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Luigi Macchi, Elina Pietikäinen, Teemu Reiman, Jouko Heikkilä & Kaarin Ruuhilehto

Patient safety management

Available models and systems

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tel. växel 020 722 111, fax 020 722 4374

VTT Technical Research Centre of Finland, Vuorimiehentie 5, P.O. Box 1000, FI-02044 VTT, Finland
phone internat. +358 20 722 111, fax +358 20 722 4374

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Author(s)
Luigi Macchi, Elina Pietikäinen, Teemu Reiman, Jouko Heikkilä & Kaarin Ruuhilehto

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Abstract

This report is a part of a Finnish research and development project in which a model for patient safety management and related innovative services are developed. The report aims to clarify basic concepts related to patient safety management and to describe available safety management approaches from health care and other safety critical industries. Management and improvement of safety in health care, as in any other safety critical organisation, are strongly determined by certain concepts and how they are understood in the organisation. These concepts are *patient safety, safety model, safety management model* and *safety management system*. On the basis of the review, the following conclusions and recommendations were drawn:

- Patient safety should be seen as an organisation's ability that emerges from the social and technological factors interacting in an organisation. Safety is improved by creating good prerequisites for work, not only by constraining performance. Some degree of flexibility is required.
- Safety model should describe the emerging safety as a systemic phenomenon meaning that both successes and failures are inevitable events in organisational behaviour. Systemic approach emphasises non-linear interactions.
- Safety management model should be in line with both the definition of patient safety and the safety model. It identifies the elements necessary for the management and improvement of patient safety. Safety should be considered together with the overall management of the organisation.
- Safety management system has to be integrated in the management system of the organisation. It aims at both assessing and eliminating risks and ensuring appropriate prerequisites for safety throughout the lifetime of the organisation. It takes into account the specific characteristics of the organisation and it is documented.

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Preface

This report is part of a Finnish research and development project called *Patient safety as an asset in social and health care* (SafetyAsset)[1]. The four main aims of the project are to:

1. Develop a model for patient safety management, that is client-centred and takes into consideration the complexity of the health care organizational network, continuity of care and the well-being of the personnel.
2. Develop tools that support patient involvement in the process of care, organizational learning, proactive risk assessment and development of overall safety.
3. Promote distribution of good practices in patient safety management in Finland.
4. Promote development of innovative services and products in relation to patient safety management.

More information concerning the project is provided in Appendix A.

This report is written by a group of researches at VTT Technical Research Centre of Finland, whose background is in safety science. Safety science is a multidisciplinary area of research that aims at the development of theories, models and methods to support safety-critical organisations in performing safely. Researchers at VTT have done research and development work for many years not only in health care (e.g. Pietikäinen et al., 2008, Reiman et al., 2007, 2010) but in several other safety critical areas as well, such as nuclear industry (e.g. Reiman 2007, Reiman & Oedewald 2009), air traffic management (e.g. Macchi et al., 2008, 2009) and railways (e.g. Haavisto et al., 2010). Besides current patient safety literature, this working report also draws learnings from that experience. The working report has also benefitted greatly from discussions and developmental workshops arranged together with social and health care organisations

[1] The name of the project in Finnish: Potilasturvallisuus laatu- ja kilpailuvaltiksi (POTILASTURVA)

and private consultant companies working in the health care sector that are involved in the SafetyAsset-project. In November 2010 a first workshop was organised to define, together with representatives of ten different organisations, the basic principles of patient safety management. In February 2011 a second workshop was arranged to clarify the special characteristics of different social and health care organisations and to describe their topical patient safety challenges.

This report is primarily made for the use of the SafetyAsset project group to provide shared understanding and framework for patient safety management model development. It can also be useful for other parties who work with patient safety development – for example hospital managers, health care authorities and safety consultants.

Contents

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1. Introduction

Improvement in patient safety is defined as one of the major objectives in social and health care by the "Finnish Patient Safety Strategy for 2009–2013" document. The concept of patient safety is rather new. At least until the 1990s, the occurrence of unwanted, unexpected, negative events in the provision of health care services was mostly associated with incompetence or carelessness of the caregiver. Punishments and sanctions were often seen as appropriate and effective measures to prevent future errors and mistakes. The underlying assumption was that well-trained, conscientious practitioners do not make errors. As a result, the entire burden of blame and responsibility was placed on individuals (e.g. medical doctors or nurses) (Sundt et al., 2005).

Things began to change during the 90s when it became evident that medical injuries happen far more often than thought before. For example Brami and Amalberti (2009) recently estimated that 10% of patients are subject to injuries. Following the publication of the USA report *To err is human* (Kohn et al., 2000), the contribution of both blunt-end (e.g. management, regulators) and sharp-end (professionals working in direct contact with the patients) to patient safety started to be widely acknowledged. Besides medical doctors, other caregivers, the support personnel working in the organisations, as well as the larger society (e.g. the regulators and the medical industry that supplies drugs and equipment) have an effect on patient safety. In order to provide social and health care services all these actors are equally relevant, and adverse events, as well as safe treatments, are to be understood as resulting from the interaction of all these actors with the patient and the patient's pathology (Leape et al., 1991).

The evolution of models of care, treatment regimes and available technologies, in conjunction with economical and temporal pressures makes health care organisations among the most complex organisations in the industrial landscape nowadays. In this scenario, providing safe (or unsafe) health care services cannot be simply explained in terms of ability and carefulness of individual practitioners. Provision of social and health care services is an organisational responsibility. Organisations, such as hospitals, clinics or health centres create prerequisites for the work of teams and individual professionals in the organisation. Organisations also interpret the requirements of the insti-

tutional environment and transform them into practices. Organisations can also have an effect on the surrounding society e.g. by commenting future laws and regulations, and by negotiating with the service providers and medical industry. Patient safety can be improved only when all the factors needed to provide health care services, as well the interactions between them are taken into account. Thus, the management of safety cannot rely on medical knowledge only. Understanding of how complex systems, such as health care organisations, work is needed. The multidisciplinary research area called safety science provides models, concepts and tools that can help social and health care organisations and managers make sense of the complexity and develop patient safety.

This report aims to clarify basic concepts related to patient safety management and to describe available safety management approaches from health care and other safety critical industries. The report also provides recommendations for how to approach patient safety management in social and health care organisations. All in all the report acts as the first step in developing a general model for patient safety management. The focus of the report is on concepts and models rather than specific tools (e.g. checklists and the like) to manage safety in the daily activities. It is important that the best current theoretical knowledge guides both the development of the general patient safety management model and the practical implementations of safety management systems in health care organisations. This theoretical understanding is also important in making sure that effective patient safety management tools are developed and that they are used in a correct way – in a way that actually promotes safety and does not just create extra work for health care professionals.

Theoretical foundations are often implicit or unclear in current patient safety research and development in Finland and internationally. However, other more traditional safety critical industries, such as aviation and nuclear power industry, are also struggling to make their theoretical assumptions, concepts and models concerning safety management more clear and sound, and to align their management systems and tools to them. It is often emphasised that the whole health care domain is lagging behind in relation to other safety critical industries in how systematically it manages safety. Safety management tools are derived from other industries and implemented in health care. However, the fact that health care is behind to other domains also means that health care has the opportunity to reflect critically what other domains have done. The fact that many health care organisations are still in the beginning of their “safety management journey” creates a fruitful opportunity to base the work systematically on clear and sound premises.

2. Basic concepts of patient safety management

Management and improvement of safety in health care, as in any other safety critical organisation, should be based on a series of fundamental theoretical and operational concepts. At first it has to be defined what **patient safety** is, i.e. what the desired result of safety management is. Safety can be understood in several different ways, and this influences the manner in which safety is going to be pursued. We will come to those in Chapter 3.

A second concept, tightly related to the definition of safety, is **safety model**. Safety models describe in some logical way what makes a system safe or – on the other hand – what makes it unsafe e.g. by producing accidents. Safety models are introduced and discussed in Chapter 4.

Safety management models constitute the background assumptions an organisation has about the management and improvement of safety. At a more practical level than the safety definition or safety model, a safety management model defines what are the fundamental elements (e.g. strategy, plan for continuous development, organisational functions etc.) to be considered for achieving the desired organisational performance. Chapter 5 presents safety management models.

The fourth basic concept for managing safety is the **Safety Management System** (SMS), i.e. collection of systematic organisational processes that are needed in order to steer the organisation to ensure and develop patient safety. At this level, a practical identification of roles, tasks and responsibilities is made. A SMS is inevitably, but often implicitly, related to the three previous concepts. What an organisation does with respect to safety cannot result from anything but what it thinks about safety, how it thinks organisations function and what should be done to prevent accidents and to ensure that the appropriate conditions for safe functioning are met. A safety management system is constituted by the detailed description and realization of the safety management model. Safety management systems are discussed in Chapter 6.

In the following sections, the above mentioned four basic concepts for managing safety are discussed with the support of examples from health care and other safety critical domains.

3. Patient safety definitions

Defining patient safety is an important and non-trivial task. Intuitively, it is possible to associate patient safety to provision of treatments in social and health care that result in improving patients' conditions without causing harm to them. But defining patient safety means also to describe which aspects are relevant for safety. Defining patient safety settles which elements are going to be emphasised in managing safety and which not, in which directions organisational efforts are going to be implemented and in which not. The definition of patient safety tells something about how an organisation understands safety as well as what it is going to do to ensure and improve it. An extensive number of patient safety definitions can be found in the literature. The European Directorate-General for health and Consumers (2008) defines patient safety as the *freedom for a patient from unnecessary harm or potential harm associated with health care*. Other, more specific and elaborated, definitions of Patient Safety are reported in the table Table 1.

Table 1. Patient safety definitions.

Safety as freedom from accidental injury. Quality of care is the degree to which health care services for individual and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Kohn et al., 2000),
[…]patient safety problems as arising from our inability to manage and contain inevitable conflicts among competiting interests in a system. What is needed are solutions that account for the needs of the group (that is system, organisation, institutions)as well as those of the individuals involved (that is patients, nurses, physicians, pharmacists…). (Grasha, 2002)
Rather than being a static property of hospitals and other healthcare facilities, safety is dynamic and often on short time scales. (Cook & Rasmussen, 2005)
[Patient] Safety can be defined as protection from experiencing or for that matter causing, harm, injury, or damage. (Sundt, 2005)
The National Patient Safety Foundation identified the key property of safety as emerging from the proper interaction of component of the health care system. The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of care. (Vincente, 2006)
Safety engineering would suggest that more reliable and cost-effective solutions for patient safety could be implemented through technological advances in fail-safe systems, and the education and policy to support this as opposed to burdening the patient with additional responsibilities when under care. (Lyons, 2007)
Freedom for a patient from unnecessary harm or potential harm associated with healthcare that can lead to or increase risk (Conklin et al., 2008)
Patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incident and impact of, and maximizes recovery from adverse events. Patient safety is both a way of doing things and an emergent discipline (Emanuel et al., 2008)
Patient safety is the principles and actions of individuals employed in health care and of the organisation for the purpose of ensuring patient safety and protecting the patient
from being harmed. From the patient's point of view it involves that the patient receives the needed and correct care that will cause as little harm as possible. Patient safety covers the safety of care, medication safety, safety of equipment, and is a part of the quality of care. (Ministry of Social Affairs and Health, 2009).
Safety is a dynamic property of the healthcare system and it does not reside in a person, device, or department, but emerges from the processes and the interfaces in the socio-technical system of governmental agencies, regulators and associations, local regulator, hospital, medical department, staff and work operation. Patient safety improvement requires organizational learning and knowledge transfer at the system level, which entails changes in organizational routines that cut across divisions, professions and levels of hierarchy (Wiig & Lindøe, 2009)

These definitions describe and emphasise some aspects of patient safety that their authors consider critical. It is possible to separate these definitions in two macro groups. One group is formed by the definitions that understand safety as freedom from harm resulting from the implementation of protection measures like procedures and safe tech-

nology (Kohn et al., 2000; Sundt, 2005; Lyons, 2007; Conklin et al., 2008; Ministry of Social Affairs and Health, 2009). Conversely, these definitions understand accidents as caused by someone or something breaking the protection measures. These definitions emphasises the idea that to achieve freedom from harm it is needed to identify all the potential ways in which incidents may happen and to design and implement robust protection measures. But the complexity of health care organisations, as explained in Chapter 4.2, makes this task practically impossible.

In the other group, definitions treat safety as a dynamic property of the health care system that emerges from the interactions of several elements (Grasha, 2002; Cook & Rasmussen, 2005; Vincente, 2006; Emanuel et al., 2008; Wiig & Lindøe, 2009). These kinds of definitions treat incidents as resulting from the ineffective interactions between the actors. These definitions emphasises the idea that safety is created by the organisation, in its normal way of functioning. They therefore call for the understanding of normal organisational functioning in order to enhance the ability of the organisation to perform and create safety.

The adoption of a definition of patient safety should be reflected on the assumptions about what makes an organisation safe (the safety model) and on the approach developed and implemented to manage safety.

4. Safety models

Implicit or explicit safety models refer to the background, underlying assumptions guiding the understanding of how an organisation functions and/or fails. Upon safety models (often also called accident models), the anticipation of unwanted events is based. At the same time, it is upon safety models that the measures to ensure the safe functioning of the organisation are based. With the evolution of technology and with the increased complexity of the industrial world, models became more and more sophisticated. At the same time, they evolved from being based on simple-linearity to multiple-linearity to non-linearity, and from being exclusively interested in accidents to address the normal functioning of an organisation. In this section, a review of linear and non-linear safety models is presented.

4.1 Linear safety models

In linear thinking, accidents are explained as: A causes B that causes C, or as A+B causes C. Since the nineteenth century until the end of the Second World War, safety concerns were mainly related to the improvement of reliability of technical systems (Hale & Hovden, 1998). Models used to ensure safety for technical systems assume that it is possible to identify root causes of accidents through the application of a linear search of cause-effect relationships. Despite the efficiency of this approach to improve systems safety, the linear reasoning shows its limitations when applied to systems that are more complex. In those systems, in addition to the acknowledgement of the human role in accidents causation, the linear thinking is unable to explain accidents. These two points (limitations of the linear reasoning and human role) brought the safety scientific community to expand the focus of analysis by including humans' role in operating and managing technology.

The first attempts to account for the human role in accidents can be found in the studies about personnel selection, training and motivation. These aspects were considered in the theoretical frame of accident proneness and their management was considered useful in accident prevention. In 1930s, Heinrich (1931) , with the well-known Domino model,

explained accidents as due to the linear combination of failures, exactly as a row of domino blocks falling one after the other. The most substantial development concerns the merging of technical safety assessment with the ergonomics/human factors studies to assure that, not only technology, but also its human exploitation is safe.

The first safety models and the associated methods, i.e. the tools used to prevent risks, (e.g. THERP, OAT SLIM/MAUD) were based on event trees representations[2] and they aimed to estimate human error probabilities and their effect on system failures. Those models applied a simple linear causal thinking to understand and explain how accidents may occur. In order to deal with organisations that are more complex and to understand accidents due to multiple failures, from simple linear thinking, models evolved towards a complex causal thinking. This means that the effect of the context on error and failure probabilities was also introduced in the analysis.

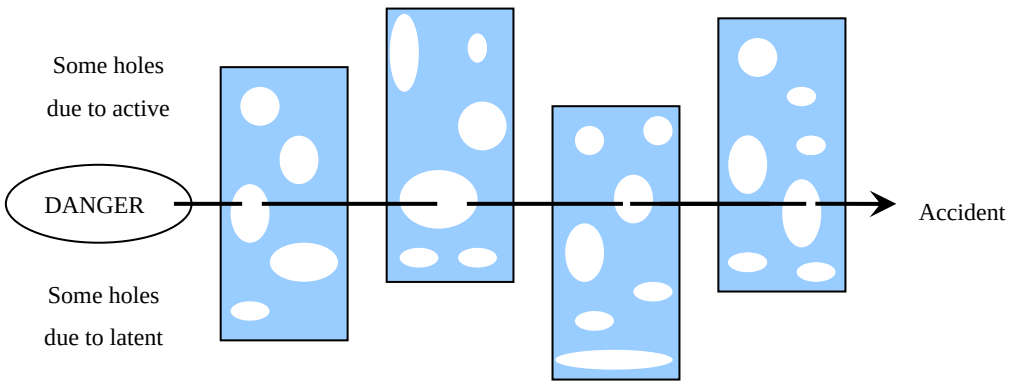

Figure 1. An accident trajectory passing through corresponding holes in the layers of defences, barriers and safeguards (Adapted from Reason, 1997).

The causal thinking behind epidemiological models is based on linear cause-effect relationships, but with respect to simple linear models, their scope is larger in time and levels of analysis. Not only the active errors occurring at the sharp end are analysed, but latent failures originating from for example design are normally considered. Hollnagel (2004) describes four characteristics of epidemiological models:

1. Instead of referring to “unsafe acts”, the more neutral term ‘performance deviation’ was used. This implies that the burden of responsibility is no longer exclusively on humans since performance deviations could be applied to individuals as well as technical components.

[2] Event trees are graphical representations of the possible outcomes following an initial event.

2. The environment was included in the analysis and was assumed to affect both humans and technical components.
3. Barriers were introduced as a way to prevent or stop an accident from evolving and to constrain performance within acceptability boundaries..
4. Latent conditions (at first called latent failures) where recognised.

The underlying assumption of the organisational accident model is that in more complex, safer and less transparent systems accidents are very rarely (or never) caused by a single factor. On the contrary, according to this model, accidents are caused by a combination of events that on their own would not have led to accidents. In the Swiss Cheese analogy, every cheese slice represents barriers and safeguards at different levels of physical proximity to the potential negative event, from operators back in the chain to managers, regulators, designers etc. The holes in the slices represent weakened or failed defences. Depending on which slice they are, some of the holes are due to active failures while others are due to latent organisational conditions. In case of alignment of the holes in the “slices” an accident may happen. In addition to pure deterministic causality of the earlier models, organisational accident models included the concepts of accident promoting factors. These accident promoting factors (like management and design) have wide effects in the organisation. The effects are linear, but not necessarily always deterministic. This model and the thinking behind it have been successfully applied and have contributed in managing safety in different safety-critical organisations.

Most traditional approaches, methods try to model incidents as chains of causes and consequences (event trees and fault trees). When trying to describe complex systems like health care, event and fault trees become very complex, and thus unmanageable. Traditional approaches, in addition, tend to emphasise the visible role of sharp-end operators while the contributions of blunt-end or organisational factors are often underestimated (Woods et al., 1994).

In addition, traditional safety approaches are based on a view of the future as relatively knowable, but modern health care systems are too complex and dynamics to be completely overseen and their future functioning predicted. Models should be able to allow reasonable prediction. Historical patterns are normally the primary source of information in linear safety models. This would be appropriate if future was predictable with an acceptable degree, but in reality this is not the case in complex organisations. Reports on quality and safety have called attention to serious shortcomings between intended performance of health care processes and actual outcomes for the patient. For these reasons, traditional methods for safety management may not be able to meet the evolving safety needs of patients and society (Uhlig et al., 2002).

A final common aspect of traditional approaches is that they are focused and interested exclusively on negative results, like incidents and accidents, and they do not address the normal successful functioning of the organisation. When discussing the definitions

for patient safety, it has been noted that patient safety is nowadays understood as emerging from the system's design, from the interactions between the elements of the system, i.e. from the way in which a health care organisation functions. Safety model should be able to take this into consideration.

The traditional safety management applications have proven to be – and still are – effective in certain conditions. In health care the model presented by Reason (see e.g. Figure 1) has helped to shift attention from blaming the individual professional to considering the contributing factors of incidents, such as organising of certain work task, equipment and facilities.

However, traditional linear approaches have severe limitations in management of complex systems like one whole hospital. Perhaps the most important shortcoming in these approaches is that they are only about preventing the negative (deviations, problems, incidents) and do not give emphasis on what is positive in the organisation. In the following Chapters, non-linear safety models are presented. Due to their more elaborated nature they can, if practical applications can be implemented, better serve the needs of complex health care organizations.

To overcome discovered limitations, new approaches with the following main improvements were developed:

- expanding the focus of analysis from the workplace and the interaction between humans and technology to the study of the organisation and its dynamics
- questioning the linear causal thinking to explain accidents and
- arguing for the development of the normal functioning of the organisation jointly with prevention of incidents and accidents.

4.2 Non-linear safety models

Non-linear safety models are the response to the need of managing safety and preventing accidents for organisations so complex that linear thinking is insufficient. In linear thinking, accidents are explained as: A causes B that causes C, or as A+B causes C. Non-linear thinking recognises that changes in one part of the system can have disproportional[3] consequences in other parts of the systems. Non-linear models are suited for organisations so complex and intractable that these reasoning are no longer valid to explain their functioning. A representative selection of non-linear models is presented here.

[3] For example, big changes can have small consequences and small changes can have big consequences.

4.2.1 Health care systems as organisations drifting into failures

One of the prominent theories for safety sees organisations as moving in a space of acceptable performance defined by three main boundaries (Figure 2): economic failure boundary, unacceptable workload boundary and (un)acceptable performance boundary, and a marginal boundary representing an acceptable risk in relation to acceptable performance boundary (Rasmussen, 1997, Cook & Rasmussen 2005). According to the Drift into failure theory, humans working in an organisation continually struggle to find a balance between economic efficiency and reduction of workload effort pressures that can push the organization outside the space of acceptable performance – meaning that an accident happens. Marginal boundary represents organisation's understanding of the acceptable risk. The risk is acceptable as far as operating point does not cross the marginal boundary.

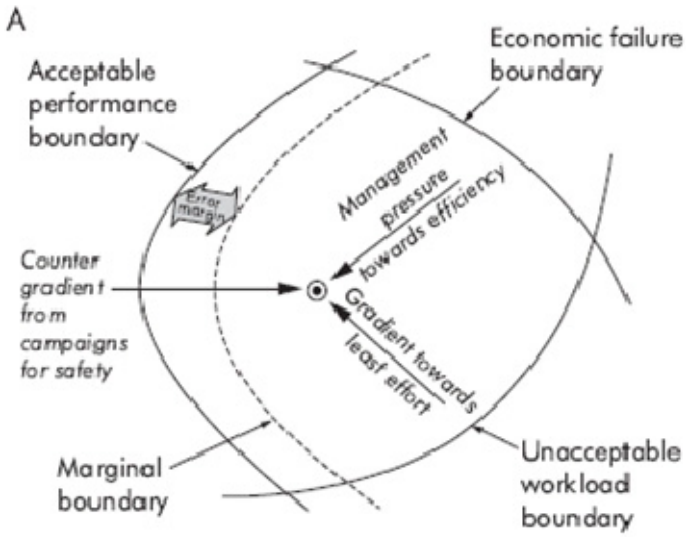

Figure 2. Drift into failures model. (From Cook & Rasmussen, 2005)

The acceptable risk boundary (marginal boundary) can shift inwards and outwards in response to exogenous pressures. For example major accidents gathering wide publicity tend to shift the boundary inwards increasing error margin (i.e. making organisation more "cautious"). On the other hand, during the period when major accidents do not happen, the boundary may creep outwards (i.e. organisation evolve into more "careless").

The area between the risk acceptability marginal boundary and the unacceptable performance boundary is referred to as the system's capacity to cope (Rasmussen, 1997). This means that the wider the zone between the marginal and acceptable performance

boundaries (i.e. the margin between the intended limit to the operation and actual point of failure) the greater a system's capacity to compensate for or adapt to pressures by occasionally crossing the marginal boundary. Compensation and adaptation is possible thanks to a set of resources that can maintain the system's operating state as close as possible to the area of minimum risk. and to humans' ability to adapt when pressures increase (Cook & Rasmussen, 2005; Cook & Nemeth, 2006).

Dekker (2006) points out how the drift-into-failure problem could be re-conducted to the need humans have to make decisions in a context where it is impossible to satisfy each and every decision criteria. The choice of taking care of financial pressure, for example, impacts the possibility to reduce workload or to be functionally safe or both. And the same happens when the decision is driven by workload and/or safety.

For example, in the hierarchy of the health care organisation, the management group's main priority is to provide the overall availability of resources needed to meet annual variation in patient demand. At lower management level, schedulers' influence pressures for acceptable workload by implementing flexible staff scheduling policies around weekly emergency patient admission cycles. At the lowest level of management, charge nurses and the in-charge anaesthesiologist work at the marginal boundary directly by coordinating daily resource allocation and the distribution of work given daily patient admission cycles. Modern health care organisations are subject to several pressures at the same time and they have to find an acceptable balance for continuing operations. All in all, patient safety should be considered in the context of other organizational demands.

The Drift into failure theory puts emphasis on the history of the organization as well as on the deviations that in the long run tend to become normal and acceptable (Dekker 2011)[4]. Another key concept is the idea of local rationality – in a complex system, no actor can have the global view of the system. Instead, actors are basing their decisions on locally rational premises. Yet, without knowing all the effects their actions will have at the system level, locally rational actions can lead to globally negative results.

4.2.2 Health care systems as High Reliability Organisations

The High Reliability Organisations (HRO) theory (LaPorte and Consolini, 1991; Rosness et al., 2004) was developed in the USA on the basis of studies of aircraft carriers, nuclear submarines, nuclear power plants and air traffic management systems (the same typology of organisations that Perrow (1984) considered as the best candidate to experience normal accidents). HRO theory reached the conclusion that they actually perform better than expected.

[4] The idea that deviations can become normal was already proposed by Vaughan (1996)

HRO's theorists tried to understand what makes those organisations perform so efficiently in safety terms. Their reliance on redundancy (of components, systems, and safeguards) has been acknowledged as a major factor enhancing HRO capability to prevent accidents occurrence. A second feature of organisations showing a high reliability level is the ability to reconfigure their structure in a flexible way. The capability to abandon temporarily a formal hierarchical structure to adopt an informal one where competences, rather than rank, define the authority is embedded in their nature. This characteristic is judged crucial for HROs facing dynamic and changing conditions where a rigid organisational pattern will not be suited to manage risks and activities (Burns & Stalker, 1961). A third peculiar feature of HROs is their "mindfulness". Weick and Sutcliff (2001) talk about "mindfulness" as the people's propensity to continually look after existing situations. Even if this surveillance is based on current expectations, people in HROs are willing to update their expectations and create new ones when needed. HROs show clearly different cultural features with respect to non-HROs. HROs are willing to exchange information, provide feedback, reconsider decisions and recover from actions (SINTEF, 2009).

From the HROs theory point of view, it is possible to help organisations, even the ones that are most difficult and risky to manage, to become extremely efficient and safe by understanding which characteristics they need to operate safely. The fact that modern health care systems share several characteristics with other safety critical industries has led to the idea that they should also struggle to become High Reliable Organisations. Amalberti et al. (2005) and Bagnara et al. (2008) identified several differences between the classical HROs and health care systems:

1. Individuals in HROs are not allowed to autonomously decide on the maximum level of performance required. This is hardly accepted in hospitals because it will imply that the level of risk considered acceptable is not determined contextually and therefore practitioners, when evaluating risks should comply with formalised rules
2. HROs professionals have abandoned much of their professional autonomy. Health care professionals are normally against this principle
3. HROs professionals consider themselves as equivalent actors and not as craftsmen or artists. Health care professionals seldom do this
4. Health care professionals tend to protect themselves at an individual level, while in HROs the evident need of a systemic approach is acknowledged
5. Traditional HROs are confronted to rare and severe events, while hospitals are affected by small and frequent accidents
6. Health care professionals are involved in accidents, but normally they are not the direct physical victims of them unlike in many of the HROs that have been studied

7. Health care professionals are emotionally involved in the relation with patients. The emotional component is normally not present in most of other HROs
8. The diversity and ambiguity of each situation in health care systems is very high, probably higher than in the HROs that have been studied. This can limit the ability to foresee or simulate the future in a similar way than in traditional HROs
9. Health care systems deal with the most changing and dynamic system in nature, the humans. This means that a lot of unpredictable variability is brought into the health care system making almost impossible to establish standard, error-free procedures and clear and effective communication strategies as in traditional HROs
10. The involvement of patients in the provision of health care services, e.g. by including him/her in the decision making process, introduces in the system further organisational, operational and cognitive variability.

With so many differences between the traditional domains of HROs and health care systems, it is hard to claim that hospital can become high reliable organisations. Nevertheless the development and implementation of some of the principles and solutions thought by HROs theorists, can promote a cultural change in the health care system and they can result in making hospital safer. Three main characteristics of HROs seem to be appropriate and applicable in health care:

1. the emphasis on flexibility of the hierarchical structures of the organisation when necessary
2. the idea of constant mindfulness as prerequisite for safe delivery of care
3. the redundancy of components, systems and safeguards.

4.2.3 Health care systems as Complex adaptive systems (CAS)

An alternative regard to health care organisations and safety management is represented by the Complex Adaptive Systems (CAS) approach. This approach recognises that health care systems are complex organisations operating in an environment that is among the most complex of organisational environments. The complexity of health care organisations is due to the variety in types of professionals and organisations interacting to provide a wide variety of services to patient, their families and their communities. CAS approach understands the system of health care as a network of networks or a system of systems, that involve an enormous number of independent stakeholders, layered by organisation, speciality and so on.

The complexity of the health care system makes it extremely difficult to understand how the elements – people and organisations – are interconnected. Failures in the health care systems, according to this theory, result from failed couplings between the elements, i.e. from ineffective interactions between the elements composing the system.

Being complex adaptive systems, the functioning and the malfunctioning of health care organisations cannot be understood by analysing their elements independently. The analysis of a CAS requires, according to this theory, to understand how elements adjust their functioning according to what the other elements in the system are doing, and in relation to the context in which the CAS is operating (Rouse, 2008)

Extension of complexity science to health care organisational theory began to emerge in the literature in the mid 1990s. A series in *Quality, Management in Health Care* examined clinical pathways as non-linear, evolving systems and provided associated tools (Sharp & Priesmeyer, 1995). The CAS approach challenges the tradition and appealing way of thinking about health care systems as machines receiving inputs, transforming them and producing outputs, such as improved health. Scholars from the complexity theory field argue that the use of a machine metaphor to describe health care system leads to a certain belief on how the system can be improved. In presence of systems not working as planned, then the broken part has to be identified and replaced. According to this approach, safety improvements in health care will be best facilitated by comprehensive application of the metaphor of the system as a living organism rather than the system as machine (Begun et al., 2003).

In the complexity theory approach, health care systems are modelled as a densely connected web of interacting agents (i.e. persons) each operating from its own schema or local knowledge. What characterises CASs is their dynamic nature that manifests in the constant changes due to the influence of external forces on the large number of agents, and on the connections among them. In this approach, it is acknowledged that relationships between agents are complicated, interdependent and non-linear. This implies that small changes in variables can have small impacts at some times and large impacts under other conditions and *vice versa*.

To manage safely an organisation constituted by a web of interacting agents embedded in larger networks and systems requires the ability to manage contradictions and competing demands. Morgan (1997) highlights the need for managers to encourage self-organisation by recognising, and exploiting the unpredictable nature of complex adaptive organisations. Managers cannot be control-oriented, but they have to discover and promote the capacities for self-organisation and to be open to the influence of resulting random opportunities. This has to be reflected in the practices implemented to manage safety. In this kind of organisations where the compliance with strict norms and procedures cannot, per-se, ensure the safe functioning of the system and employees have to be allowed to explore and act on the basis of their experience and competences.

The use of the Complex Adaptive System approach for safety management poses two main problematic issues that deserve to be briefly addressed here. The first one concerns the proactive identification of risks. Risk identification and assessment is based on the prediction of what can happen in the future. In the complexity theory approach, the future is relatively unknowable since the emergent properties characterising a CAS cannot

be predicted from the analysis of individual parts, due to the multiple non-linear interaction and feedback loops among the parts. Risk identification therefore has to rely on methods focused on the potential interactions among the elements of the system. In addition, in this approach, the environment is part of the domain of study, and the co-evolution of the relationships between the organisation and the environment acquires relevance. Relationships are analysed across several levels of systems to understand how an organisation adapts to an ever-changing landscape. According to the complexity approach, relationships and their co-evolutions define the strategy of the organisation.

The second issue is related to the traditional use of incident reporting systems for organisational learning. In complexity theory, history holds a relevant place, but it does not remove the expectation that novelty can emerge in a CAS at any given time. In this respect, the analysis of past events is considered informative, but not necessarily deterministic. The usefulness of retrospective data for the prevention of future negative events seems, in this approach, scaled down with respect the traditional approaches. Possibilities for organisational learning have to be found in the analysis and understanding of how interactions among elements and between the system and the environment normally take place.

4.2.4 Health care organisations as cultures

Cultural approaches to safety management have a lot in common with the earlier described modern safety management models. For example, similarly to the HRO theory, cultural approaches to safety have a proactive focus. Cultural approaches are interested in evaluating and developing the performance or abilities prevalent in an organisation before something bad happens. Like the complex adaptive systems theory, cultural approaches to safety often view organisations as involving different subunits, personnel groups and elements and are interested in how these work together in a dynamic way to produce safety. The additional insight cultural approaches bring to the earlier described approaches is the emphasis on the social nature of organisations and the importance of shared conceptions. Reiman (2007) argues that when the complexity of the work, technology and social environment is increased the significance of the most implicit features of organisation as a means of coordinating the work and achieving safety and effectiveness of the activities also increases. This is why a cultural perspective can provide additional insight into the safety management.

The concepts of organisational culture (e.g. Reiman, 2007), safety culture (e.g. Halligan & Zecevic, 2011; Reiman et al., 2010; Singer et al., 2003; Sorra & Nieva, 2004) and safety climate (e.g. Sexton et al., 2006; Zohar, 1980; 2007) have been widely used in relation to safety management. Different authors have defined these terms differently and there is no clear consensus on the relationship of these related concepts. However,

they are all considered focusing more or less on the same phenomenon: how social context is formed and what kind of effects it has in an organization.

Especially in recent years, the concept of safety culture has raised attention in health care. The concept was first used in the nuclear industry (IAEA, 1991). Introduction of the concept of safety culture meant increased emphasis on leadership, organisational structures and social phenomena. In a similar manner, patient safety culture has been proposed as a concept tackling the organisational properties of patient safety. The concept has been used to highlight group level and organisational level processes for creating safety. Survey studies (e.g. Sorra & Nieva, 2004; Sexton et al., 2006) have revealed different sets of dimensions of patient safety culture (see also Halligan & Zecevic, 2011). Most these dimensions can be called organisational because they depict key activities of the organisation in ensuring patient safety (Reiman et al., 2010).

According to Reiman et al. (2010) patient safety culture can be defined as the willingness and ability of an organisation to understand safety and the hazards as well as the willingness and ability to act on safety. They state that safety culture is about long term potential or ability of an organisation to act safely in changing situations. Patient safety culture affects patient safety in an individual case by creating the preconditions of work and influencing the situational possibilities for action. According to them managing patient safety requires controlling and steering organisational dimensions or functions and being mindful of the social processes and psychological states prevailing in the organisation.

4.2.5 Health care systems as resilient organisations

According to the Resilience Engineering approach organisations are socio-technical systems whose successful or unsuccessful performance emerges from the interactions between social and technological factors. As socio-technical systems, health care organisations are complex and intractable, i.e. it is in practice impossible to specify their mode of functioning in a complete manner. Even though the provision of social and health care services is standardised as much as possible, health care professionals are expected to deviate from the protocol if this is done in the interest of patient's safety (Bohmer, 2010). Further, each patient is unique and has special needs and conditions that are hard to predict beforehand in general procedures or standards of care. To accommodate those deviations and still continue operating, health care organisations shall have the ability to adjust. Being resilient for an organisation means to be able to adjust its functioning prior to, during or following changes so that the required operations are maintained (Hollnagel, 2011). An important aspect that distinguishes Resilience Engineering from traditional linear safety models is that it proposes that a resilient system should be able to respond also to unexpected irregular variation of conditions.

The aim of Resilience Engineering is not only to prevent things from going wrong, but also to ensure that things go right, therefore its focus is the overall set of organisational outcomes, both things that go right and things that go wrong.

Four premises constitute the basis of Resilience Engineering:

1. Performance conditions are always underspecified, i.e. it is impossible to foresee all the possible conditions in which the system might have to perform. This implies that safety cannot be ensured by the respect of rules and procedures. Rules and procedures are means an organisation uses to prepare itself for dealing with expected conditions, both normal and abnormal. But since sooner or later the organisation will be required to perform in unforeseen conditions, rules and procedures will not perfectly match the requirements set by them. In those situations, individuals and organisations must therefore adjust what they do to match current demands and resources. Because resources and time are finite, such adjustments will inevitably be approximate.
2. Some adverse events can be attributed to a breakdown or malfunctioning of components and normal system functions, but others cannot. The latter can best be understood as the result of unexpected non-linear combinations of performance variability.
3. Safety management cannot be based exclusively on hindsight, nor rely on error tabulation and the calculation of failure probabilities. Resilience Engineering can complement that reactive approach with a proactive management to enhance the conditions in which work is performed.
4. Safety cannot be isolated from the core (business) process, nor vice versa. Safety is the prerequisite for productivity, and productivity is the prerequisite for safety. Safety must therefore be achieved by improvements rather than by constraints.

For the health care sector Resilience Engineering offers the opportunity:

1. To address the issues of dealing with incidents that emerge from the combination of performance variability, and
2. To enhance the conditions for performing safely.

5. Safety management models

The background assumptions of an organisation about the way in which safety should be managed and improved constitute safety management models. Safety management models include and address, implicitly or explicitly, e.g. the unit of analysis, the concepts and means needed to develop safety, the way in which safety management is integrated in the overall management of the organisation, and the phenomena to be considered in the development of a safety management system. This Chapter presents some examples of safety management models in health care as well as in other safety critical domains.

5.1 Safety management models in health care

The study and systematic development of patient safety is still quite new in health care. In first stages of patient safety research and development, emphasis has been on the actions of individual professionals and in modifying immediate preconditions of their work. Widely recognised "best practices" of patient safety improvement are for example improvement of hospital hygiene, development of medication dispensation practices and implementation of surgical checklists. There is not yet much published research that deals with patient safety as a systemic, organisational phenomenon and as a matter of managing the health care organisation. However, there are more and more practical efforts to that direction. For example many countries have launched their national strategies for improving patient safety (e.g. Ghirardini, Murolo & Palumbo, 2009; The National Steering Committee on Patient Safety 2002; Ministry of Social Affairs and Health, 2009). These national guidelines give directions on how patient safety work should be organised in health care organisations. As such they can be interpreted as describing safety management models – the background assumptions that an organisation has or should have on managing safety. They describe the general principles organisations should embrace and the scope and means of safety management

In Finland, the Ministry of Social affairs and Health has launched the Finnish Patient Safety Strategy for the years 2009–2013 (Ministry of Social Affairs and Health, 2009). The strategy identifies elements that deserve to be considered by health care organisations in managing safety. For this reason it can be considered as a safety management model. This strategy aims at guiding Finnish social and health care to adopt a uniform patient safety culture and at promoting its implementation. The strategy's vision is that patient safety "*will be embedded in the structure and methods of working: care and treatment is effective and safe"*. It is worth noting that the strategy – or the safety management model – refers to patient safety as a systemic phenomenon, and acknowledges that attention should be shifted from individuals to the "*service system"*.

According to the Finnish model, the promotion of patient safety is part of quality and risk management and has to be tackled from four different perspectives:

1. **Safety culture**, that involves a systematic way of working that promotes the safe care and treatment of patients and the management, values and attitudes underpinning it
2. **Responsibility**, that is matter of all the professionals working in the social and health care sector, but in the end, it is given to the leadership of the organisation
3. **Management,** that should stress the importance of patient safety in all activities and ensure that the working conditions are adequate for the safe provision of care and treatment
4. **Legislation,** which requires activities to be performed professionally on the base of evidence and good care and rehabilitation practices.

According to the Finnish Patient Safety Strategy, quality and risk management is the appropriate way for improving safety in Finnish social and health care sector. Concerns are expressed towards the need to identify, likely by mean of risk assessment, the hidden factors that may lead to incidents. Reporting and analysis of different types of events are important in the prevention of adverse events and they shall be used for the development and implementation of effective solutions.

During the first workshop held in the SafetyAsset project (see Appendix A) in November 2010, the project's consortium agreed on the importance of several components to be included in the safety management model:

- **Management commitment**: safety management is successful only if management is truly committed to safety and if it understands its role in promoting and steering safety. In this respect management shall define the strategy for develop safety, the plan for continuous improvements etc.
- **Development of a supportive climate:** safety management model shall promote an open and non-blaming climate within the organisation. Supportive climate is

the preconditions for reporting and discussing accidents and for organisational learning

- **Definition of structures for patient safety**: safety management models shall clearly set guidelines for system's organisation, resources allocation, responsibility among actors, reporting of events etc.
- **Definition of the role of the patient**: if and how the patient can be involved in managing safety has to be addressed in the safety management model
- **Definition of processes**: safety management model shall address the way in which things are done and not only what their result is. This includes the development of procedures, technical and non-technical skills, etc.
- **Integration of safety management**: safety management model shall define how safety management is integrated with other management functions (occupational safety, economics, information safety, production etc.).

In the Netherlands there is also an ongoing national effort to develop patient safety management. According to the material available in English[5], the Dutch approach to patient safety aims at supporting Dutch hospitals in implementing a patient safety management system so that they will all have a certified system by December 2012. The Dutch approach encompasses the development of basic requirements for the implementation of patient safety management system; the development of material and training for hospitals to support implementation of safety management systems; and finally the support to hospitals in reducing preventable harm.

As a safety management model, the Dutch approach identifies several requirements for patient safety. The requirements cover issues such as leadership and communication, prospective and retrospective risk analysis, incident reporting, operational control measures and monitoring of the results. As in many other cases, the participation of patients in developing safety is considered an important feature of the Dutch safety management model along with the need to manage organisational changes in the health care sector.

In the United Kingdom, the National Patient Safety Agency identifies seven steps for patient safety (NPSA, 2004):

- **Step 1: Build a safety culture**. Carry out an audit to assess safety culture
- **Step 2: Lead and support your practice team**. Talk about the importance of patient safety; demonstrate you are trying to improve it
- **Step 3: Integrate your risk management activity**. Regularly review patient records
- **Step 4: Promote reporting**. Share patient safety incidents

[5] Documentation available on http://www.vmszorg.nl/

- **Step 5: Involve and communicate with patients and the public.** Seek patient views; Encourage feedback using patient surveys
- **Step 6: Learn and share safety lessons**. Hold regular Significant Event Audit meetings
- **Step 7: Implement solutions to prevent harm.** Ensure that agreed actions are documented, implemented and reviewed, and agree who should take responsibility.

These seven steps for patient safety, once more, address the main areas of a safety management model, from management commitment to communication, from open and non-blaming culture to incident reporting and analysis, from integration of safety management in other management functions to their implementation and documentation. These seven steps represent a typical example of a safety management model since they define the background for the development of actual organisational processes for safety management. In other terms, they define the general approach that, according to the National Patient Safety Agency, should be followed in social and health care organisations to improve safety.

Principles for patient safety management can also be inferred from organisational safety culture models. For example, the DISC-model (Design for Integrated Safety Culture) (see Figure 3) describes the elements of an organisation with good potential for patient safety. The DISC-model also describes key organisational functions that are needed in creating good organisational potential for patient safety. The DISC-model was developed at VTT in several case studies in different safety critical industries and it has been utilised in evaluating and developing patient safety culture in Finnish hospitals.

According to the DISC-model an organisation has good potential for safety when the following criteria are met in the organisational activity:

1. Safety is a genuine value in the organisation which reflects to decision making and daily activities
2. Safety is understood as a complex and systemic phenomenon
3. Hazards and core task requirements are understood thoroughly
4. Organization is mindful in its practices
5. Responsibility for the safe functioning of the entire system is taken
6. Activities are organised in a manageable way.

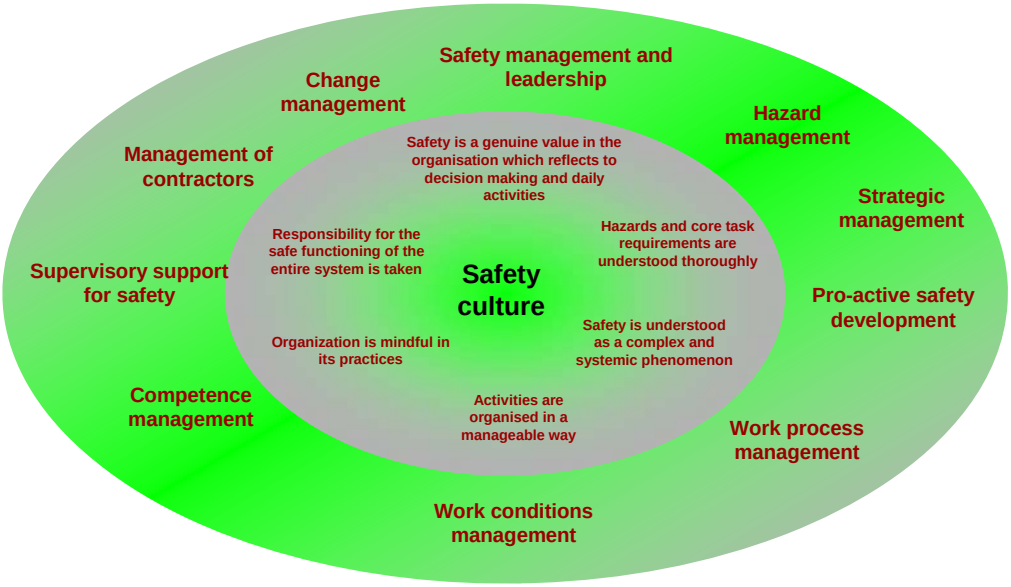

Figure 3. DISC-model describes the criteria for good safety culture and the organisational functions which are necessary for developing good safety culture in the organisation (Adapted from Reiman et al., 2009)[6]

What is special in the DISC-model, when compared to other safety culture models, is that it depicts safety culture as something more than correct attitudes and mindset. Right mindset is necessary but safety also requires well-designed and functioning structures and processes to ensure good preconditions to carry out the activities with sufficient quality. Another important cornerstone of safety culture, according to the DISC-model, is understanding. Unlike most other safety culture and safety management models, the DISC-model pinpoints the importance of knowledge and understanding on safety and the core task requirements and hazards inherent in the system. Without thorough understanding of safety and risks the organisation might focus on irrelevant challenges, make risky decisions or be blind to new threats.

The DISC-model emphasises that the employees' working practices are not guided directly by the official processes and visible control mechanisms but rather by their interpretations and feelings towards these organisational processes and control mechanisms. In the end, employees base their decisions and activities on their own understanding and reasoning. It is crucial to bear in mind that the social workplace norms, climate and other social aspects also affect the activities. There may be, for example, historical reasons why certain practices are not considered worth executing or tacit norms not to bring up

[6] See also Oedewald et al., in press; Pietikäinen, 2011

certain challenges. These social processes affect more or less all the members of the organisation, usually in an unconscious manner.

The DISC-model also states that certain organisational functions are necessary to develop high safety potential in an organisation. These include for example hazard management practices (such as risk assessments, redundancy of safety systems and personal protection equipments), competence management practices (such as training courses on the specific technologies or treatments used, mentoring of newcomers), pro-active safety development practices (such as reporting and analysing incidents, periodical organisational assessments) and work condition management practices (such as assessing the adequacy of the staffing, and ensuring necessary equipment for work).

To sum up, the DISC-model suggests that safety culture is organisational potential for safety. If an organisation fulfils all of the six safety culture criteria very well, it has high potential for safe performance now and in the near future. When applied in patient safety management the six criteria of the DISC-model can be interpreted as the goal or direction of patient safety management. Respectively the functions on the outer layer of Figure 3 can be seen as ways to approach these goals, as necessary elements of patient safety management.

5.2 Safety management models in other safety critical domains

The development of safety management models in health care is, as previously said, a relatively recent effort of this sector to reduce the number of incidents. Other safety critical domains have been facing this challenge for much longer time. In this section, two examples are presented to illustrate what more “mature” industries have done. The first example concerns the nuclear industry where safety issues are constantly at the edge of development. The other example is provided by the Health and Safety Executive, which is an independent regulator acting to reduce work-related death and serious injury across Great Britain’s workplaces.

5.2.1 Nuclear industry

In the nuclear domain, the International Atomic Energy Agency (IAEA) requires all nuclear installations to establish, implement, assess and continually improve a management system. IAEA sets some requirements for the development of a safety management system. It should integrate safety, health, environmental, security, quality and economic elements. However, safety is the fundamental principle on which the management system has to be based upon. Thus, the main aim of the management system is to achieve and enhance safety by (IAEA 2006a, p. 5):

- bringing together in a coherent manner all the requirements for managing the organization
- describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied and
- ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements.

Furthermore, the management system should promote and support a strong safety culture by, e.g. providing means by which the organization supports the personnel in carrying out their tasks safely, and reinforcing a learning and questioning attitude at all levels of the organization (IAEA 2006a, p. 6). IAEA emphasizes that organizations should integrate all their "components" into the integrated management systems. IAEA further argues that the components "include the structure, resources and processes". IAEA then goes on stating that "individuals, equipment and culture should therefore be as much a part of the integrated management system as the documented policies and processes" (IAEA 2006b, pp. 3–4). Processes are further divided into core processes (operation, maintenance, etc), supporting processes and management processes (IAEA 2009).

The management system needs to be documented. IAEA endorses a three level structure of information. Level one provides an overview of how the organization and its management system are designed to meet its policies and objectives. The information at this level should include the policy statements of the organization, organizational structure, an overview of the organization's processes and a responsibility and accountability structure for the organizational units as well as managers. Level 2 describes the processes of the organization and provides specific detail on which activities should be performed and which organizational units should carry them out. Level 3 includes the detailed working documents, procedures and instructions, and job descriptions for different types of jobs. (IAEA 2006b, pp. 14–18)

5.2.2 Safety management model as proposed by Health and Safety Executive

The Health and Safety Executive approach emphasizes the importance of positive health and safety culture. To achieve this, structures and processes are needed to establish and maintain management **control**, promote **co-operation** between individuals, safety representatives and groups so that health and safety becomes a collaborative effort, ensure the **communication** of necessary information throughout the organization and secure the **competence** of employees (HSE 1997, p. 22). Control is considered the foundation of positive H&S culture, and as requisites for control the report considers **key functions for successful health and safety management** as 1) formulating and developing policy 2) planning, measuring, reviewing and auditing activities 3) ensuring effective imple-

mentation of plans and reporting on performance. These control arrangements should form part of the organisation's written statement about safety (HSE 1997, p. 23).

The report also describes the components of the health and safety management system: 1) risk control systems, 2) management arrangements and 3) workplace precautions. Management arrangements correspond with the five elements describes above (policy, auditing etc). Risk control systems are needed to ensure that the necessary workplace precautions are implemented and kept in place. Risk control systems are needed for various activities such as recruitment, procurement, operations, maintenance, product and service design and pollution control. Workplace precautions can range from technical equipment (ventilation, machine guards) to instructions to permit to work systems. Further, the process of risk control for the establishment of precautions can be approached from the management point of view through the five basic elements. Thus, the report seems to distinguish between **health and safety management** (composed of the five elements) and **health and safety management system**. The latter is a means for achieving H&S management and implementing the H&S policy by a planned and systematic approach (that is, the H&S management system).

6. Safety management systems in health care

In Finland there is a new health care law coming into operation in spring 2011 that will require health care organisations to have a plan for quality and safety. It is not yet self-evident what such a plan should include, but a statute to clarify this is currently in preparation. Some health care organisations, mainly large hospitals that provide special health care services, have already started to work with their plans. It seems that they have interpreted the plan to mean closely the same as a description of a safety management system. It is therefore of interest to here present and describe how safety management systems have been developed in other countries. The relationship between the quality and patient safety is defined in Finnish definition of patient safety so that patient safety is a part of quality of care. In the law and in the current version of statute the quality and patient safety are treated as equals (but integrated) for example so that the quality and patient safety plans (systems) can be combined or separate.

Safety management systems (SMS) are the collection of systematic organisational processes that are needed in order to steer the organisation to ensure and develop patient safety. Thus, the objective of a safety management system is to provide a structured management approach to control risks in operations as well as to enhance the ability of the organisation to function in a safe manner. Typically, safety management systems are designed similarly to quality management systems and they include **processes** for planning, organising, communicating and providing directions for protection from risks and for organisational development. These processes are implemented across the organisation and they have to take into consideration the operational and structural characteristics of the organisation.

In current literature concerning patient safety the term patient safety management *system* is rarely used. Instead of describing patient safety management systems, articles and reports that somehow deal with organisational patient safety management, often use terms with a more temporary flavour, such as program (e.g. Frankel et al., 2003), strategy (e.g. Frankel et al., 2003), step (e.g. Botwinick et al., 2006), plan (e.g. Franke et al., 2003) or project (e.g. Frankel et al., 2003). This implies the evolving nature of patient safety work. The other, more worrying, interpretation is that patient safety problems are

understood as a passing issues that can be corrected by putting some effort on the issues for a couple of years instead of seeing patient safety as characteristic of how the system works that needs constant and permanent attention. One reason for the avoidance of the term "system" could be that the term is considered referring to quality systems that have sometimes been considered too stiff and laborious in health care organisations. There might be worries among health care professionals that patient safety management systems become redundant systems to quality systems that would require lots of administrative work with small, if any, improvements. As the UK Health care commission report (2009) states, health care organisations should not be happy only with having systems in place to manage safety effectively, but they should strive *"to be proactive in thinking about potential risks and, ultimately, to make safety an integral part of everything they do."*. Another reason for not using the term *system* when discussing about safety management, could be relate to the assumption, often shared by health care professionals, that patient safety is a matter of individual expertise and carefulness.

Even though there are not many scientific documents that would explicitly use the term patient safety management system, there are some practical guidelines published for managers and board members on what they should actually do to improve patient safety (e.g. Bader & O'Malley, 2006; Botwinick, Bisognano & Haraden, 2006; Monitor, 2010). These guidelines can be considered as describing important aspects of patient safety management. However, patient safety management systems should not be *only* about what the management or board does. A patient safety management system should encompass all activities and actors of the organization, not only the management.

Some authors that do use the term patient safety management system actually refer to rather narrow processes of ensuring organisational safety. For example in their article Van der Starre et al. (2006) describe a patient safety management system in paediatric ICU's in the Netherlands. However, the system they are actually describing focuses on how incidents are reported and handled while many other processes that are typically considered important in safety management systems in other industries are left out.

Multiple actors are involved in the definition and development of a patient safety management system (PSMS). Their different positions and roles shall be reflected in their accountability for ensuring patient safety.

Two examples of PSMSs with a wider, organisational focus are presented next.

First, in Australia, the government bears the highest level of accountability for the development and implementation of a patient safety management system. In the Australian system, the government is responsible for defining the legislative, and regularity framework for system safe operation. Within every health care organisation, CEO and top management are accountable for patient safety in their area(s) of responsibility. Managers and clinician managers are accountable for actions in their work area, including the operations of their teams. Health care professionals are responsible for day-to-day practice within their sphere of work, and are accountable for their own individual

actions. Patients as well are involved in this accountability chain. Within their possibilities, patients have to reduce their exposure to risks and increase their safety e.g. by seeking information and assistance as required.

In the Australian system, PSMSs are systematic, explicit, and comprehensive processes for managing the risks that patients face in a health care setting. Three attributes are part of the Australian safety management system:

1. the discovery and assessment of the hazards of particular operations
2. the specification of how these hazards are to be managed
3. what is to be done if things go wrong.

In the Australian PSMSs the processes to be implemented address mainly the protection from risks and preparation for incidents. This kind of SMS can be appropriate for organisations that are relatively simple. As underlined by current theories for safety management, as the safety culture approach and resilience engineering, the improvement of safety in health care requires also the management of the qualities for safe organisational functioning as to enhance the safety potential of the organisation.

Second, in Italy, the Tuscany Centre for Clinical Risk Management and Patient Safety has designed a patient safety system that is divided in four main axes (Bellandi et al., 2005; Tartaglia et al., 2006; Bellandi et al., 2007):

1. organization for patient safety
2. training
3. patient safety management system
4. campaigns for patient safety.

The organisation for patient safety starts with the definition of roles, in local agencies, to start-up initiatives. Three roles have been defined:

1. Clinical risk manager: promoter of the clinical risk management culture and activities among clinicians
2. Patient safety manager: responsible for the implementation of the action plan and recommendations about clinical risk management
3. Forensic medical doctor: responsible for the sharing data on incidents and accidents.

According to the description of the Tuscany SMS, safety management is embedded in everyday practices of health care professionals. This has the advantage that by the direct involvement of operators, the organisation maintains a high level of alertness and mindfulness.

In the Tuscany example, the training has the main objective of promoting a new safety culture based on a systemic approach to clinical risk and patient safety. To facilitate

the development of a non-blaming open reporting culture, training has been based on the discussion of adverse events presented by participants

In the Tuscany example, goals for patient safety management are divided into a mid-term action plan for clinical risk management and short-term patient safety campaigns and laboratories for patient safety. Mid-term action plan aims at developing a participatory process to create a local clinical risk management system, connected with the regional network. Short term campaigns focus on specific problems for an immediate answer to well known risks, demonstrating the institutional commitment for patient safety (Tartaglia et al., 2006)

7. Recommendations for patient safety management

As a summary of the review of available approaches for safety management in health care and in other safety critical domains, it is possible to draw the following conclusions and recommendations.

It is worth to start by recalling the four concepts addressed in this document:

- **Safety definition**: what the desired result of safety management is
- **Safety model** the description of the way in which organisation functions and accidents happen
- **Safety management model:** the background assumptions made in an organisation to manage and improve safety
- **Safety management system:** collection of systematic organisational processes that are needed in order to steer the organisation to ensure and develop safety.

Safety definition determines the goal the safety management (system) is heading to. Safety management model – the assumptions on how the safety is managed is based on the underlying safety model – i.e. the understanding of how accidents happen and safety is built up. Further, the safety management system is based on the assumptions of the safety management model.

This review of the literature highlights a series of key messages which should be taken into account for the management of safety in health care:

1. An organisation should explicitly define patient safety, safety model and patient safety management model.
2. Patient safety definition, safety model, patient safety management model and patient safety management system should be coherent with each other.

The following recommendations are made for the four basic concepts:

1. **Defining safety:**

   When formulating safety definition, the following aspects should especially be taken into account:

   a. Safety is an ability of an organisation to function safely. Safety emerges from the social and technological factors interacting in an organisation. An organisation does safety.
   b. To improve safety, emphasis should be on creating prerequisites for safe work in the organization, rather than on trying to constrain performance. In the provision of safe services, some degree of flexibility is required. Providing safe services cannot be done only by ensuring that things are done exactly the same way every time. There is a limit to what standardising procedures can contribute to safety.

2. **Safety model:**
   a. Safety model has to represent patient safety as a systemic phenomenon. Adopting a systemic approach means that both successes and failures are considered emerging from the same organisational behaviour. The systemic approach puts emphasis on non-linear interactions within the organisation and with the environment (i.e. the same impulse may result in different reactions according to the context).

3. **Safety management model[7]:**
   a. Safety management model should be in line with both the definition of patient safety and the safety model. It identifies the elements necessary for the management and improvement of patient safety.
   b. A safety management model should include elements for both protecting from risks and enhancing prerequisites for safe functioning.
   c. Safety should be considered together with the overall management of the organisation.

4. **Safety management system:**
   a. A safety management system has to be integrated in the management system of the organisation.

[7] Examples of elements in various safety management models are given in Chapter 5. The identification of the specific elements of the patient safety management model is needed in the future development of the SafetyAssset project.

b. A safety management system shall aim not only at assessing and eliminating risks, but also at ensuring that the appropriate prerequisites are present throughout the lifetime of the organisation.
c. A safety management system shall be developed taking into account the specific characteristics of the organisation. A SMS shall be documented to keep track of responsibilities for the implementation of actions aiming at ensuring the presence of appropriate conditions for safe work.

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Appendix A: Description of the SafetyAsset research and development project

Background

Systematic development of patient safety is considered necessary internationally and in Finland. Insufficient quality of health care causes human suffering and financial costs. It has been estimated that hundreds of people die every year in Finland because of harm caused by medical care. Ministry of Social Affairs and Health has launched a patient safety strategy in 2009. The strategy describes national objectives for a culture change and obligates organizations to be active in patient safety work. New Finnish health care law requires organizations to make a plan for quality and patient safety actions. Safety of social and health care services will be a significant asset for organizations in the eyes of both patients and potential employees.

In first stages of patient safety development, emphasis has been on the actions of individual professionals and in modifying immediate preconditions of their work (e.g. improvement of hospital hygiene, development of medication dispensation practices, implementation of surgical checklists). Besides this, it is essential that patient safety is understood as a characteristic of the whole system and as a matter of management.

There is little expertise on safety management in health care compared to other safety critical domains (e.g. nuclear power industry, aviation), where a lot of effort has traditionally been devoted to systematic management of safety. There is lack of expertise on patient safety management and of functional, research based practices and tools.

Goals

The “Patient safety as an asset in social and health care” (SafetyAsset) research and development project aims to:

- develop an innovative model for patient safety management, that is client-centred and takes into consideration the complexity of the health care organizational network, continuity of care and the well-being of the personnel
- develop tools that support patient involvement in the process of care, organizational learning, proactive risk assessment and development of overall safety
- promote distribution of good practices in patient safety management in Finland
- promote development of innovative services and products in relation to patient safety management.

Participants

- VTT Technical Research Centre of Finland
- Vaasa hospital district
- Finnish Institute of Occupational Health
- Huperman
- Awanic
- NHG Audit.

Associate contributors in the project are:

- City of Espoo (social and health care)
- Centre for Military Medicine
- Mehiläinen
- Kårkulla Samkommun.

Funding

The SafetyAsset project is funded by the participants and the Finnish Funding Agency for Technology and Innovation, Tekes.

Schedule

The project started in August 2011 and ends in December 2012.

Tasks and methods

The SafetyAsset project consists of different subtasks that are presented in Figure 1. Different research and development methods are utilised in different tasks. Workshops and seminars that aim for constructing the patient safety management model and embedding into the practices of the Finnish social and health care organisations constitute the foundation of the project. An integral part of the project is also the evaluation and development of patient safety work in the case organisation, Vaasa hospital district.

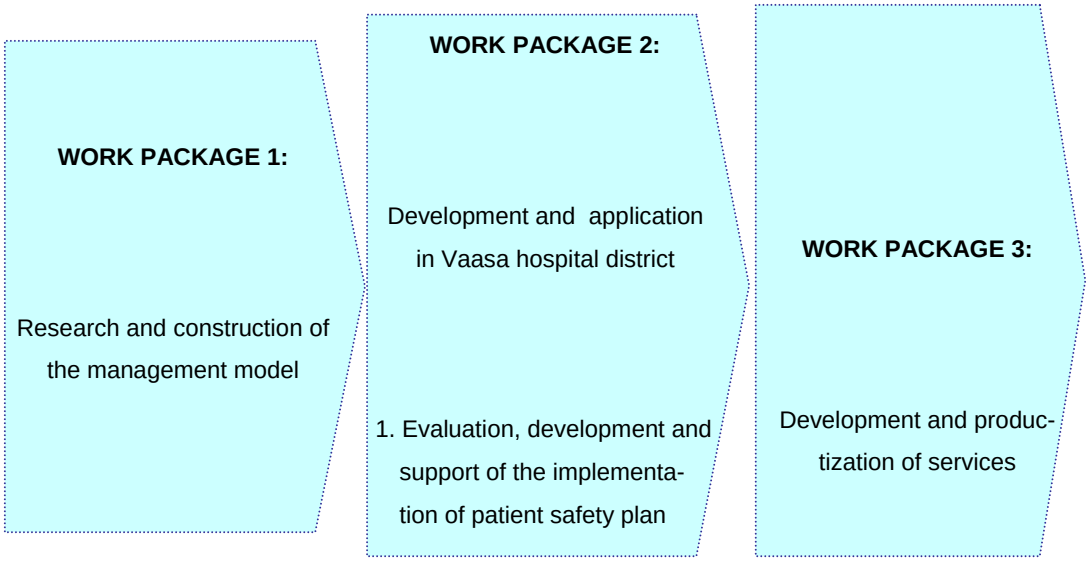

Figure 1. Tasks of the SafetyAsset project.

More information

Elina Pietikäinen, VTT,
elina.pietikainen@vtt.fi
+358 40 826 8113

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