, the idea is that simplicity is a theoretical virtue; that simpler theories should be regarded as preferable (Baker 2010). In Health Care, this implies that in the diagnosing process, the physician must try to look for a minimum of hypotheses to explain all of the symptoms the patient have, i.e. Diagnostic Parsimony. In order to achieve this aim, only the most probable hypotheses will be tested. What is probable to be true in this perspective is what is probable for the patient as belonging to a large group of homogeneous “patients”. However, if the view is that patient is not a member of a homogeneous group of earlier patients, but instead a unique individual with a unique set of patient-specific data, the perspective will change. Harvey et al. (1979) expresses this as follows:

“In making the diagnosis of the cause of illness in an individual case, calculations of probability have no meaning. The pertinent question is whether the disease is present or not. Whether it is rare or common does not change the odds in a single patient. ... If the diagnosis can be made on the basis of specific criteria, then these criteria are either fulfilled or not fulfilled” (Harvey et al. 1979, p.15).

Accordingly, Ockham’s Razor of Diagnostic Parsimony has been frequently questioned. Even if the approach towards simplicity has advantages, it also has serious disadvantages. One counterargument is Hickam’s Dictum. Referring to the hypothetico deductive approach in the diagnosing process, the principle of Hickam’s dictum insists upon that, at no stage of the process, should a particular hypothesis be rejected because it does not seem to fit the principle of Ockham’s razor. If the “Zebra” is a popular adage based on the
principle of Ockham’s Razor, Hickam’s Dictum is sometimes expressed as simple as “Patients can have as many diseases as they damn well please”. This text en clair could be exemplified by Saint’s triad (of hiatus hernia, gallbladder disease, and diverticulosis), affirming Hickam’s Dictum, and simultaneously questioning Ockham’s Razor. Another counterargument to Ockham’s Razor is Walter Chatton’s “Anti-Razor” or the “Chatton Principle”, however not further described in this chapter. Rules-of-thumb might be useful for most cases, and the “Zebra” should be successful for most patients as the most probable diagnosis is diagnoses that statistically is most common to have in relation to the symptoms occurring. We must conclude that this is not a problem. On the other hand, there is a rather serious problem closely connected to Patient Safety and the chances to increase Patient Safety. The problem is the “Zebra”, or, even, the “Fascinomas” (slang). Even more problematic are multi illness and systemic diseases. It seems to be momentous to develop protocols and tools to handle atypical and complex situations, in order to prevent mistakes, information misses, injuries and deaths.

3.1 The rare cases and the probable

Traditionally, Clinical Decision Support Systems (CDSS) are guiding tools, often grounded in probabilistic reasoning and/or knowledge based rules. The different reasoning mechanisms are implemented as differential diagnosing algorithms, i.e. methods of elimination. In a statistical view, where the patient is regarded as belonging to a large group of earlier patients, this notion will cover the majority of every possible cause of a symptom. Most diagnoses based on this view will probably be true. For example, the symptom “Headache” is most probably caused by muscular tension (in turn caused by nervous tension/stress) or it might be caused by migraine processes. Such more common diagnoses seem to be the first hand choices, which might end the hypothetico deductive process prematurely. Headache could be a symptom of encephaloma (brain tumor) or Stroke; which might be considered as “Zebras” at a glance. Furthermore, it should be noticed that more than one diagnosis might be true: referring to the example above, the cause of a headache could be multiple.

Consequently, the problematic cases are when the rule-of-thumb fails. For those reasons, “Occams Razor” is fairly questioned. Probabilistic thinking might limit the domain of possibilities in which a physician ventures to reason. To override such directions, preventing prematurely abruption of the diagnosing process, more relevant data is needed. The next section presents two cases where this need for more data is identified as crucial for the outcome. Data collection is not a simple task which also is observable. Context of a patient is complex, not periodically limited, and not entirely coverable by a traditional anamnesis and medical history available for the physician to make vital decisions on. The cases pinpoint a need for a more concrete time-line of events, alerting for “Zebras” if needed.

4. Case study I and II

These studies, Case study I and Case study II, comprise two different cases of which the first case describes a fatal “Zebra-case” and the second describes a life-threatening “Zebra-case” and simultaneously a typical “Fascinoma” where the diagnosis is preposterous in relation to probability. In addition, obviously in both cases, prematurely abrupt hypothetico deductive processes were noticeable. It might be presumed, that a potential cause of the
abruption was heuristic thinking and an apprehension of probability in relation to certain, in these cases misleading, variables: data about immediate circumstances and data about the patient, such as age etc. Simultaneously, crucial data was missing.

In Case I, the crucial point is invisibility of earlier events and also the potential importance of earlier events. In Case II, initial invisibility of evidently important earlier events, in a time critical point of the care process, was directly jeopardizing Patient Safety. Interestingly, the roles of patients and the relatives were essential for both cases. They were the keys to whether the cases would prove fatal or not. However, even if patients and relatives always are important in the care process and always must carry patient specific information (Ådahl 2007), this must not be a single-handed task of the kind that the patients survival is directly dependant on if, or what, the patient or relatives report of the former medical history. Such tasks should also be automated, as a safety foundation for further interactive discussions with the patient/relatives.

4.1 Case study I: A retrospective longitudinal case study
This case is a retrospective longitudinal qualitative study, in progress for a period of ten years (1999-2009) and grounded in observations, interviews with the patient and relatives and analyses of medical records. This case presents situations in which hypothesis testing, in retrospect, seems to have failed. It demonstrates that patient specific information, collected for a long time, might be crucial for the Differential Diagnosing task.

Situation 1 (CISIT1): Transitory hemiplegia
In 1999, a 74 year old woman suddenly experienced an evident weakness in the right part of her body. The relatives, present at the time for the incident, called an ambulance whereupon the woman was transported to the Emergency Ward at the local hospital. After some days of hospital treatment, the physicians diagnosed the woman with Migraine. The hemiplegia was transitory and as she had suffered from frequent occurrences of flittering scotomas during the period of hospital treatment, in addition to a long term history (since childhood) of migraine, revealed in the anamnesis, and since she had experienced some months of increasing social stress factors, this was the exclusive focus for the physicians. One CAT scan was performed, revealing nothing suspicious in the brain. The diagnosis Migraine was established despite the absence of the usual migraine headache and, to the patient, the newly occurring neurological symptoms of scotomas and hemiplegia. As migraine is considered rather harmless, following up visits to Primary Health Care providers was not planned or recommended. The woman was, as many in her generation, reluctant to bother health care with more visits, even though the flittering scotomas continued to occur in the years to come. However, she was seriously bothered by this; in addition to the fact that she did not experience the usual symptoms of migraine by which she was spared after her menopause at the age of 58-60. Furthermore, she was since many years suffering from high blood pressure, but when she visited her physician for a routine blood pressure check, the information about the transitory hemiplegia was not accessible for the physician and the patient did not mention it either as she trusted the diagnosis “migraine” despite some skepticism.

Situation 2 (CISIT2): Weakness after syncope
A few years later, in 2002, the woman (now age 77) was found lying over her kitchen table with bilaterally very weak muscular tonus, nearly unconscious. She was able to answer when spoken to but not to move her body or keep her eyes open. She said that she had suddenly fainted, sitting on the chair, and after that not being able to move and still very close to fainting again. An ambulance was called and she was transported to the Emergency Ward at the local hospital.
After a few days, she was sent back home with no follow-up directions for the Primary Health Care. As she, when she arrived to the ward, had some unclear fever, and earlier that day, when she experienced the syncope and general weakness, had visited the local care center for the annual vaccination against the influenza, the diagnosis this time was “Reaction against the vaccination”, after excluding Septicaemia by receiving repeated negative blood cultures. Furthermore, the general weakness disappeared within the first 24 hours. As she, after the Emergency Ward, this time was transferred to the Specialist Ward for Infectious Diseases, the physicians did not study the medical record from the Medical Ward and were not aware of the former situation (SIT1) with transitory hemiplegia. Furthermore, this time the weakness was general, occurring after the syncope, so the patient believed that these symptoms were dependent on the reaction of the vaccination. She also trusted the physicians’ decision about the symptoms being dependant on a reaction of the immune defense.

Situation 3 (CISIT3): Hip bone fracture

The following situation occurred in 2008, when the woman, now 83, suddenly felt faintly weak and fell in her staircase, resulting in a fracture of the hip bone. For a year, she had problems with weakness, feebleness and dizziness which she thought was natural decrepitude. Not even her district medical officer thought of any other reason. She went by ambulance to the emergency ward where the physicians were puzzled by her, at this time, frequently intermittent unconsciousness: off and on she went unconscious, with a snoring breath. Furthermore, she felt very sick, by nausea and frequent vomiting.

However, they noticed that she did faint in spite of lying down in bed and having a slow pulse of 30 when it happened. She also had too low levels of oxygen (SaO2 90 at most) and therefore required oxygen supply. The ECG revealed a momentary asystolia and attacks of atrioventricular block (AV block III), not compatible with her medication: metoprololtartrat³ (beta-blocker) which immediately was removed. Furthermore, obviously by notes in her EHR, she already was diagnosed by AV-block I which was unknown by the woman herself. Accordingly, she was not in an operable condition, so she was directed to the intensive care unit for cardiology until her heart was considered stable enough.

Two days after the accident, she was transferred to the orthopedic clinic for surgical operation (hip replacement) which was a success. However, the day after she was, again, medicated by metoprololtartrat (Selokén), which obviously did not fit to her AV-block history stated at the emergency ward and the cardiology unit. In the subsequent rehabilitation at the orthopedic clinic, she fainted at least three times when trying to walk (one time in the arms of a physician) and probably, not recognized, some times lying down in bed. She felt very weak, but despite these indications, no one seemed to understand the connection between Selokén and her AV-Block and did not check her blood pressure, nor her pulse, at the moments of fainting. Instead, the dosage of metoprololtartrat was increased as the presumption was fall in blood pressure due to the operation, and her inconveniences of palpitations. The woman did not reach her habitual state, but instead she was very weak and faintly, seeming much “older” and more fragile than the last year before the accident.

Nevertheless, after a week, the orthopedic treatment programme was finished and she was about to be sent home. The daughter, being a nurse by profession, attended the care planning meeting at the ward, now gaining information about the current treatment, and according to this raised sharp protests against the decision to move her out of hospital. She claimed that her mother was not analyzed due to the cardiac failure and that the medication was lethal, at least a considerable risk factor for further accidents. The attending nurse did not seem aware of this situation but did after all pause the meeting and informed one of the physicians of the orthopedic ward who, in turn, consulted physicians at the intensive care unit for cardiology for a new standpoint on this “new” information.

³ Contraindication for metoprololtartrat: AV-block II and III. (http://www.fass.se/)
However, the intensive care unit for cardiology was also unaware of the registered attacks of AV-block III at the emergency ward, solely focusing on cardiac stability for the orthopedic surgery! As a result, Selokén was still prescribed but due to the uncertainty of the situation and special arrangements in the woman’s home, she was allowed to stay for some days more. Two days later, Selokén was suddenly removed and she was allowed to stay until she might be stable enough for short-time housing or home. An anemia was also discovered the day after the planning meeting and she was ordered a blood transfusion and iron tablets. After 2 months of recovery, partly on a rehabilitation clinic, she was able to go home and now the symptoms of fainting, faintness and decrepitude were also completely gone.

**Situation 4 (CISIT4): Stroke**

Seven months after the Hip Bone Fracture, in 2009, the woman, now almost 84, went to bed after a day feeling tired and feeble. In contrast to her usual active life style, she only wanted to sit in a chair, resting that last day. Some of her relatives, visiting her in the afternoon, did notice this change for the worse and her adult granddaughter decided to stay for the night as a result of a premonition of danger. After just about three hours of sleep; her granddaughter heard her calling for help and rushed into the bedroom. This time the woman, again, experienced the general weakness, difficulties in opening her eyes and felt very sick, vomiting and close to fainting. The granddaughter called an ambulance and the woman was, again, transported to the Emergency Ward at the local hospital. This time the physicians had no immediate explanation to present. They discussed if the symptoms could be caused by a stroke, but the general weakness did not clearly answered to that. The relatives was present at the ward and the daughter, being a nurse herself, asked for a CAT scan which was rejected as it was in the middle of the night.

After one hour, the woman suddenly experienced an approaching faint and called for help. She had an ECG, monitoring her heart rate, and a moment later the electric waves became straight as a result of a cardiac arrest. The daughter sounded the alarm and the personnel managed to revive her. After this occasion, the woman was transferred to the intensive care unit for cardiology for monitoring and acute treatment. The attending physician at the Emergency Ward, after consultation with the senior physician on standby duty, who did not want to order a CAT scan in the night, excluded stroke as the diagnosis, purely on clinical basis, despite suspicious signs. The patient herself, at this moment still being able to talk, pose the risk of a stroke, but got the answer it could not be. The relatives knew about new treatment methods for strokes caused by blood clots, but also that such methods must be initiated within hours after the stroke began. This made them feel very frustrated. However, the condition seemed to stabilize and the physicians were determined about it not being a stroke, so the relatives were sent home as the patient did want them to do so, to sleep and to being able to go to work in the morning.

However, in the morning, when a CAT-scan eventually was performed, it revealed escalation of thrombosis (blood clot) in the brain and brain oedema in progress. Two older infarctions were also revealed, not diagnosed before. A short while after that, the condition went worse. It was at this time too late to use any method to treat the clot (thrombolysis) and stop the stroke from proceeding. Accordingly, the woman rather quickly got an explicit paralysis in her right side (hemiplegia) and lost her ability to speak understandable (expressive aphasia). The following hours, she went worse, in the afternoon also unconscious and finally she died late in the afternoon, 17 hours after the first symptoms.

This case embraces four apparently different situations, with four different pathophysiological explanations of the symptoms occurring, and, as a consequence, treated with reference to four different diagnoses. In CISIT1, the DD process resulted in the diagnosis Migraine. The patient herself did find this strange, as she did not suffer from migraine since her menopause at the age of 58-60, approximately 15 years earlier. However,
the CAT-scan did not reveal any pathological alterations in the brain and the inevitably most common cause of such symptoms is Migraine. Consequently, Migraine was the most probable diagnosis. However, in retrospect, we might question this by asking if CAT-scans are quite reliable or if MRI-Scanning (Magnetic Resonance Imaging) would have revealed something else. This imaging tool provides physicians with more detailed information, especially of the brain as it can “see through” bone (the skull). However, prescribing MRI is costly and must be done only if negative results from other tests require more testing. We know, with reference to CISIT4, that older blood clots in the brain at that time were identifiable by CAT-scan which must raise questions about when (during 1999 and 2009) those were originating. CISIT1 could have Stroke as the true cause of the symptoms. However, the hypothesis of Migraine as the most probable cause of the symptoms was chosen and the iterative process of a hypothetico deductive approach (Shortliffe 2006, Elstein et al. 1978, Kassirer and Gorry 1978) to the problem was decided to be stopped. No further tests were prescribed.

Analyzing this, both heuristic thinking in the DD-process and ambitions of cost-reduction might be influential to the decision. An elderly patient, with high blood pressure and migraine in the anamnesis, are at increased risk for Stroke. The occurring symptoms should have alerted for this. Furthermore unfortunately, critical information of CISIT1 was lost in the coming visits to the care center as an outpatient. Limitations of (electronic) information management at that time (1999), and deficient routines and protocols in Health Care for such information flow, was a probable cause of information breakdown. The patient herself was the only link to the earlier CISIT1.

Next episode (CISIT2), in retrospect now pointing at Stroke as a reasonable hypothesis to be tested more closely, the symptom Fever and the fact that she had a vaccination against Influenza earlier that day did override the symptoms of general neurological weakness and syncope. Furthermore, information from CISIT1 was not visible or easily accessible in CISIT2. Therefore, the actual (considered most probable) hypotheses this time were Reaction against the vaccination or Septicaemia (due to the vaccination). Septicaemia was excluded as the blood tests were negative and other symptoms of Septicaemia did not occur. Lacking crucial information from earlier alarming and critical events, the other symptoms were explained with reference to a rather unusual immune defense reaction on a vaccination. The patient was discharged with no further follow-up. Already in this phase of the study, we must consider other strategies for anamnesis creation, as information, potentially crucial for the differential diagnosing process, was obviously lost between CISIT1 and CISIT2.

Moving the attention for our analysis to CISIT3, we will absolutely agree about the diagnosis. There is no doubt about this. Diagnostic radiography (“X-ray”) revealed a hipbone fracture (neck of the femur) in addition to inability to move the leg due to pain, the fracture and tissue lesions in the area. However, in this situation, we might inevitably bring Ockham’s Razor of Diagnostic Parsimony to mind. Furthermore, as in the preceding situations, the “Zebra” is probably basically adopted. We will also emphasize that information about CISIT1 and CISIT2, occurring about nine and six years earlier, was not available or presented in a way that the symptoms of these preceding situations could be related to this event. Information about the patients frequent occurring flettering scotomas, evident since CISIT1, was not either visible. Accordingly, in this situation (CISIT3) the patient fell and broke the neck of the femur. The main focus was on the fracture and towards a decision about treatment (surgery), the occurring heart problems of the patient were, at least temporarily, also in focus. A more comprehensive perspective would have
been to question why the patient fell and try to identify this in relation to how she normally acts and related incidents in her anamnesis. As the focus was on the fracture and its treatment and the occurring cardiac arrhythmia identified at the emergency ward, this perspective was not entirely investigated. In retrospect of CISIT1 and CISIT2, and with knowledge about the woman in everyday life, we could create a new hypothesis of another diagnosis, as the main cause of the others. It is conceivable that Stroke was the main pathophysiologic explanation of the other diagnoses; Hipbone Fracture and Cardiac Arrhythmia as she might have fallen in the stairs due to a thrombosis in the brain and the heart was affected both by the thrombosis and the physical trauma. This would have been impossible to hypothesize without instant visualization about earlier events and their symptoms.

However, an even more serious conclusion, immediately jeopardizing Patient Safety in the situation, is that life critical information was lost within CISIT3, simply due to commonplace transfers of patients between wards. The EHR-system in use at this hospital was Systeam Cross providing access to medical records of other clinical departments, at least for physicians. Moreover, more traditional protocols for oral reporting in transfer situations are also, since many years, put into practise. An even newer protocol is adopted at the emergency ward; SBAR (Situation, Background, Actual condition and Recommended actions), a model for structured communication in Health Care. But still, the information flow was broken, probably because the system did not actively visualize important events in patient transferring situations which became evident in this situation where a relative had to act as information carrier for the patient. Human agents as well as Information Systems in Health Care such as EHR must have access to relevant patient-specific data. The identification, collection, management and presentation of such data seem to be crucial.

The last situation in this case, CISIT4, occurred only a few months after the patient was discharged from the rehabilitation clinic, and also for this situation a lack of former information is evident which also became decisive for the result. The symptoms were vague and because of that, and an occurring situation of cardiac arrhythmia and cardiac arrest, the focus was on the heart. Now both the relatives and the patient realized that this, in relation to CISIT1, CISIT2 and CISIT3, could be caused by a stroke, trying to convince the physician on duty that night to prescribe a CAT-scan to find out if there were cerebral causes to the symptoms. But as the symptoms were undefined (as in CISIT1, CISIT2 and CISIT3) and the patient also has mentioned mushrooms (chanterelles) that she earlier that day had eaten, the nausea and attack of vomiting was primarily explained as a probable result from food poisoning, or even gastric influenza (the most probable cause of nausea statistically viewed).

A decision was made about waiting to prescribe a CAT-scan, based on cost-reduction ambitions in Health Care and the lower probability of a serious cause of the symptoms, which delayed treatment in case of a more rare and serious diagnosis (stroke by thrombosis).

For many rarer diagnoses, the time aspect is decisive and a delay might even be life threatening. Stroke is one of these diagnoses. Heuristic thinking in the form of rules-of-thumbs is common for human agents, but in Health Care, other strategies may be needed to compensate for mistakes and misses dependant on hidden information. Health Care personnel are often working under pressure. For example, in the night, only one physician is at duty at the clinical department s/he is connected to (in addition to the emergency ward and the intensive care unit in cases related to the department) and usually must handle parallel multiple cases at the different wards. Even in the daytime, the pressure is severe and physicians often experience a lack of time to spend on each patient. A solution for
insufficient routines and protocols in this matter must not be time consuming in itself. Instead, it must release time at the same time as it increases Patient Safety by providing a more holistic view of the patient and his/her entire medical history.

4.2 Case study II: A rare case

This study, in progress for a period of ten months (2010-2011), grounded in observations, interviews with the patient and relatives and analyses of medical records. The case study provides an example of a very rare case, where an initial impulse to follow “the Zebra” obviously was too firm, overriding every sign of something else being in progress resulting in a fatal situation. The time aspect was also in this case, as in Case study I, very decisive to the forthcoming events after the first misleading diagnosis. In addition to “the Zebra”, the philosophy of simplicity in Ockham’s Razor was initially noticeable in the decision making process. Furthermore, this case exemplifies a causality dilemma (“Chicken or the Egg”) for which an acceptable solution might have been decisive for prevention of any recurrences.

Situation 1 (CIISIT1)

“A young woman, 24 years old, diagnosed at birth with a complicated congenital heart condition with repeated open heart surgeries since then, falls suddenly to the ground with low blood pressure (syncope). At the emergency ward the body temperature rises quickly to 40 degrees (Celcius). No other symptoms are present. The physicians are not able to find any sign of a bacterial infection so she is permitted the following day to go home, despite a rising Bilirubin in serum, however not communicated to her or the relatives. Diagnosis is “virus infection – influenza” despite no other clinical influenza signs than the syncope and high fever. Her mother, being a nurse by profession, did raise a protest against the influenza diagnosis as she found it strange to have an “influenza” with no other symptoms occurring. She was under apprehensions about septicaemia, but the physician rejected this as it is a rather rare diagnosis and not probable at all for the young woman to have; “she would have been in a much worse condition if so”, the physician reasoned. Accordingly, and as the fainting tendency has disappeared, the patient and her mother now were open to any other symptoms coming, pointing at “influenza”.

The next day the young woman experiences nausea and frequent vomiting in addition to pain in the stomach and a mild nose bleed when she vomits. As those symptoms might be signs of influenza (such as gastric influenza), and intense vomiting might result in nose bleed, she and her relatives do not find this very suspicious with reference to the first apparently certain diagnosis. However, in the evening she starts to feel very weak and the pulse rises to the frequency of 120/min. At this point in time, two days and nights have passed since the first signs of illness. The mother did find this alarming, either as a symptom of heart failure or as a symptom of shock. After some advice from the Swedish medical advice telephone service “Sjukvårdsrådgivningen 1177”, as the young woman was reluctant to see a doctor again after the first diagnosis, she was transported to the Emergency Ward. At the Emergency Ward, the examination, the blood sample, blood pressure and pulse shows that she most likely has developed severe Sepsis with a Septic Shock reaction, multiple organ failure and, basically, she was suffering from a Cholecystitis probably causing the Sepsis or vice versa.

Immediately, intra venous antibiotics are ordered, and the patient is transferred to the Intensive Care Unit for continuous supervision and treatment. However, after 12 hours at the ward, the patient is considered stable, and therefore transferred to a Surgery Ward for treatment of the Cholecystitis, a rare condition designated Acalculus Cholecystitis⁴. The physician at the Intensive Ward was told,

⁴ A biliary infection, without stones. (http://emedicine.medscape.com/article/187645-overview)
by the mother, that the patient has a complicated congenital heart condition and that the cardiologists, both at the local hospital and at the University Hospital, where the patient has her attending cardiologist, must be consulted as she has inserted biological material inserted by operative surgery in her heart. As a result, the risk that she develops an Endocarditis, as a complication to the Sepsis, is rather high. Furthermore, her mother tells the Intensive Care Unit physician that the Cardiologist at the University Hospital has asked for information about changed health status as she also waits for a new surgery. She finds the answer she gets as “non sequitur” and “patronizing” and despite this information from the relative, the young woman is suddenly transferred to the Surgery Ward without further discussions and without any further supervision of the heart function. The time at the Intensive Care Unit is also questionably short. The mother, being a nurse by profession, and the supervising nurses at the Intensive Care Unit, find this odd and is worried about the situation. The mother immediately, by her own initiative, in person, contacts the Cardiology Unit at the hospital and, by e-mail and telephone, gets in contact with the cardiologists at the University Hospital. This causes an upset reaction, where the chief physician at the Cardiology Unit visits the young woman at the Surgery ward and informs her and her relatives that she now will be transferred to the Cardiology Unit for further treatment and supervision of the heart. He says, rather upset, that “he has been present at the hospital since nine a.m. and now it is six p.m. without anyone informing him about the patients’ arrival and condition”. Further on, the status of the heart is carefully examined, to avoid Endocarditis and heart failure caused by the bacteria in the blood and the substantial strain caused by the current disease.”

Situation 2 (CIISIT2)

The patient survived the serious illness but recovered very slowly, taking several months. The heart condition seemed to affect her more after the disease than before, increasing the heart failure. Five months later, she suddenly experienced fatigue, diarrhea and nausea, later in the day also vomiting. As she started to feel something in the area of the liver, she contacted Sjukvårdsrådgivningen 1177 where she was directed to the “emergency care center”, a care center open until 9 p.m, receiving an appointment time. She and her mother, helping her in this situation by driving, thought the choice of health care center was completely wrong, but because she was directed there they went there first. However, the mother started communication with the nurse at the care center with the assumption that the patient most likely was suffering from a recurrence of the acalculous cholecystitis five months earlier, which hastened the appointment time with the attending physician to occur one hour earlier. The physician immediately redirected the patient to the emergency ward, with a letter of referral with a question at issue: “Acute Cholecystitis?”. At the emergency ward, the patient was examined by a surgeon which immediately questioned both the assumed diagnosis and diagnosis five months earlier based on that the symptoms (again) was atypical and that he could not find the information in the EHR at a glance. He strongly doubted the relatives repeated assurance of that this young woman actually had suffered from acalculous cholecystitis (the diagnosis is rare and the woman “too young”) until the laboratory report arrives: Rising s-Bilirubin again, just as the relative said was missed at the earlier event. Now the surgeon did read the entire EHR report for the medical history of the last occasion and quickly ordered antibiotics intra venously. However, an ultrasound of the biliary passage and the gall bladder should have been prescribed immediately to collect patient data for future events. The patient was transferred to the Specialist Ward for Infectious Diseases, and when arriving to the ward, the day after, some physicians again questioned the rare diagnosis, suggesting a more probable explanation to the symptoms: “gastric influenza”. A physician decided to change the treatment, in the weekend, as she found it very unlikely to contract a rare disease such as acalculous cholecystitis more than once. However, the mother, being a nurse and medically trained, this time objected very firmly to this point of view, this time. She had found out that, despite the rare condition
not likely at all to affect a young woman, of normal weight, even slightly underweight, a state of severe heart failure might cause ischemia in the gall bladder and this is one of the causes to acalculous cholecystitis. The mother had to be very firm, both in discussions with the physician and by leaving a written report of this hypothesis. Finally, she gained a hearing. The young woman did rather quickly recover from the symptoms, and also from the soreness and swelling over the liver, by treatment for the true diagnosis in a very early stage of the disease. When she later on made another visit to the clinic to control how she had recovered, she also met the doctor at the ward that treated her earlier that year, when the acalculous cholecystitis first appeared. He made a note in the medical record about paying attention to the fact that she might have this rare condition if she develops symptoms like the ones she already had twice. In cases of such symptoms occurring, a ultrasound of the gall bladder must immediately be performed, to be able to collect unquestionable data for proof. Early treatment is crucial in cases like this.

Situation 3 (CIISIT3)

Two months after the recurrence of the acalculous cholecystitis, she had to undergo another open heart surgery for her heart condition as her heart failure now was severe and might have been directly life threatening. It was discovered that her aortic valve (a biological xenograft) had an ejection fraction of only 37 percent. The surgeon deemed the valve as “destructed”. Most probably were the initial missed diagnoses Septicaemia and acalculous cholecystitis, with the delayed treatment, a direct cause of the accelerating degeneration of the valve. Consequently, it was crucial to her survival that she received early treatment when the cholecystitis reoccurred.

This case study, divided in three situations, is pointing at several alarming deficiencies in both information handling routines and the decision making process. The first situation points at abruption of the differential diagnosing process prematurely, i.e. the hypothetico deductive process. In the continuation this situation, there are also (as in Case study 1) occurrences of information loss: when the patient is transferred between wards. Both crucial information of the current period of care and potentially crucial information about the previous medical history were lost, probably as information in the EHR is noted down by human agents, with individual apprehensions of the value of patient specific data, and that important data is not clearly visualized for the physician at the point of care.

A causality dilemma was also arising when the true diagnoses were decided (CIICIT1). It could not be concluded if the acalculous cholecystitis was the cause of the sepsis or vice versa. The most probable hypothesis was the first assumption. However, the strain of bacteria found in the blood test (culture) was not bacterias normally expected to be found in the biliary passage. Therefore, the probability of this was low. Instead the strain of bacteria was a rather common bacteria normally found the respiratory passages; Haemophilus Parainfluenzae. Even more intriguing was that acalculous cholecystitis is a very rare condition and the patient was not at all the typical patient in danger of such a condition. Most patients affected with this infection are elderly, seriously ill patients or trauma patients at the intensive care unit. This patient was a young woman; hastily and totally unexpectedly falling ill at work with no preceding warnings. Beyond her heart condition, with some inconvenience with a heart failure, she was completely healthy. It should sometimes be of importance to also identify the cause of the diagnosis, not only the diagnosis as a cause of the symptoms. In this case, it seems to be crucial. Acalculous cholecystitis is a life-threatening condition with a high mortality rate. Severe septicaemia with multiple organ failure is also extremely serious. For both conditions, the time aspect is critical for the possibility to survive. Consequently, causation is very important for the development of further events such as recurrences. The following could be hypothesized:
1. The Septicaemia is a result of the Acalculous cholecystitis.
2. The Acalculous cholecystitis is a result of the strain of the Septicaemia.
3. The Septicaemia and the Acalculous cholecystitis are separate, independent, conditions, randomly appearing simultaneously.
4. Due to the strain of a heart failure, the Septicaemia is a result of some undetected infection in the throat or respiratory passages.
5. The Acalculous cholecystitis is caused both by the strain of the Septicaemia and a potential ischemia in the gall bladder due to a heart failure.
6. The Acalculous cholecystitis in CIICIT2 is caused by an increasing heart failure.

Lack of time and high workload, unfortunately often evident in Swedish Health Care, prevent physicians from hypothesis testing aimed at finding a causal explanation for the origin of the diagnosis itself. Nevertheless, such testing might decrease the number of recurrences or further illness. In this case, the most probable hypotheses for this particular patient, with reference to hidden patient data, should be no. (2), 4, 5 and 6. However no. 1 and even 3 were the hypothesis in focus, but only occasionally. The different perspectives are dependant on presence or absence of critical patient data. Visualization of such information might change the perspective and provide possibilities of treatment to prevent recurrences.

Returning to the initial situation (CIICIT1), the physicians deciding on a very common, and therefore also most probable, diagnosis (Influenza due to a virus), were using the principle of Ockham’s Razor interpreted in the shape of the “Zebra”. The actual disease started with a syncope and sudden high fever (ague) that declined until the next day. Interviews with the patient afterwards reveal a sense of confusion during the night at the hospital and an inability to communicate this experience clearly to the personnel. The patient was also exhausted when she was discharged the day after and despite notes in the EHR of being in good condition, she was not capable of walking and had to borrow a wheel chair to be able to make it to her mothers’ car: This information had unfortunately been lost and the physicians were not aware of it. The time aspect was crucial for a true diagnosis to be found in this case. The blood tests were performed too early in the process and not repeated the next day. Therefore, the CRP-test (C-Reactive Protein) was rather low, pointing at a virus infection, and also the level of white blood cells was not alarmingly high. With reference to this, neglecting a rising Bilirubin in serum, and with a (false) apprehension of the patients apparently good condition, the hypothetico deductive process was ended and a simple and common virus diagnosis chosen. However, with a continued process, with repeated tests before a decision, a fast rising CRP and level of white blood cells, in addition to Thrombocytopenia (decreased number of platelets in the blood) and increasing stomach pains would have lead the physicians to another conclusion. Furthermore, more attention to patient specific data reported from the patient and the relatives would probably have diverted the physicians’ from attending to the “Zebra-rule”, instead trying to extend the hypothetico deductive process a little more until there was certainty.

Even more problematic was situation 2 (CIISIT2). In the EHR, the information from the first situation about four months earlier was not immediately visible at all for the physician at the emergency ward. Instead, the patient herself and her mother had to inform the physician about their apprehension of the current symptoms and how they related to the symptoms occurring in situation 1. This physician trusted this information and started to search for more information in the EHR, resulting in early treatment of the illness as the blood tests, with an increased Bilirubin in serum, also was evidently the same this time. Furthermore,
the area of the liver was swollen and sore. However, again this information was incomplete and not clearly visible after transfer from the emergency ward to the Specialist Ward for Infectious Diseases. Some crucial information about the choice of treatment was lost, and therefore questioned which might have been jeopardizing for patient safety. Again the principle of “Zebra” was adopted and the physician at the new ward insisted on gastric influenza as the most probable cause of illness for a young woman. The burden of proof was on the patient and the relatives which is not a preferable or safe situation in Health Care.

5. Visual incidence anamneses (VIA)

Patient Empowerment (PE) is the underlying approach to VIA. Patients are providing Health Care with valuable information in many ways, generally being capable of cooperating for their own recovery. Participatory Medicine (PM) is a concept, developing from PE and related to Patient Centered Medicine (PCM). Empowerment Systems, suggested in the licentiate thesis “Transparency of Critical Information for Patient Empowerment in eHealth” (Ådahl 2007), are systems supporting these approaches. In the thesis (Ibid), architecture and design of Empowerment Systems, specifically supporting teams, were in focus. The following Figure 3 captures a comprehensive design context of such systems. It might be worthwhile to survey in order to grasp the idea of Empowerment Systems.

![Fig. 3. Design context of Empowerment Systems. The main supporting components are Foundations and Functions in context. The latter includes Activity theory based on ethnographic studies while Foundations focus on issues related to interaction and semantics.](image-url)

The picture captures some concepts, important for the design of an Empowerment System. Furthermore, it involves some design aspects, considered important for the functionality in such a system (Ådahl 2007). From this perspective, the VIA is developed. The Empowerment systems of Figure 3 are exemplified as prototypes in the Licentiate thesis (Ibid). The portals (interfaces) investigated were server-oriented allowing users to
access network based tools and information. A classical CDSS can be seen as an Empowerment System of Figure 3. However, a VIA Empowerment System need a more refined architecture and design. Figure 4 outlines the basic idea of a VIA tool in diagnosing decision processes:

![Diagram](https://viaempowerment.com/diagram.png)

**The structure of VIA expanded**

Fig. 4. Evidence Based Medicine for the application of general medical knowledge should be the foundation for any decision. In addition, Patient Specific Data is decisive. The VIA tool supports the collection of such data, viewed in a visual chronological perspective, independent of fragmenting specialist knowledge divisions in Health Care.

Consequently, considering the counter arguments to the use of Ockhams Razor, we argue that the patient should be viewed as the unique individual s/he is, which means that the probability of a certain diagnosis should not only depend on what diagnoses earlier patients as a group statistically had, but also on what kind of critical individual information the unique patient holds as a result of his/her earlier medical history. The sum of the symptoms experienced by a patient during the entire medical history must be considered as potentially reciprocal, caused by a common disease. Regarding atypical occurrences of symptoms, rare, or complex medical states such as systemic diseases where vague symptoms occur over a (longer) period, we have found that CDSS as such, based on probabilistic algorithms, i.e., average values in a population, might not be sufficient, or even inappropriate in diagnosing an individual.
To remedy some of those shortcomings, we propose an additional tool, a Visual Incidence Anamnesis (VIA), to help Health Care professionals use available CDSS towards individualized care and increased patient safety. The VIA collects the actual medical history of a patient, that enables reassessments of earlier diagnosis towards a more reliable patient-centric grounded health care (Figure 2). The VIA should be available as a patient (individual) centered workflow, quickly visualizing vital information such as symptoms, incidents and diagnoses, occurring earlier in the medical history, at different times, to make further vital decisions patient and context centric.

In effect this entails that the VIA enabled Empowerment system should be configurable from selected components and tools rather than a fixed client – server system. For example, the users could use IPads with selected Apps configured using Memory Sticks to ensure flexibility and information security. An example of such experimental environment is given in (Stahl et al. 2010). Furthermore, some of the input information to the entire VIA system could be provided by proper sensor networks (Lundberg & Gustavsson 2011). However, the VIA is basically an information visualizing tool, presenting valuable data graphically, in chronological order, for the physician and the patient to discuss in cooperation.

5.1 Core principles
The VIA is grounded in three main principles:
1. Clinical decisions in health care must be grounded in a sufficient amount of relevant and (potentially) important patient specific information.
2. Information of importance for decisions must be easy to comprehend; visualized in the anamnesis processes.
3. Clinical Decision Support Systems and additional tools to support diagnosis complement (such as the VIA) must be tailored to empower stakeholders of the work flow and not regarded as time-consuming and of doubtful value for the task.

Concerning the first principle, a sufficient amount of relevant information is information that will provide individual medical histories in such way that no vital information is missing or can be missed. The information must be presented in chronological order, with relations between important events along the time-line. Patient-specific information in this perspective is counterbalance to unfettered use of Ockham’s Razor in Health Care. It should be emphasized that Patient Empowerment and the development of this movement, Participatory Medicine, must be adopted in order to collect and classify relevant and important information. For example, in the anamnesis phase of the medical examination, certain input to the VIA-system can be performed interactively with the patient and/or relatives.

The second principle is the principle of Visualization. Information is considered more visible if it is graphically expressed. Large amounts of information are hard to survey and grasp, especially in a glance. The time aspect in the Anamnesis phase must not be neglected as this might be decisive for many cases of information misses. The physician must mentally construct an internal model of the information available, to decide which information is relevant to use in the hypothetico deductive process. Under the impact of stress and high work load this might fail. Visualization of information from earlier events, easily accessible in the EHR, will offer more input for the creation of such mental models.

The third principle concerns usability. A tool must be valuable for the task to motivate its usage. It must facilitate the work and the work load, as well as it must enhance the work flow in the activity. As already mentioned, the time aspect in Health Care is crucial and
therefore it must not be time consuming or complicated to use. Above all, it must not jeopardize patient safety by being so.

5.2 Methodology

Our current work with VIA is entirely conceptual. The basic idea is, as described, outlined by the result of ethnomethodological studies, pointing at an evident need for additional decision support tools to avoid devastating or lethal information breakdowns. Decisions in Health Care must be supported, not only with existing CDSS but also with tools for elicitation and coordination of information. Consequently, VIA is not yet implemented in any setting. We are at this moment approaching the design phase, aiming at implementation and testing of a prototype within the next year. We have experienced positive feedback from Health Care personnel such as physicians. Furthermore, patients seem to be positive towards such a direction. A deep frustration about information misses and bad coordination of tasks exists, resulting in a situation of jeopardized Patient Safety. Accordingly, we believe and hope that VIA would be regarded as a missing link for an unbroken flow of information in future testing situations.

5.3 Pros and cons of VIA

Our proposal for VIA is grounded in our conclusions from in-depth analyses of actual cases in Health Care, where Patient Safety has been jeopardized due to identifiable information handling deficiencies and information breakdowns in the care process. In Section 4, we have presented two such cases. VIA should be an additional tool to the EHR, viewed as a decision support tool, and to traditional CDSS. The advantages of using VIA are visualization of otherwise hidden information (not visible or known to the physician). VIA also visualizes not easily accessed information, crucial for a correct diagnosis to be made in time. If VIA are designed in participation with the user, the use should be a part of work-flow, reminding the decision maker of information that should be considered before decision. Fewer information misses and mistakes based on lack of decisive information increases Patient Safety as the opportunity of correct diagnoses early in the decision process increases by correct information.

However, if not developed and implemented to fit requirements of Sociotechnical systems such as Information processing systems for Health Care, and with lack of understanding of which type of information that must be brought to focus, there is a risk of having a system not fit for purpose. This would not encourage the use of the system. Furthermore, with bad design, there is a risk that VIA visualizes too much information, resulting in information overload that paradoxically could make relevant information invisible. Therefore, system development based on the VIA model must comprise the users of the system (participatory design) and preferably also be grounded in close studies of the activity in which the VIA is intended to be implemented.

Furthermore, a VIA system is never completed. It must be continuously maintained during its lifetime to have the intended usefulness.

6. Conclusions

To be able to screen out unnecessary alternatives and decide on the cause of illness, a sufficient amount of significant patient-specific information is needed. This is the basic principle of the VIA. The patient specific information is unique to the individual patient and
that point is necessary in dissociating the patient from overly firm expectations of hypotheses that are the statistically most probable.

7. References


Strokepatient fick farligt läkemedel

En läkare på [redacted] kritiseras av Socialstyrelsen sedan denne ordinerat ett nässpray till en 71-årig man som nyss haft en stroke.

Det handlar om läkemedlet Imigran som inte får ges till patienter som drabbats av stroke tidigare.

Enligt Socialstyrelsens utredning fick inte patienten några bestämmelser med att ha använt läkemedlet men man konstaterar att den 71-åriga mannen besvärats i onödan då han känt tryck över bröstet, blivit kallsvettig och fått stickningar i armen efter att ha tagit nässprayet.

Viktigt med stöd

Han fick även genomgå flera undersökningar innan man visste hur han påverkats av det. I sin kritik påpekar Socialstyrelsen vikten av stöd för läkare när de skriver ut läkemedel och hänvisar även till flera handböcker.
Läkare missade hjärntumör – prickas

Tre läkare i Malmö missade att en 14-årig flicka med huvudvärk och domningar i kroppen hade en livshotande sjukdom. Nu prickas två av dem av Hälso- och sjukvårdens ansvarsnämnd, HSAN. Vid det första besöket drog läkaren slutsatsen att flickan kunde ha migrän. När hon en tid senare återkom med värre symptom borde nästa läkare ha utrett flickan vidare. Vid det tredje besöket hade hennes andning påverkats, men behandlande läkare vidtog inga vidare åtgärder. Senare visade det sig att flickan hade en hjärntumör, som hon dog av. HSAN anser att de två sista läkarna agerat oäktsamt och ger dem en erinran, respektive en varning.

Juan Flores

Appendix 3
### Appendix 4

#### Muntlig rapportering av patientinformation

<table>
<thead>
<tr>
<th>S</th>
<th>Situation/problem</th>
<th>B</th>
<th>Bakgrund</th>
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<tbody>
<tr>
<td></td>
<td>Presenters sig själv</td>
<td></td>
<td>Relevant medicinsk historia</td>
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<tr>
<td></td>
<td>Patient, ålder</td>
<td></td>
<td>Nunnans behandling/medicinering</td>
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<tr>
<td></td>
<td>Patientens tillstånd</td>
<td></td>
<td>Ev. allergidåverkansighet</td>
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<tr>
<td></td>
<td>Vad som hänt</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>När det hände</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### A |Aktuellt tillstånd/möjlig diagnos |

|   | Vitalfunktioner: |
|   | Airway-luftvägar | Fri luftväg, sökar helstyrig |
|   | Breathing-andning| Andningsfrekvens, SaO₂ |
|   | Circulation-cirkulation| Puls, Blodtryck, kapillär återfyllnad |
|   | Disability-medvetande | RLS, GCS, AVPU (medvetelo, somnolent, orkar, vaken) |
|   | Exposure-inspection | Feber, EKG, smätta |

#### R |Rekommendation/ förlag på lösning |

|   | Vilka åtgärder som är vidtagna |
|   | Reaktioner på dessa åtgärder |
The task of ensuring Patient Safety is, more than ever, central in healthcare. The report “To Err is Human” [Kohn et al. 2000], was revealing alarming numbers of incidents, injuries and deaths caused by deficiencies in healthcare activities. The book initiated assessment and change of healthcare methods and procedures. In addition, numerous reports to Swedish HSAN (Medical Responsibility Board) have shown a high rate of information and communication deficiencies in healthcare has a direct or indirect cause of incidents, injuries and deaths. Despite numerous of new sophisticated tools for information management in recent years, e.g., tools such as Electronic Health Records (EHR) and Clinical Decision Support Systems (CDSS), the threats to Patient Safety have not been redeemed. Rather to the contrary. Underlying reasons for this paradox are twofold. Firstly, advancements in diagnosing techniques have given rise to increasing volumes of data at the same time as the number of patients has increased due to demographic changes and advancements in treatments. Secondly, the information processing systems are far from aligned to related workflow processes. In short, we do not at present have interoperability in our healthcare systems.

In this doctoral dissertation, we present an in-depth analysis of two different “HSAN-typical” cases, where Patient Safety was jeopardized by incomplete information flows and/or information breakdowns. The cases are mirroring the apprehension of Simplicity, that is, Occam’s Razor of Diagnostic Parsimony. A well-known protocol used in healthcare and implemented in most (knowledge-based) CDSS. This rule of thumb is the foundation for the well-known adage: “when you hear hoof beats, think horses, not zebras”. Hickam’s Dictum is one well known objection to the simplifications of Occam’s Razor stating “Patients can have as many diseases as they damn well please”. Of course, this Dictum is harder to implement effectively! In the thesis we suggest a visualization tool Visual Incidence Anamneses (VIA) to provide middle out compromise between Ockham and Hickam but providing means to increase Patient Safety.

The findings of our study for the thesis have resulted in a number of Aspects and Principles as well as Core-principles for future CDSS design. That is, tools and methodologies that will support designing and validating interoperability of healthcare systems across patient-centric workflows. The VIA tool should be used as the initiating point in a patient (individual) centered workflow, quickly visualizing vital information such as symptoms, incidents and diagnoses, occurring earlier in the medical history, at different times, to ground further vital decisions on. The visualization will enable analysis of timelines and earlier diagnoses of the patient, using visually salient nodes for visualization of causalities in context. Furthermore, support for customization of the tool to the views of stakeholders, members of healthcare teams and empowerments of the patient, is crucial.