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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
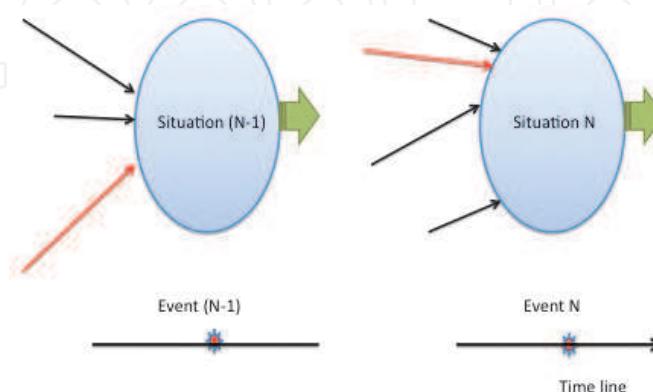

Fig. 1. Separate earlier events (N-1), randomly reported by the patient to the physician in the actual anamnesis phase (Situation N).

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.*
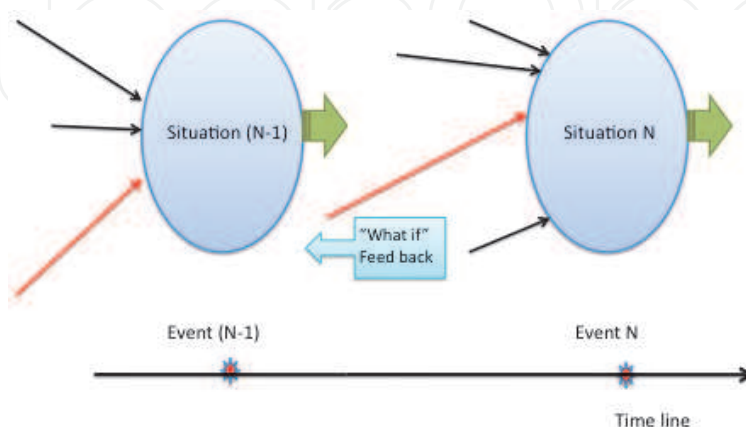

Fig. 2. Separate events (in situation/-s N-1) concatenated by automation of data; a visible historical feedback for the physician to consider, study and discuss with the patient in the actual anamnesis phase (Situation N).

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 dependant 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 illustrates 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 anamnesis, 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 *Diagignoskein*, 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

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[1] http://www.etymonline.com/index.php?term=diagnosis

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

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[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 Chattons "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 "Fascionoma" 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 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 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: metoprololtartrat[3] (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.

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[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 flittering 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 (**S**ituation, **B**ackground, **A**ctual condition and **R**ecommended 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 Acalcuolous Cholecystitis[4]. The physician at the Intensive Ward was told,

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[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 anthibiotics 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.
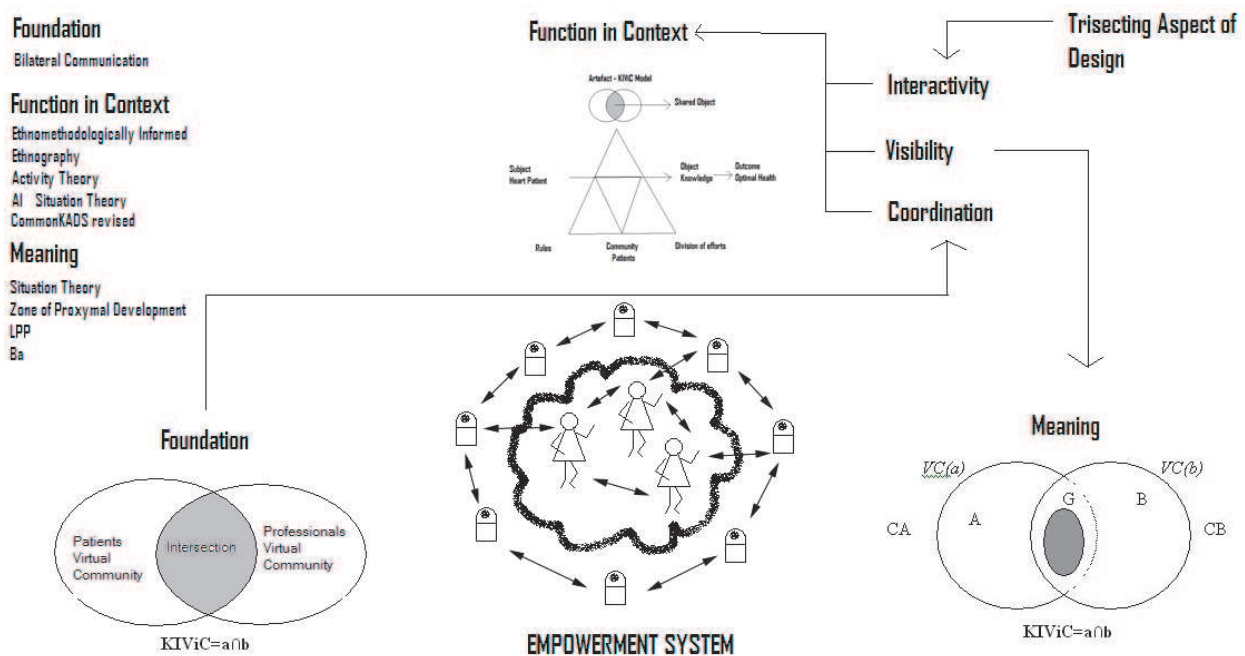

Fig. 3. Design context of Empowerment Systems. The main supporting components are Foundations and Functions in context. The latter includes Activity theory based on ethnographic studies while Foundations focus on issues related to interaction and semantics.

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:
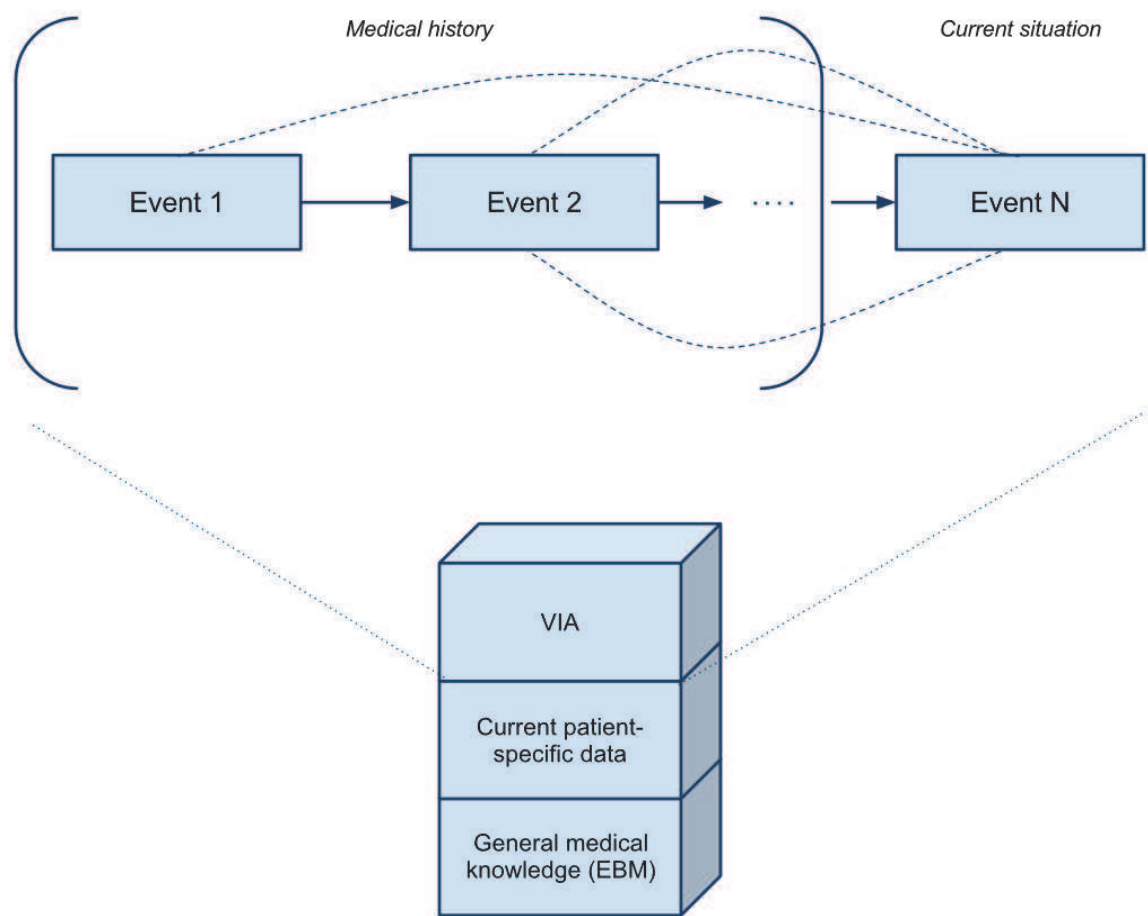

Fig. 4. Evidence Based Medicine for the application of general medical knowledge should be the foundation for any decision. In addition, Patient Specific Data is decisive. The VIA tool supports the collection of such data, viewed in a visual chronological perspective, independent of fragmenting specialist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

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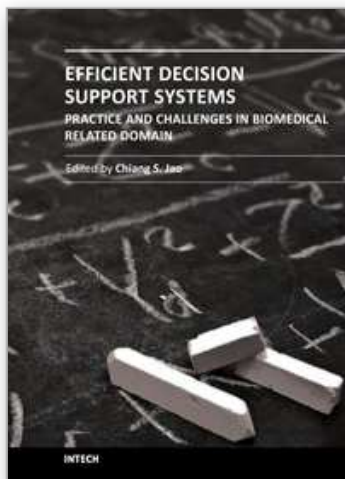
Efficient Decision Support Systems - Practice and Challenges in Biomedical Related Domain

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