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COMPREHENSIVE EVALUATION OF E-HEALTH SOLUTION FOR PATIENT SAFETY APPLICATION TO THE REMINE PROTOCOL

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Abstract

Within the recent years, patient safety has taken great attention and became one of the priorities of health care services. As information and communication tools are highly advanced, they are started to be used in the patient safety area with a great potential to mitigate risks. With the recent developments e-Health became a glittering subject. The European e-Health Market was estimated as 14.269 million Euros in 2009 and expected to read 15.619 million by 2012 with a growth rate of 2.9%.

The ReMINE Platform is a high performances prediction, detection and monitoring platform for patient safety risk management. Main objective of ReMINE is to design, implement and test an IT platform for the prevention and management of risks to patient safety in hospitals. ReMINE consists of tools for collecting data from the hospital information system, real time monitoring of clinical risks and triggering of the most suitable countermeasures, preventing clinical risks through the predictive rules which are based on process simulation models and modeling and implementing new risk management procedures.

ReMINE will be tested on 3 pilot hospitals and assessment of ReMINE impacts in these pilots, namely, stroke management (Niguarda, Italy), labor monitoring (Sacco, Italy) and infection control (TRFT, UK) will be made. ReMINE is not designed to change clinical supports but to support them. At each hospital, ReMINE's impact assessment will be done via different indicators.

In this study brief information about the recent status of patient safety is given, current e-Health market and its potential are explained. Moreover, data analysis of ReMINE will be performed and its benefits and potential are discussed.

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1. Patient Safety as an Organizational Issue

1.1. Introduction

Nowadays, applying wrong plans for treating patients and/or medical errors which are defined as failure of a planned action to be applied in the treatment process are the primary problems of the health care systems. When causes of death and severe injuries are examined, these unfavorable events have been detected with a high incidence rate. Besides being ethically unacceptable, these events result in losing high amount of money for the health care systems due to augmentation in clinical negligence claims (Kohn et. al., 2000).

Considering these problems, in the last ten years, patient safety has taken great attention expectedly. Several systems and organizational policies and procedures are interfered as the patient safety becomes the primary objective of the healthcare service improvement. However, it is not a very easy task to observe the benefits of the provided solutions since patient safety can only be measured in terms of the "absence of adverse events" (Hollnagel et. al., 2006).

Meanwhile, Information & Communication Technology tools are spread and became the attractive subject as they can play an important role in the development of healthcare in western countries (European Commission, 2006). Without a doubt, they have a great potential for the improvement of safety (National Coordination Office for Information Technology Research and Development, 2004). However there is still some more potential is to be exposed, since:

Most of the healthcare Information & Communication Technology tools are concentrated on the operational support to clinical practice, but not on helping the management to assess and analyze factors that have an impact on patient safety (Bates, 2008);

As the modifications provided by Information & Communication Technology tools are about clinical processes, ICT becomes a new source of risk for patient safety and security (de Wildt et al. 2007; Wears and Leveson, 2008).

1.1.1. Historical Background

"First, do no harm" is one of the oldest principles in the history of medicine. Nowadays, implication of medicine within the complex health systems is one of the challenging events for researchers and practitioners in the health care sector. Complexity is started to be treated as a system because of a continuous specialization of disciplines and generalized access to the health system and technologies progress. As a result, complexity became of the main characteristics of health care (Casolari and Grilli, 2004).

Therefore, good organizations' priority was to provide good care in both management and clinical aspects. Dr. Ernest Codman in 1910 claimed that a hospital should observe its inpatients to understand the effectiveness of the treatments for finding possible errors so that becoming more successful in the future (Donabedian, 1989). In 1913, with the demand of Dr. Codman's colleague Dr. Franklin Martin, the

American College of Surgeons (ACS) was funded to define a system for evaluating the results of care. In 1917, the ACS announced the first Minimum Standard for Hospitals (Table I).

Table I: Minimum Standard for Hospitals, 1917 (Source: Mallon, 2007)

The first Minimum Standard (1917)
1) Each hospital should have a medical staff.
2) The members of the medical staff should be chosen based on the graduation from medical school (not a given in that era), competence, and character
3) There should be regular staff meetings to review cases (end results; these became the forerunner of morbidity and mortality conferences).
4) Medical records should be written and filed for all cases.
5) Each hospital should have a clinical laboratory and radiology section.

According to ACS on site surveys in 1919, only 89 out of 692 hospitals were satisfying the standards. In 1951 the ACS, the American College of Physicians, the American Hospital Association, the Medical Association and the Canadian Medical Association formed the Joint Commission on Accreditation of Healthcare Organizations (JCHAO), with the aim of defining a system for the voluntary accreditation of hospitals.

Until 1990s, not many papers considering all dimensions that play a role in the care quality in the presence of a trade-off between costs and effectiveness were published. James Reason has made studies on human error while dealing with patient safety problem which encouraged a new conception of healthcare quality. Reason's arguments depend on two principles:

- "To err is human", making a mistake is a characteristic of human being, and the countermeasures that are based on the personal responsibility, are aimed to decrease variability of behaviors by laws, fines and so on.
- Although it is known that a big portion of errors is due to cognitive characteristics of the person who made the mistake, reaction to errors by the social context is to look for someone to be blamed and punished.

With reference to the model by Rasmussen and Jensen, Reason's first principle can be explained as that the errors are result of an organized acting. Therefore, by changing the working conditions within a system, one can avoid mistakes caused by operators. To explain events in complex systems can be related to multiple dangerous actions or omissions. Although these actions have small impact, they may result into catastrophic and unpredictable consequences once they are in a chain reaction. Occurrence can be due to design and management errors which determine the absence or the vulnerability of the safety barriers within the system itself.

2nd principle stated by Reason the comparison of human errors in healthcare and other complex systems where errors are unacceptable such as nuclear plants or air traffic control where effective control systems can be implemented to mitigate risk of catastrophic failures.

The publication of the Harvard Medical Practice Study I and II (Brennan et al., 1991 I and II) is a milestone for modern approaches to healthcare safety (Leape, 2008). 30,000 randomly chosen cases in New York, 1984 are analyzed in the study. It has been found that 3.7% of the patients were victim of an adverse event defined as "damages caused by medical treatments". 14% of those damages resulted in fatalities and 69% could have been predicted and prevented. 70% of the adverse events were surgery and drug therapies.

In addition to Harvard Medical Practice Study I and II, the relevance of adverse events due to medical errors are also approved by other studies such as "Utah and Colorado Study" (Thomas et al., 2000) and "Quality in Australian Healthcare Study" (Wilson et al., 1995). 1st study was conducted in 1992 and 2.9% of the inpatients were subject of an adverse event of which 53% could have been preventable. 2nd study was conducted in Australia, in 1995. 28 hospitals were examined and 16.6% of hospitalized patients were victim of a medical error where half of them could have been prevented. Medical errors cost approximately 4.7 billion dollars per year with more than 18,000 deaths and more than 50,000 permanent injuries.

Leape's research (1994) on patient safety is another significant work. According to his study, even 1% rate of preventable iatrogenic adverse events on the total number of inpatients would be way above than the other complex sectors. In a different way of speaking, a similar failure rate in air traffic control would state 2 jets falling down every 3 days. According to Leape, everyday clinical practice errors are not acceptable because they are related to negligence. In addition, due to their educational system, physicians are required to be infallible and emotional side effects cannot be recovered by colleagues or patient's relatives. As a result errors tend to be hidden.

Traditional approach to prevention is reactive: Once an incident is occurred, mistakes are discovered and the corrections are addressed to the person who caused the mistake so that that person will not repeat it. However no search is done on underlying causes unless it has to be done due to legal issues.

Following points are the forerunners in approaching the problem of adverse events in the health sector, for example anesthesia and drug administration:

- Cooper et al. published the results of a research on the human factors related to incidents in anesthesia in 1978. In 1984, Cooper also published a methodology for risk assessment with other authors. They have suggested 10 strategies to prevent and identify incidents. Webb et al. described incident reporting system of anesthesiology in 1993.
- Management of drug therapies became a significant subject for patient safety researches. They are generally treated as a separate category of incidents called Adverse Drug Events (ADE) because of their incidence and complexity that goes from the prescription to the administration of the right drug to right patient, in the right dose, frequency and route and through right procedure. Moreover, ADEs has an older research history than all other

medical errors. However it is still one of the most challenging events for healthcare operators.

1.1.2. The "To Err Is Human" Report and Its Consequences

"To Err Is Human: Building a Safer Health system" (Kohn et al., 2000) was published by Health Care in America Committee of U.S. Institute of Medicine (IOM) at the end of 1999. The committee defines the issues of patient safety as "subset of overall qualify-related concerns" and aims to mitigate errors in health care, thus improving patient safety.

Although the Harvard Medical Practice Study (Brennan et al., 1991) was published 10 years ago and several researches justify these studies' findings, not many actions were taken to improve patient safety and the authors agree that it would not be acceptable to wait another 10 years. Main purpose of the report is "to break the cycle of inaction" because "the status quo cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by some health care system that is supposed to offer healing and comfort."

As the title indicates, that errors are human, therefore the main concept is not to point out persons or rules, but to acknowledge that errors are predictable and preventable. As a consequence, attention should be given to prevention of future errors with a safer system design rather than blaming individuals. To improve safety in the health care system, 4 strategic approaches are defined in the report:

- Improvement of the knowledge on safety by getting national attention to create leadership, research, tools and protocols;
- Finding and learning from errors by creating mandatory reports, and encouragement of voluntary efforts so that the system continues to be made safer for patients;
- With the actions of oversight organizations, group purchasers and professional groups, raising standards and expectations for improvement in safety;
- Implementing safe practices at the delivery level to create safer systems inside the health care organizations.

Considering these strategic approaches, a set of recommendations is developed to create a guideline for a safer health system:

- RECOMMENDATION 4.1: Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality. This center should:
    - Set the national goals for patient safety, track progress in meeting these goals and issue an annual report to the President and Congress on patient safety;
    - Develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

- RECOMMENDATION 5.1: A nation wide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should:
    - Designate the National Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
    - Require all health organizations to report standardized information on a defined list of adverse events;
    - Provide funds and technical expertise for state governments to establish or adapt their current error reporting system to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory system, the Department of Health and Human Services should be designated as the responsible entity; and
        - Convene states to share information and expertise and to evaluate alternative approaches taken for implementing reporting programs, identity best practices for implementation and assess the impact of state programs;
        - Receive and analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or a broader based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).
- RECOMMENDATION 5.2: The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:
    - Describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
    - Convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
    - Periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs;
    - Fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.
- RECOMMENDATION 6.1: Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purpose of improving safety and quality.

- RECOMMENDATION 7.1: Performance standards and expectations for health care organizations should focus on greater attention on patient safety.
    - Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.
    - Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.
- RECOMMENDATION 7.2: Performance standards and expectations for health professionals should focus greater attention on patient safety.
    - Health professional licensing bodies should
        - Implement periodic re-examinations and re-licensing of doctors, nurses and other key providers, based on both competence and knowledge of safety practices;
        - Work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.
    - Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should
        - Develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
        - Disseminate information of patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
        - Work with the Center for Patient Safety to develop community-based, collaborative initiatives fir error reporting and analysis and implementation of patient safety improvements;
        - Collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

"To Err is Human" report was impressive not only in U.S but worldwide on healthcare practitioners and managers, researches, local and central governments and on the general public. Although recommendations described above are met in different levels, there is still not a general agreement for measuring organizations advances towards safety.

In 2006, a review study of articles on patient safety and medical errors which were published in 10 years around the "To Err is Human" report (from 1994 to 2004). There has been a recognizable increment in the number of articles on patient safety (59 articles in 1994, 164 articles in 2004, Figure 1). Prior to the "To Err is Human" report, main subject of patient safety was malpractice; however after the publication it became organization culture which implies a significant change in the approach. In addition, research awards on patient safety were increased from 5 to 141 (Figure 2).

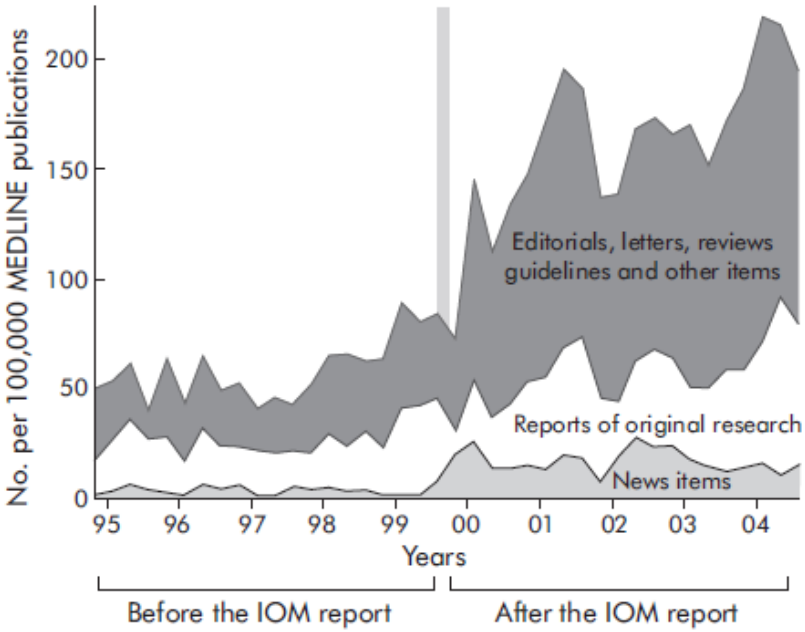

Figure 1: Patient safety publications before and after the publication of the "To Err is Human" report (Source: Stelfox et al., 2006)

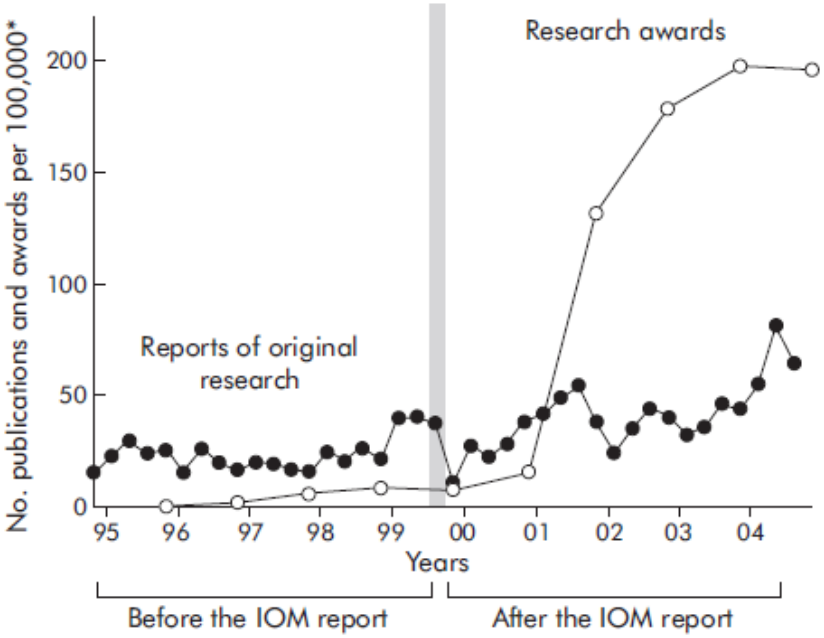

Figure 2: Patient safety research and awards before and after the publication of the "To Err is Human". (Source: Stelfox et al., 2006)

It can be clearly seen that many studies, initiatives, models and tools have been developed to improve patient safety within practice after the "To Err is Human" report.

1.2. Information Technology and Patient Safety

1.2.1. Supporting Care Decisions

During the treatment of a patient, multiple decisions are made by several healthcare professionals who are responsible of the patient's care. As a consequence, each professional has a potential to make an error or contribute to an event for future errors to be occurred.

Therefore, information technology should be used to make optimum decisions at each step of a patient's treatment. Moreover, information technology must limit making very obvious mistakes and prevent making decisions which can result in an iatrogenic harm. However, one should keep in mind that doing nothing could be as harmful as making an incorrect treatment.

Computerized Decision Support Systems (CDSS) use patient data to create an advice for a specific case. Aim of these systems is to support decision care where high sophistication is involved. At first sight, there are good reasons to believe that these systems are useful. First of all, CDSS guarantees the consistency of decisions, as a result, mitigates the risk of violation and/or omission. Moreover, by incorporating contingencies for unusual presentations conferring specific risks, errors associated with cognitive lapses or bias can be controlled.

For CDSS, data completeness is a significant safety issue. A recommendation given by the system might be inappropriate only in specific conditions. Accurate medication history, details of allergies and comorbidities are most likely to have an effect on the decision of care. However, these data can only be gathered at the initial assessment of the patient. Once these data is captured, it should be accessible in the future for all health care encounters and shared securely.

In this sense, Electronic Patient Records (EPR) support several e-Health applications like CDSS. Saving records electronically minimizes the risks of losing data. However, EPR systems are not very common in developing countries. Although EPR system improves accuracy and completeness, poorly designed interfaces may result in introducing new risks. Currently, there is limited empirical evidence for benefit (Centre for Population Health Sciences, The University of Edinburgh, UK).

1.2.2. Combating Medication Error

Prescribing errors are the most common medical errors which may result in serious, sometimes even to death or disability for the patient (Avery 2002). Common errors at the stage of the prescribing process can be summed up as:

- **Decision Errors:** Failure to take comorbidity, previous reactions into account, incorrect decision.
- **Calculation Errors:** Failure to calculate appropriate dosage.
- **Communication Errors:** Dosage is written incorrectly, bad handwriting.
- **Monitoring Error or Incorrect Length of Treatment:** Failure to track drugs with the risk of toxicity.
- **Slips:** Using incorrect drugs, giving drugs to wrong patient.

One solution to avoid prescribing errors is to use Computerized Provider Order Entry, which uses computer based tools to record specific clinic actions (for example, tests, interventions). As the care pathway gets sophisticated, tools can integrate with the relevant history and related medication risks. In addition to this, by using barcode systems to identify patients, drugs, potential slips can be avoided. Also automatic flagging up of missed prescriptions and/or tests is also possible with e-Prescribing systems.

Dosage advice of CDSS can be affective in preventing calculation errors and it could also improve performance when the drug level has to be monitored against toxicity (Walton 2001,).

Flagging systems are seemed to be used infrequently and generally counted as undesired distraction. According to the survey in 2002 in UK, 28% of general practitioners admitted to dismiss alerts frequently even without reading (Magnus, 2002). Ignoring alerts is clearly a problem for these tools.

Using e-Prescribing tools creates a new source of risk. There could be failures of human-machine interaction. Structuring input can result in undesired consequences, specifically; usage of lists for medication dosages could result in slips that would not occur if the practitioner input the information manually (Koppel, 2005).

1.3. The Hype Cycle for Healthcare

Hype Cycle is a graphic representation of maturity, adoption and social application of specific technologies and created by Gartner. Hype Cycle for healthcare is depicted in Figure 3. It represents the applications and systems that contribute to the value to Care Delivery Organizations (CDO). Each dot on the Hype Cycle shows a technical profile, its position and the adoption speed. Moreover benefit rating, relative maturity and market penetration are also provided. One should keep in mind that the graph shows the U.S. market and any differences are explained in the appropriate section.

At first sight, one can see that several applications and systems are approaching the 'Peak' such as advanced disease management support, personal health management tools and personal health record (PHR). Around one third of the applications and systems in the cycle are placed throughout the "Slope of Enlightenment" and they are on their way to mainstream adoption. They are easier to deploy and better supported by the industry, and contributing highly to the benefits of CDOs such as computer based physician order entry (CPOE) and remote hosting.

Applications that are placed within the technology trigger phase (on the rise), are going to the plateau of productivity at different speeds. These applications consist of advanced disease management support and patient decision aids. Within 10 years, CDOs will offer patients to evaluate their treatment options.

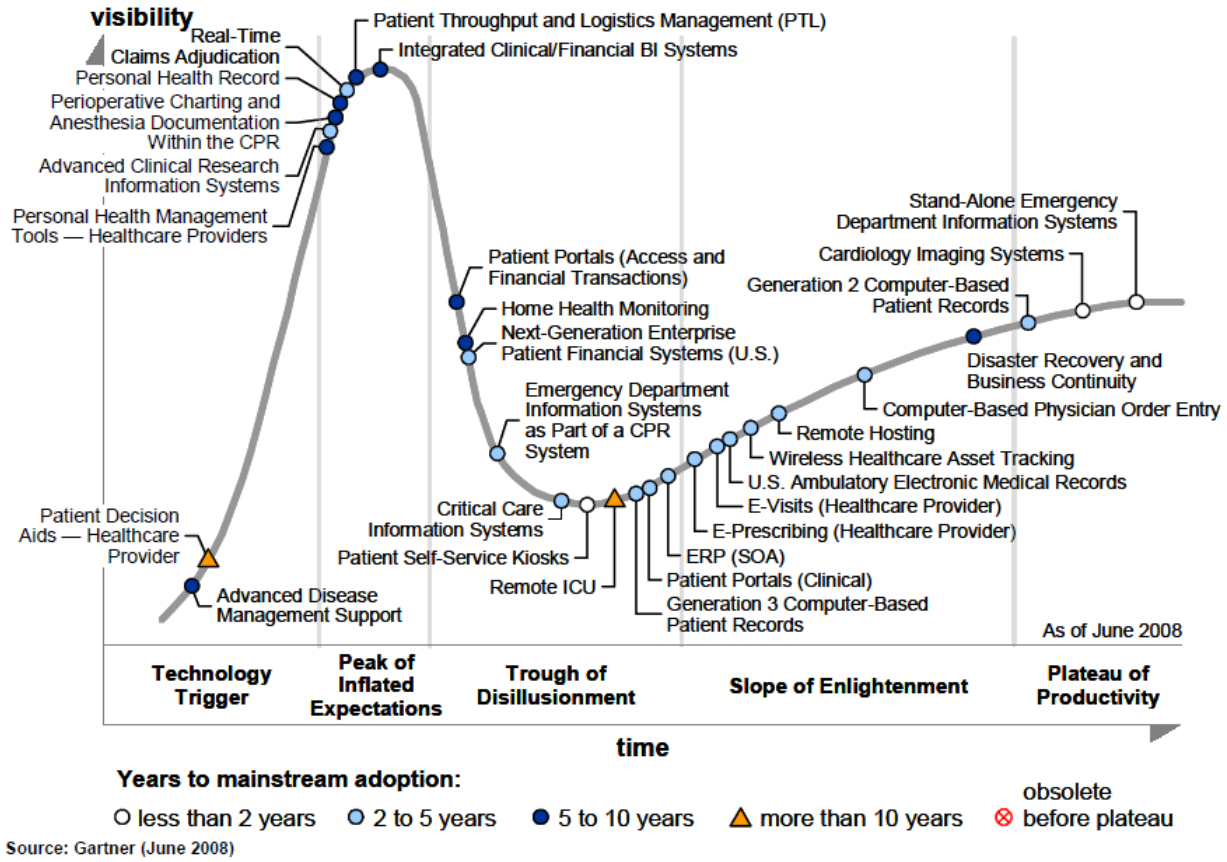

Figure 3: The Hype Cycle for Healthcare.

1.4. The Priority Matrix

The priority matrix (Table II) accompanies the Hype Cycle graph. It represents a technology's benefit to its time to maturity.

Table II is obtained from the benefit rating and the time to plateau values for each technology profile. Priority matrix easily answers two questions:

- How much value will an enterprise get from a particular technology?
- When will the technology be mature enough to deliver that value?

As a rule of thumb, if it is red, it is hot; and if it is gray it is not. Technologies like CPOE, e-visits and patient portals are considered "warm" profiles which have a high value for CDOs in the next 2 to 5 years. These technologies provide new ways of business and may result in cost savings or increased revenue. For home health monitoring it will take 5 to 10 years to start offering concrete implementations and provide value.

Table II: The Priority Matrix

Benefit	Years to mainstream adoption			
	Less than 2 years	2 to 5 years	5 to 10 years	More than 10 years
Transformational		• Generation 2 Computer based patient records • Generation 3 Computer based patient records		
High		• Advanced clinical research information systems • Computer based physician order entry • E-visits (Healthcare provider) • Patient Portals • Real-time claims adjudication	• Home health monitoring • Integrated Clinical / Financial BI Systems • Patient throughput and logistics management (PTL) • Personal Health Record	
Moderate	• Cardiology Imaging Systems • Patient Self-Service Kiosks • Stand-Alone Emergency Department Information Systems	• Critical care information systems • Emergency Department Information Systems as part of a CPR system • E-Prescribing • ERP • Next-Generation Enterprise Patient Financial Systems (U.S) • Remote hosting • U.S. Ambulatory Electronic Medical Records • Wireless Healthcare Asset Tracking	• Advanced Disease Management Support • Disaster Recovery and Business Continuity • Patient Portals (Access and Financial Transactions) • Personal Health Management Tools - Healthcare Providers	• Remote ICU
Low			• Preoperative Charting and Anesthesia • Documentation within the CPR	• Patient Decision Aids - Healthcare Provider

1.5. Detailed Analysis of the Technologies on the Hype Cycle

On this part, selected technologies on the hype cycle will be examined in details according to their place on the cycle. Benefit ratings and maturity levels are explained in Table III and Table IV .

Table III: Benefit Ratings

Benefit Rating	Definition
Transformational	Enables new ways of doing business across industries that will result in major shifts in industry dynamics
High	Enables new ways of performing horizontal or vertical processes that will result in significantly increased revenue or cost savings for an enterprise
Moderate	Provides incremental improvements to established processes that will result in increased revenue or cost savings for an enterprise
Low	Slightly improves processes (ex: improved user experience) that will be difficult to translate into increased revenue or cost savings

Table IV: Maturity Levels

Maturity Level	Status	Products/Vendors
Embryonic	* In labs	* None
Emerging	* Commercialization by vendors * Pilot and deployments by industry leaders	* First generation * High Price * Much customization
Adolescent	* Maturing technology capabilities and process understanding * Uptake beyond early adopters	* Second Generation * Less customization
Early mainstream	* Proven technology * Vendors, technology and adoption rapidly evolving	* Third Generation * More out of box * Methodologies
Mature mainstream	* Robust technology * Not much evolution in vendors or technology	* Several dominant vendors

1.5.1. On the Rise

1.5.1.1. Advanced Disease Management Support

Advanced disease management systems are designed to support provider efforts on managing the course, progress and outcome of care for significant disease processes, both chronic and acute, through a continuum of care spanning setting and time. Significant disease processes are those with high volume, high risk or high cost. Benefit rating of these systems is moderate and the maturity is embryonic.

Although there have been very few formal disease management efforts can be seen, by implementation of the computer based patient record systems and electronic medical record systems, accessing to digital healthcare date and advanced clinical decision support systems will improve the ability to perform disease management. Importance of advanced disease management systems has taken attention by the healthcare providers. Implementation of these systems will result in increased clinical quality and cost reduction.

1.5.2. At the Peak

1.5.2.1. Personal Health Management Tools

Personal health management tools are online applications to help patients managing their own health and disease processes. These applications generally consist of routine screenings, exercises, disease identification, and common treatments and so on. Patients can keep track of their diet, exercise and routine care and also monitor typical chronic illnesses such as diabetes. Advanced applications are planned to work with computer based patient records and electronic medical records and so on.

Although there have been an interest on online personal health management tools for a long time, available tools were very simple that only tracks weight or health status. As the consumer involvement is advanced, better tools have been grown very quickly. Benefit rating of these tools is moderate. Once these tools are capable of working with patient data, healthcare providers will be the dominant supplier of this market. However this will require some time as not many organizations are focused on this market.

1.5.2.2. Advanced Clinical Research Information Systems

An advanced clinical research information system (ACRIS) is a combination of capabilities that can rapidly assemble data assets for research questions and provide data mining and research process support to meet the needs of clinical and translational research. Once the computer based patient records are spread, more valuable data will be available for the systems to support care rather than research, and is one trigger for this demand.

An ACRIS includes are data warehouse and is capable of bringing data from CPR systems and other clinical sources. Moreover, it enables data acquisition and puts into a common frame of reference from a big data source diffused in several places throughout the institution. Also, it ensures patient privacy and security mandates.

Enterprise data warehouse and other tool investments may be shared between ACRIS and an enterprise business intelligence system that assembles data from some of the same sources but for the purpose of performance management. However, the requirements for clinical research are very different and much more complex than the requirements for business intelligence (BI).

Increased adoption of commercial CPRS and rapidly increasing interest for genomics and translational research triggers the demand for ACRIS. Translational research means that research transforms scientific discoveries arising from laboratory, clinical or population studies into clinical applications to reduce the risk of disease, morbidity and mortality.

ACRIS market is a subset of the total health system market and mostly limited to academic medical centers and some private health systems. As a result, adoption is measured against a much smaller set of organizations than most other applications in the Hype Cycle.

Academic medical centers which do not invest in ACRIS will face difficulties competing for research contracts and grants. Benefit rating of ACRIS is high and the maturity is embryonic.

1.5.2.3. Personal Health Records

Personal health records (PHR) are electronic applications by which individuals can access their health information and share their information with authorized people in private. These technologies can also improve healthcare by enhancing the users' interactions with healthcare providers enabling choosing better care options.

The information in the PHR should be under control of the individual described by the record and should offer the consumer the ability to accumulate data originating in the systems of many healthcare organizations.

PHR are present for almost 10 years and for the last 3 years, they have been getting a high level of attention from employers and government agencies. However the necessity for consumers to enter their own data in U.S. has blocked receiving the data electronically from the sources.

In 2007, Google Health and Microsoft HealthVault have entered the PHR market. The influence and the marketing prowess of these companies can provide a high level of interoperability among PHR and the IT systems of care delivery. Moreover, efforts by these companies have increased the public attention on PHR.

PHR provide consumers a shareable medical record and improve patient safety and quality through the availability of the clinical data at the healthcare point. Advancing in PHR can accelerate the information system support needed for medical home care models. Benefit rating of PHR is high and the maturity is emerging.

1.5.2.4. Patient Throughput and Logistics Management

Patient throughput and logistics management (PTL) is a next generation evolution that springs bed board/bed management applications as well as current patient and healthcare asset location systems. Moreover, these systems aim to provide real-time visibility into operations, patients and resources. PTL analyzes patient flow, anticipate downstream demand, monitor and alert to progress against clinical pathways and adjust in real time to changing circumstances. For contributing higher values, PTL applications require to work with multiple other applications.

Importance of optimizing patient throughput and capacity management is well understood by most healthcare organizations. Bed boards in emergency departments are fairly common and bed board applications to facilitate patient flow and nursing are also finding their places in the market. PTL applications are not yet fully substantiated and offer long term potential to improve efficiency and effectiveness of healthcare delivery organization processes; however their benefit rating is high and the maturity is emerging.

1.5.2.5. Home Health Monitoring

Home health monitoring is the use of IT and telecommunications to monitor the health of patients in their homes to help ensure that appropriate action is taken. Devices that are given to the patients, measure variables like blood pressure, pulse, blood oxygen level and weight and so on and deliver the data to the clinicians. In addition to these devices, other devices are used for messaging and getting information from patients about symptoms and behaviors and giving advice.

Home health monitoring is suitable for chronically ill, homebound patients who are needed to be monitored frequently. If home health monitoring can be implemented correctly, it could be a very powerful tool and reduce the requirement of the patient to travel to the hospitals and can avoid delaying admission into inpatient facilities. There are technical (exchanging data between monitoring devices and electronic medical record applications) and non technical barriers (legal and licensing restrictions) for home health monitoring. Moreover, new ways of staffing and information sharing are required.

Many of the deployments of home health monitoring are pilot projects which are generally funded by governments or vendors, but there are some important examples of standardized ongoing services. U.S Department of Veterans Affairs (VA) has deployed home health monitoring for patients with chronic heat failure, chronic obstructive pulmonary disease, diabetes and depression. According to the estimates of VA, by 2011, home health monitoring will enable half of its patients who would previously have needed to live in nursing homes to live at their homes. The Canada Health Infoway program is making high investment in home health monitoring. On the other hand, in Europe, use of home health monitoring is limited at present and in Asia/Pacific, home health monitoring is in its infancy. Benefit rating of home health monitoring is high and the maturity is adolescent.

1.5.3. Climbing the Slope

1.5.3.1. Computer Based Physician Order Entry

Computer Based Physician Order Entry (CPOE) is directly inputting by a physician of orders into an acute care automation system. This contains both physician preferences and predefined order sets. Once the clinical decision support systems become more sophisticated, CPOE will highly rely on automated clinical decision support.

CPOE is one of the highest value aspects of implementing a computer based patient record system, but in order to imply CPOE, there has to be a successfully working computer based record system. As a consequence, CPOE will always lag behind CPR adoption. Moreover, CPOE is difficult to implement specifically for care delivery organizations with a large proportion of community physicians. But, on the other hand, it represents an opportunity to reduce practice variability.

CPOE cam result in improved physician efficiency and dramatic medical error reduction related to ordering process. As a result, it improves quality in the clinical care process. Order sets are started to be used to enable care delivery organizations to encourage best practice medical care in line with recommendations arising from the practice of evidence based medicine. Benefit rating of CPOE is high and the maturity is early mainstream.

1.5.3.2. E-Prescribing

E-prescribing is using software and connectivity tools by physician offices ad ambulatory clinics to create and send prescriptions electronically directly to pharmacy or to a printer. It has reduced medication errors, improved efficiency and lowered medication costs. Expectedly, there is a high interest on e-prescribing by healthcare organizations. For physician offices, e-prescribing enables clinical productivity, operational efficiency, patient safety and patient/customer satisfaction. Benefit rating of e-prescribing is moderate and the maturity is adolescent.

1.6. Clinical risk management: Models and Methods

Clinical risk management is applied research field which stimulates patient safety with managerial methods. There are very few practical implementations of risk management methods in the health sector and statistical data is lacking. Therefore, there is a significant interest on adopting the methods for controlling operation risks in the industrial sector to the hospital settings by the clinical operators and researchers.

One of the advantages of evaluating industrial approaches for handling risks is that generally, healthcare practitioners are not familiar with the terms to describe the concepts related to “error”, “threat”, “hazardous condition”, “incident”, and “adverse event” and so on. It is an important step that hospital managers and operators are aware that the risk is defined as the product of probability of an error mode and the severity of it is consequences. In addition, “adverse event” is an injury caused by medical management regardless of the condition of the patient. According to Reason (1990) the error definition is the failure of a planned action to be completed as intended (i.e. error of execution) or the use of wrong plan to achieve an aim (i.e. error of planning). Therefore, it can be concluded that a

medical error is not a clinical failure, but a care treatment which shifts the risk level of a patient above the acceptable limit related to the disease.

Generally the researches are dealing with development or evaluation of methods which take into single safety issues and/or specific care processes. Considering the patient safety as an organizational issue and the study of the industrial attitudes towards operation risks, overall approach can be considered as a continuous improve cycle (Deming, 1986) which is depicted in Figure 4.

Figure 4: Clinical Risk Management Phases

Continuous Improvement Cycle has 4 periods that follow each other continuously. 1st step is the identification of the objectives. This is done by the top management; however information sharing should be done with the people who are involved. 2nd step is the evaluation and done by the clinical operators and risk assessment experts. Output of this step is the proposition of some corrective actions for reducing risks. 3rd step is the implementation of the actions. 4th step is the assessment where the effects of the actions are monitored and overall results are evaluated.

Methods for clinical risk management in the literature are mainly on the 2nd and 4th steps. In the following paragraphs some methods will be briefly examined.

- **Root Cause Analysis (RCA)** is the most common retrospective method for risk analysis in healthcare. It deals with the identification of human and system factors that have an effect on adverse event or a near miss that occurred within a specific care setting (Ministero della Salute, 2004; Timmons and Marx, 2004). It is a complex and time-consuming method and requires quality experts and consultants for the planning and execution of the analysis (Pradhan et al. 2001). In most of the cases an accident cannot be referred to a single (or few) root cause; therefore the effectiveness of this method is still in doubt (Vincent, 2003).
- **Incident, near miss and sentinel event reporting** are other retrospective methods that the healthcare managers and practitioners are into. When an incident occurs, a form in paper based or electronic form is filled by an operator who confirms the event and its characteristics. To

provide statistical analysis, forms are saved in a structured database. Depending on the policies of the national health systems, reporting could be voluntary or mandatory. Although there are some doubts about completeness and reliability of the reporting systems (Pietro et al., 2000; Naeessens et al., 2009; Office of Inspector General, 2010), reporting systems are spread due to their easiness and flexibility.

- **Failure Mode, Effects and Criticality Analysis (FMECA)** structure procedure for the identification and prevention of problems in process before their occurrence. It is a prospective method and well known in the industrial sector. It suggests improvements to the existing system and it does not require any accidents or near misses to have happened. The probability of failure modes and severity of their consequences are estimated with a scale. Risk Priority Number(RPN) is calculated by:

$$RPN = OSR\ x\ SSR \quad \text{Equation 1}$$

Where OSR stands for "Occurrence Scale Rank" and SSR stands for "Severity Scale Rank".
Criticality Index (CI) is calculated by:

$$CI = OSR\ x\ SSR\ x\ DSR \quad \text{Equation 2}$$

Where DSR stands for "Detectability Scale Rank".

Tradition 1 to 10 ranking is applied by the user to the occurrence, severity and detectability. Although equations are involved, this method is qualitative, because it does not need to refer to statistical data but only to estimation. After deciding on the priorities, a "FMECA Worksheet" is prepared to analyze risks and identify corrective actions. FMECA is an effective method for improvement without statistical data.

- **Healthcare Failure Mode and Effect Analysis (HFMEA)** is developed by National Center for Patient Safety of the Department of Veterans Affairs (De Rosier et al., 2002), to develop the adoption of FMECA. It is a predictive and qualitative analysis and requires some other tools:
    - The HFMEA Worksheet that follows all the steps of analysis.
    - The Hazard Scoring Matrix for the calculation of the Hazard Score that identifies the risk level of a failure mode.
    - The Decision Tree that supports the detection of the failure modes which require an organizational intervention in order to be put under control.

Although it is a qualitative method, HFMEA is proved to be very effective to support decisions on very important aspects of the system. When no statistical data is present, HFMEA is one of the best methods for analysis. On the other hand, there is a design error on HFMEA since estimation of severity is also a source of risk which does not make sense, because severity should be evaluated on the effects.

- **Clinical Risk and Error Analysis (CREA)** is a quantitative method which supports analysis related to organizational vulnerabilities within healthcare settings (Trucco and Cavallin, 2006). For the

objective basis for risk evaluation, available data and information in the literature is used. CREA consists of 4 phases:

- Identification and description of the process' activities.
- Detailed analysis of the specific tasks within each activity considering the cognitive work done by the operators, through the Cognitive Task Analysis (Schraagen et al., 2002);
- Identification and classification of the error modes with respect to the activities according to the Human Hazard and Operability Study technique (Redmill et al., 1999)
- Risk assessment by calculating risk values for error modes in each activity, from the judgments of an expert panel by using available data in literature.

CREA can be considered as the most complete and accurate method, however it requires statistical data where in many cases it is not available. Moreover it requires collaboration between clinical operators and management experts. As a result costs could be higher. Moreover CREA does not provide suggestions for corrective actions.

1.7. Ten Years after: advances and limitations

Trying to measure the advances and the limitations is also another contribution to the patient safety researches. First of all, one of the important problems is that safety is defined as the absence of adverse events; therefore it is not measurable (Hollnagel, Woods and Leveson, 2006). As a result, safety is generally measured in a negative way, namely, the number of adverse events which occur within the system. Moreover, a method for identifying adverse events and detection methods for different adverse events are still missing (Naessens et al., 2009). In addition, investments in information systems are required to reduce the burden of data collection (Pronovost et al, 2004).

Despite the lack of reliable information on safety and quality in literature, after the publication of "To Err is Human" report (Kohn et al., 2000) there has been an opportunity for researchers to make progress on patient safety on a system level. However, there had been no significant improvement observed 5 years after the IOM report (Wachter, 2004; Leape and Berwick, 2005; Longo et al., 2005). But this situation is changed in 2009-2010. Good commitment towards patient safety was found among healthcare managers and practitioners; but no significant changes in the rates of adverse events were observed (de Vries et al., 2008; Agency for Healthcare Research and Quality, 2009; Department of Health and Human Servies, 2010; HealthGrades, 2010; United States Government Accountability Office, 2010; Wachter, 2010).

1.8. Current eHealth policy and commercial environment in Europe: an overview

1.8.1. EU eHealth policy context

Information has a significant role in the provision of healthcare. Hospitals create and process information when they attend to patients. Meanwhile, patients also create, access, process and exchange information about their health. Information and communication technologies (ICTs) about health may have a big impact on the management of this data in terms of efficiency, financial savings, quality of care and patient safety.

European healthcare systems are the basis of Europe's social infrastructure. Goals and priorities like universality, access to good quality care, equality and solidarity are commonly shared although there are differences in terms of operational and financial structure. In addition to common goals and priorities, EU states also share common challenges. Population ageing has a direct impact on the overarching dependency factor and pathological map of Europe. Pomerleau et al., (2008) state that ageing is changing disease composition with a rise in chronic diseases. However these are not limited to ageing. Artman et al., (2007) state that the increment in chronic diseases is also related to unhealthy behavior. As the citizens are provided more and better information about healthcare they are indirectly pushed for better quality and safety.

In Europe, there exist 3 methods for healthcare financing: a system on public taxation (the Beveridge model), compulsory social insurance (the Bismarck model) and private finance through voluntary insurance that operates on top of standard social insurance. Moreover, there is also several cost sharing mechanisms through which patients contribute to healthcare financing. However these mechanisms are not compatible with low-income citizens. In this context, the provision of healthcare services using innovative ICTs is seen to be one of the elements helping the containment of healthcare delivery costs while maintaining the expected levels of quality of care and safety (Akematsu et al., 2009).

1.8.2. Current and future market size for eHealth in Europe

Social and policy factors that are explained above, is the basis of a demand for eHealth services and applications in Europe. According to the analysis by Capgemini Consulting, the European eHealth Market was estimated as 14.269 million Euros in 2009 and expected to read 15.619 million by 2012 with a growth rate of 2.9%. France, Germany, Italy, Spain and the United Kingdom are the principal European eHealth markets. Figure 5 shows the total eHealth market in 2008 and 2012 for European countries.

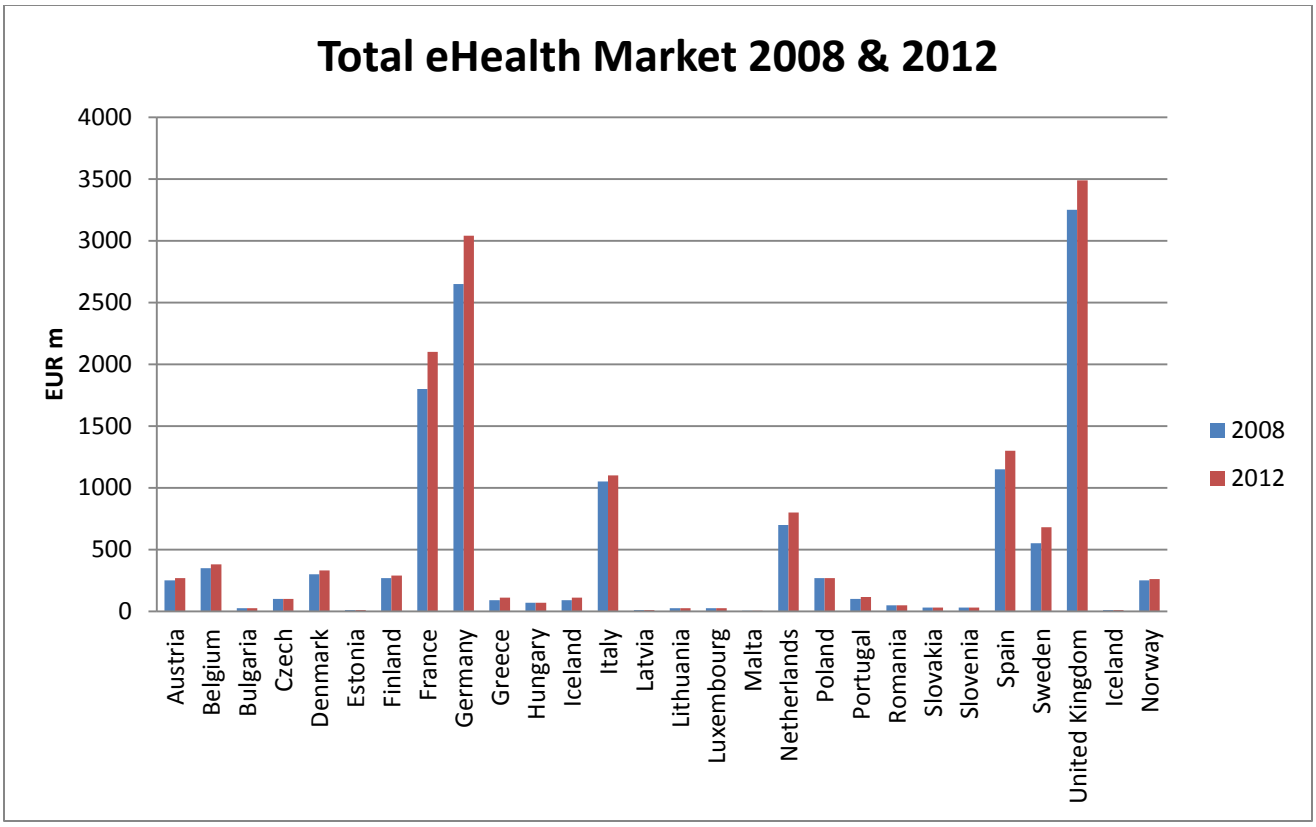

Figure 5: Total eHealth Market

Differences in the current and future market size of the four specific markets identified by the European Lead Market Initiative and are described in the Table V.

Table V: Lead Market Initiatives: market sectors

Market	Description
Clinical Information System (CIS)	(a) Specialized tools for health professionals within healthcare institutions (e.g. hospitals). Examples are radiology information systems, nursing information systems, medical imaging, computer-assisted diagnosis, surgery training and planning systems, (b) Tools for primary care and/or for outside care institutions, such as general practitioner (GP) and pharmacy information systems.
Secondary Usage Non-clinical Systems (SUNCS)	This category includes: (a) System for health education and health promotion of patients / citizens, such as health portals or online health information services, (b) Specialized systems for researchers and public health data collection and analysis, such as biostatistical programs for infectious diseases, drug development and outcome analysis; (c) Support systems such as supply chain management, scheduling systems, billing systems, administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals.
Telemedicine	Personalized health systems and services, such as disease management services, remote patient monitoring (e.g. at home), teleconsultation, telecare, telemedicine and teleradiology.
Integrated Health Clinical Information Network (IHCIN)	Distributed electronic health record systems and associated services, such as e-prescriptions ore-referrals.

In addition, Secondary Usage Non-clinical systems (SUNCS) accounted for 71.6% of the total eHealth market in Europe. Clinical Information Systems (CIS) represented about 13.5% of the total European eHealth market and Integrated Health Clinical Information Networks (IHCIN) fare at about 5%. Telemedicine is accounted for 0.9%. Between 2008 and 2012, eHealth systems are targeted more towards supporting the operational processes of healthcare professionals. Figure 6 shows the eHealth market compounded annual growth rate between 2008 and 2012 per market sector.

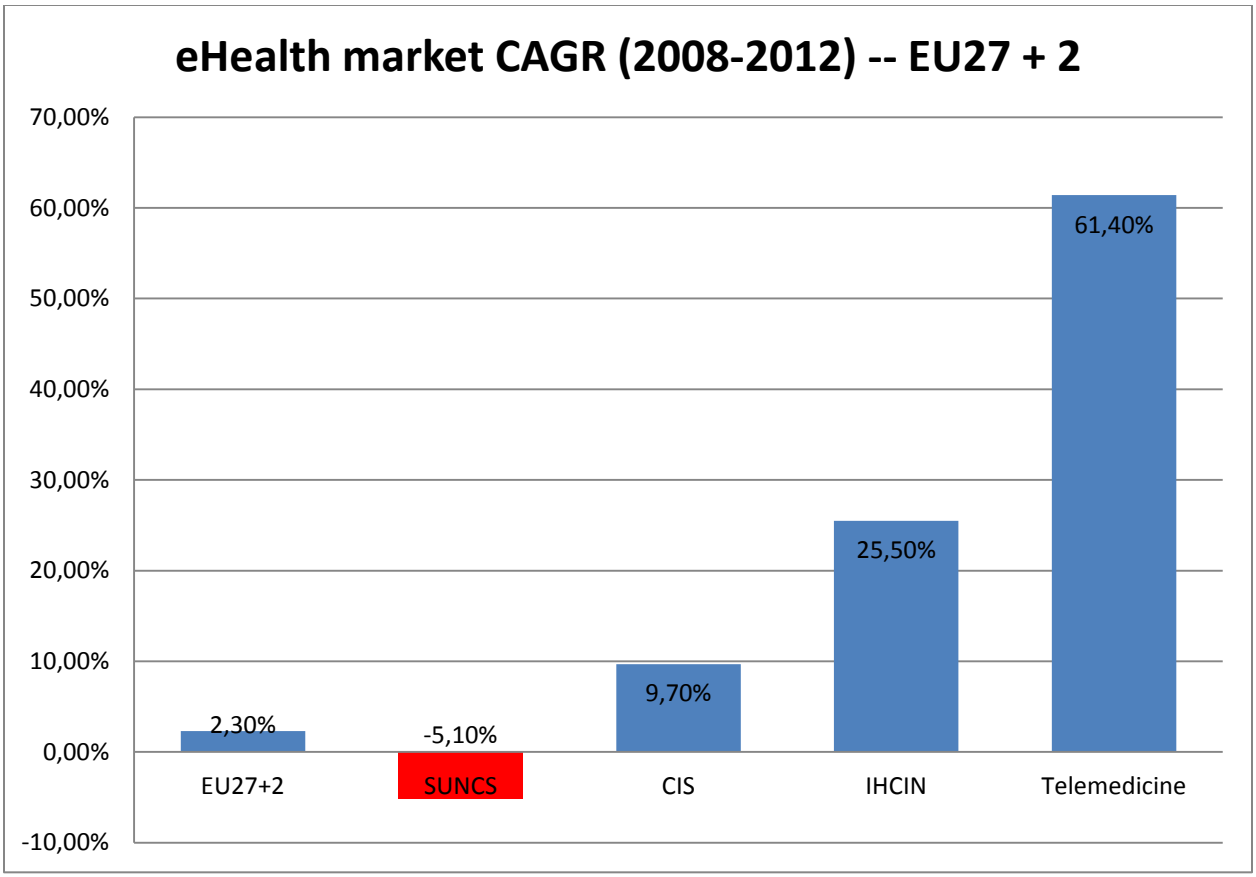

Figure 6: eHealth market compounded annual growth rate between 2008 and 2012 per market sector

Figure 6 represents that eHealth is a significant commercial opportunity for European industry.

Following Figure 7, Figure 8, Table VI and Table VII summarize the computer and internet usage, different electronic data storage and electronic exchange of data in top European countries and show the average of European Union countries. All the numbers are the percentages.

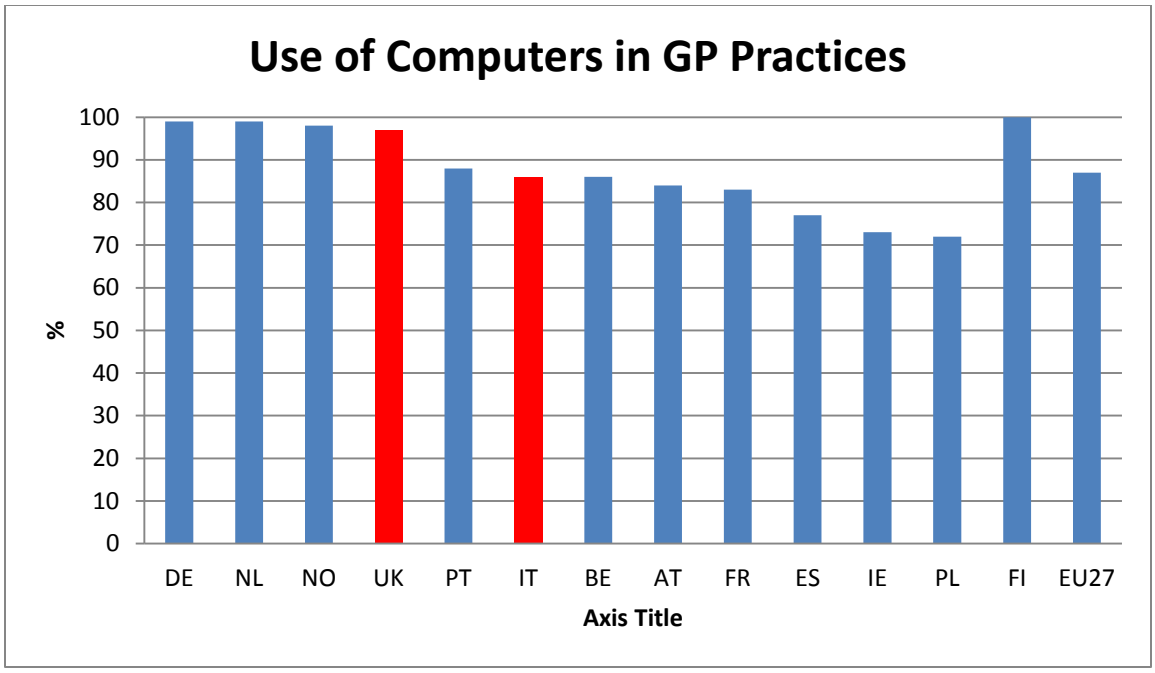

Figure 7: Use of computers in GP Practices

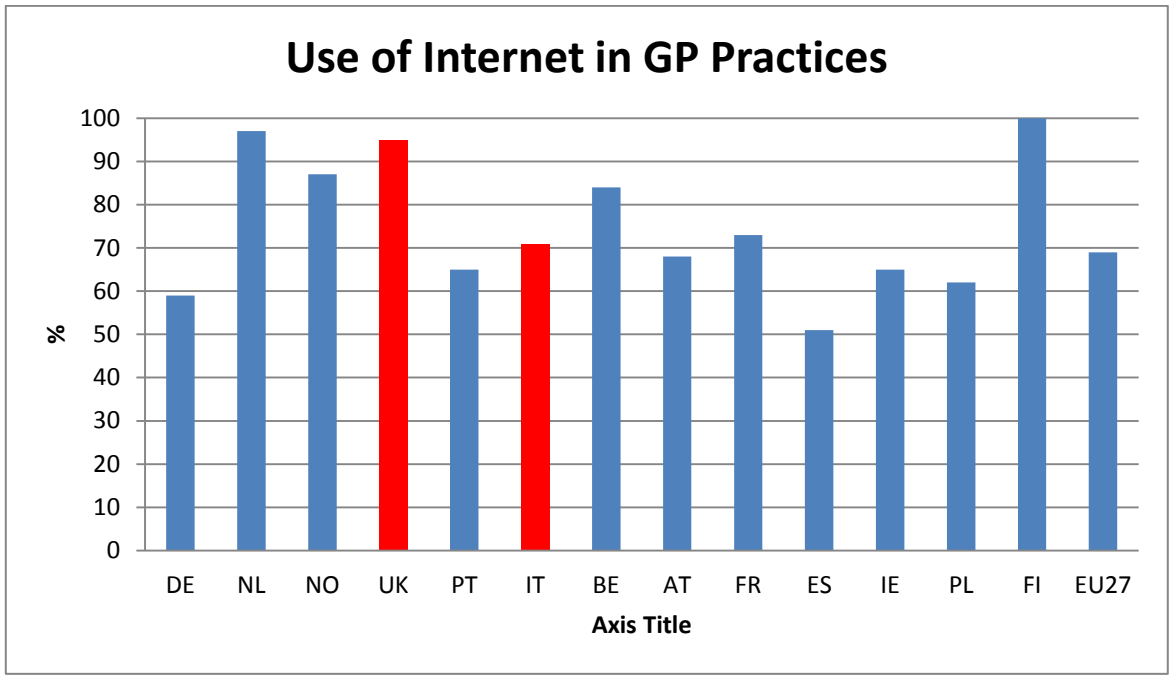

Figure 8: Use of internet in GP Practices

Table VI: Electronic Data Storage of different types

%	DE	NL	NO	UK	PT	IT	BE	AT	FR	ES	IE	PL	FI	EU27
Diagnoses	99	96	100	94	77	85	93	88	89	89	79	73	81	90
Medications	93	97	99	98	85	95	93	84	91	94	95	55	96	90
Basic medical parameters	80	94	84	98	63	85	91	80	93	88	85	35	90	83
Lab Results	78	95	98	96	59	75	96	79	77	81	82	53	98	79
Symptoms/reasons for encounters	67	96	95	92	73	64	89	82	92	82	80	46	96	77
Medical history	52	95	97	95	63	70	89	69	89	86	84	46	98	75
Examinations and results	56	95	98	88	67	82	87	76	81	81	68	55	98	75
Vital signs measurement	59	92	85	92	70	69	88	63	88	80	73	34	93	74
Treatment outcomes	52	94	91	77	52	58	81	77	66	76	53	49	88	65
Radiological Images	15	43	54	30	29	5	53	49	65	55	23	40	95	34

Table VII: Electronic Exchange of Different Types of Medical Patient Data

%	DE	NL	NO	UK	PT	IT	BE	AT	FR	ES	IE	PL	FI	EU27
Medical data with careers	4	26	35	26	8	7	13	12	5	13	2	2	55	10
Analytic results from labs	63	84	88	85	1	8	73	37	33	30	40	10	90	40
Telemonitoring	1	3	0	2	1	0	1	1	1	1	1	0	1	1
Medical data across borders	0	5	0	0	0	0	1	1	2	1	0	0	0	1

1.9. Healthcare system setting in Italy

1.9.1. Country Introduction

Italy consists of 20 regions, 105 provinces and 8.100 municipalities. Italian healthcare system is based on universal coverage free of charge at the point of service. Within the system, there are 3 levels: national, regional and local. National level ensures the general objectives and fundamental principles of the national healthcare system. Regional governments ensure the delivery of a benefit package through a network of population based health organizations and public and private accredited hospitals.

In Italy, life expectancy at birth is 81.6 years, healthcare expenditure as % of GDP is 8.7%, and public sector healthcare expenditure as % of total healthcare expenditure is 76.5% (OECD 2007).

1.9.2. ICT use among general practitioners

Following results belong to 2007 however there is no recent European survey available. 86% of the Italian general practitioner practices use a computer where this is a very high percentage among its European neighbors. Right now, 71% of the Italian practices are connected to Internet of which around %50 have broadband connections. Considering the usage of eHealth applications, best results are achieved for the storage of administrative data and the use of a computer for consultation. Electronic patient data storage is also common in Italy. At least one type of individual medical data is stored in 83% of the general practitioner practices. In the consultation room, a computer is available in 84% of the Italian general practitioner practices. Almost all of these practitioners use the computer for consultation with the patients. 69% of the Italian general practitioners use a decision support system. 8% of the general practitioner practices receive results from laboratories and the ePrescribing usage is 1% in Italy. eHealth usage in Italy is depicted in Figure 9.

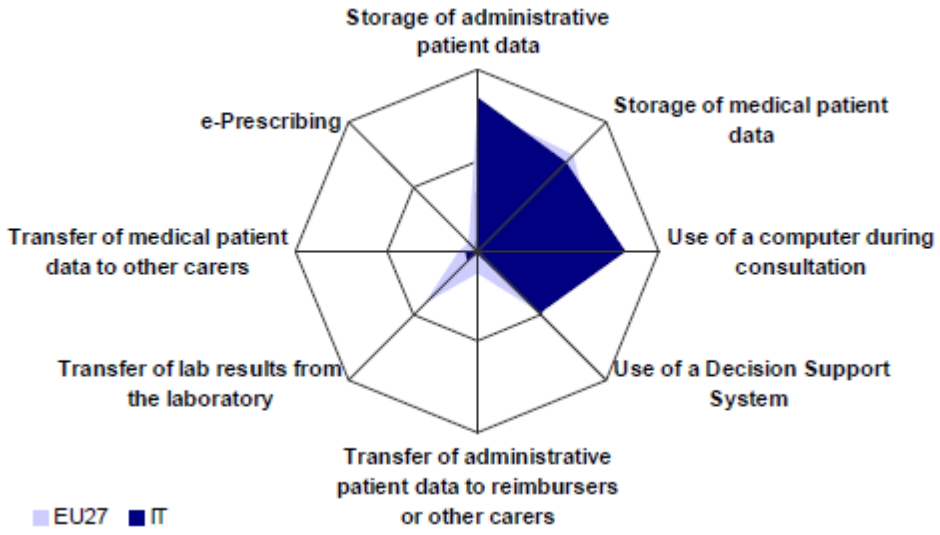

Figure 9: eHealth usage in Italy

1.9.3. Deployment of eHealth applications

1.9.3.1. Patient Summary and Electronic Health Record (HER)

Patient summary projects at national level in Italy:

- Technological infrastructure of patient summaries (Infrastruttura technologica del FSE): Involved in this project are the Ministry for Public Administration and Innovation and the National Centre for Research. Stipulate protocol and activation of the project is completed and the working in progress is 40%.
- National interoperability project of patient summaries (Interoperabilita nazionale del FSE): Involved are Ministries of Labor, Health and Social Policy. Furthermore, at the regions Lombardy, Friuli-Venezia Giulia, Veneto, Emilia-Romagna, Tuscany, Umbria, Marche, Sardinia, Abruzzi, Molise, Stipulate interregional agreement and execution of the project is completed.
- Pre-disposition guidelines of patient summaries (Tavolo tecnico MLSPS – DDI – DigitPA – Garante Privacy – Regions). Status of the project is 90%.

These projects are linked to the "E-Government Plan 2010" which was developed by the president of the council together with the minister for Public Administration and Innovation. The goal is to develop an 'electronic health records' (FSE) for compatible regional health systems, both Italian and European.

1.9.3.2. ePrescription

Pilots for the regional use of ePrescription are ongoing in Lombardy and Emilia-Romagna since 2002. In Lombardy the main project is "Healthcare Extranet" (SISS), which links operators, social services, organizations and citizens, tracking all the events which occur in the patient treatment and providing value added services. In Emilia-Romagna the program is called "SOLE – Online Healthcare". In this project, it is aimed to develop an integrated telematic network for the interoperation of hospitals and healthcare professionals to provide value added services to citizens. This is achieved by:

- Electronic management of prescription – referring to life cycles
- A regional registry that indexes clinical events stored into healthcare structures
- Electronic management of the pharmaceutical prescription life cycle. It is still ongoing. In comparison, the relative share of ePrescription compared to paper-based prescription is less than 20%.

1.9.3.3. Telemedicine

For telemedicine, different projects and pilots are ongoing in Italy, two of these projects are:

- The IBM project for teleassistance at home (2009)
- The participation in a home monitoring system project by Spanish research and development firm "Telefonica"

Other telemedicine services in Italy are:

- Home telemonitoring services concern chronic diseases (diabetes, COPD, Congestive Health Failure)
- Teleconsultation (doctor-to-patient) service is not much common, mainly used in relation to telephone consulting about chronic diseases
- Teleconsultation or videoconferences between health professionals mainly concern second opinion about image processing (radiology, neuroradiology)

Another important telemedicine project ongoing in Italy since 2010 is the "Renewing Health" project which aims to implement large scale real-life test beds for the validation and subsequent evaluation of innovative telemedicine services using a patient-centered approach and a common rigorous assessment methodology.

1.10. Healthcare System Setting in United Kingdom

1.10.1. Country Introduction

Total population of United Kingdom is 61,411.69 (OECD 2008).

Life expectancy at birth is 79.9 years (OECD 2007).

Healthcare expenditure as a % of GDP is 8.4% (OECD 2007).

1.10.2. Healthcare service providers

There are 152 Primary Care Trusts in England which are responsible for the commissioning of health services for their local population. Primary Care Trusts take care of approximately 80% of the total National Health Services budget, managing budgets for local services. National Health Care services are run and managed by National Health Care Trusts. There are 3 main types of trusts:

- Acute trusts, providing medical and surgical care and are usually centered on a teaching or district general hospital
- Mental health trusts, either providing services in hospitals or in the community
- Ambulance trusts

Important features of primary healthcare organization in England are tabulated in Table VIII.

Table VIII: Important features of primary healthcare organization in England

Political/Administrative unit responsible for primary health care	The National Health Service provides the majority of healthcare in England, including primary care, in patient care, long-term healthcare, ophthalmolgy and dentistry. The national Health service Act 1946 came into effect on 5 July 1948. Private healthcare has continued parallel to the National Health Service, paid for largely by private insurance: it is used by about 8% of the population, generally as an add-on to NHS services. In the first decade of the 21st century the private sector started to be increasingly used by the NHS to increase capacity.
Consumer Choice	General practitioners are usually the first point of contact for nearly all National Health Service patients. They can direct a patient to other National Health Services. A person has the right to be registered with the general practitioner surgery (i.e., office) of their choice. It is the general practitioner who advises the patient about choosing the best.
Financing	The National Health Service is largely funded from general taxation. The government department in England responsible for the National Health Service is the Department of Health. Scotland, Wales and Northern Ireland have their own devolved health administrations. Most of the expenditure of the Department of Health in England (£98,7 billion in 2008/2009) is spent on the National Health Service.
Public or private providers	Many general practitioners are self-employed. They hold contracts, either on their own or as part of a partnership, with their local primary care trust. The profit made by general practitioners varies according to the services they provide for their patients and the way they choose to provide these services. Those salaried general practitioners who are employed directly by primary care trusts earn between £53.249 to £80.354 a year depending on their length of service and experience.
Gatekeeping function of the General Practitioner (GP)	General practitioners are usually a patient's first contact point. If a patient needs to go to hospital to see a specialist, he/she has the right to choose to which hospital the general practitioner refers him/her. This legal right was introduced in April 2009. It enables the patient to choose from any hospital offering a suitable treatment that meets National Health Service standards and costs. The patient can choose the hospital according to what factors matter most, including location, cleanliness, waiting times, reputation, clinical performance, visiting policies, parking facilities or patients' comments.

1.10.3. Deployment of eHealth Applications

1.10.3.1. Patient summary and electronic health record

Summary Care Report (SCR) is used in England for basic patient summary. It has been piloted in 2007 and implemented nationally in 2008. A great percentage of practitioners have been using computers since mid-nineteen eighties, as a result they used some form of a patient record. SCR Record contains significant information about demographic details, medications, allergies and adverse reactions to support safe treatment in emergency care.

Data are kept in the Personal Spine Information System (PSIS) database which is one part of the NHS Care Records Service. The other important data component is the Personal Demographics Service (PDS) database which holds each patient's demographic information. It was implemented in 2004. ePrescriptions and Choose and Book services support these spine applications.

Summary Care Records are viewed in emergency care settings, for example in general practitioner out of hour's services, walk in centers and hospital emergency departments. These records can be viewed by authorized staff through web based summary care report or through clinical systems which are directly integrated with summary care records.

1.10.3.2. ePrescription

ePrescribing and Electronic Prescription Service (EPS) are used for electronic prescribing in England.

EPS involves the generation, transmission, receiving and dispatching of the prescription for payment. The Department of Health stated in September 2009 that "in terms of services currently routinely used by clinicians and patients, on any typical day in NHS the national program already enables: Over 500,000 prescriptions to be transmitted electronically, reducing errors and inefficiencies".

ePrescribing is aimed at hospitals and other acute healthcare settings. It also has a decision support component. Some kind of electronic prescribing is used for over ten years in several institutes.

Right now, there are three challenges in England for ePrescribing: organizational, resourcing and technological issues.

Considering the organizational perspective, healthcare staff must acquire confidence in the technology in order to adopt it which includes changes to job design and work organization. In addition, external and internal IT support and healthcare staff time are required for implementation and for training.

1.10.3.3. Telemedicine

Currently different alarm systems (including e.g. a personal alarm or motion sensors) and telehealth equipment for home monitoring of e.g. blood pressure, blood glucose are available in England.

Public financing of telemedicine and telehealth services in England is provided in many forms. Examples include ICT equipment, software and skills training in eHealth, scholarships for formal education in eHealth, initiation of regional pilot projects and ongoing support for eHealth programs.

1.10.3.4. Financing and reimbursement issues

The department of Health has an overall annual budget of approximately 100£ billion. The projected costs of national program for IT from 2003/04 to 2013/14 were 12.7£ billion at 2004/05 prices. To march 2009, 4.5 £ billion had been spent. Table IX shows the details (source Public Expenditure on Health and Personal Social Services 2009) of English expenditure on health and personal social services. All figures in the table are in GBP millions.

Table IX: Public Expenditure on Health and Personal Social Services in England

	Category	Projected lifetime costs	Expenditure to 31 March 2009
Core Contracts			
	London	1.021	326
	South	1.104	133
	North East	1.035	276
	East	930	237
	North West & West Midlands	1.042	271
	Spine	889	791
	N3 Network	554	554
	Choose and Book	144	133
	Amount retained by Accenture	110	-52
Total core contracts		6.829	
	Products added to scope	666	420
	Other central costs	1.599	615
Total central costs		9.094	
	Local costs (estimated)	3.562	772
Total		14.921	4476

1.11. Chapter Review

In this chapter, patient safety as an organizational issue was described briefly from birth to development. Effect of the "To Err is Human" report by U.S. Institute of Medicine (Kohn et al., 2000) and the hype cycle (Gartner, 2008) were examined in details. Models and Methods which are developed in last 10 years are explained with their benefits and limitations. Lastly, main problems of safety measurements and the requirement of more effective solutions have been noted.

Current and Future of the market size in Europe is stated. Moreover healthcare system setting for Italy and United Kingdom are also explained. These are the countries where the pilots are located.

2. The "ReMINE" Platform

2.1. Introduction

Recent studies imply that "Risk against Patient Safety (RAPS)" is one of the significant factors of death in hospitals. During the treatment process at the hospital, more than 8% of the hospitalized patients suffer from additional diseases. 50% of these diseases result in either death or serious health problems. RAPS may occur at any level of the patient care process.

Basis of the ReMINE Protocol comes from the difficulty in making a detailed analysis, an early identification and an effective prevention of RAPS when a large amount of inhomogeneous data sources that are stored in multimedia databases and different care professionals are involved.

With the definition of framework architecture, demonstrated and confirmed in a proof of concept, a collection and analysis of RAPS related data and a semantic approach which provides a fast and secure extraction of data, ReMINE will improve the RAPS management process.

Futures of ReMINE are:

- Time reduction in collecting data;
- Time reduction in RAPS analysis;
- Standardization of common language;
- Evolution in the interaction model;
- Reference framework;
- Patient safety Improvement;
- Healthcare cost saving.

2.2. Overview of Business Rules for RAPS Prediction, Detection and Control

The "business rule" term can be found in several domains like IT and economics and so on and there is no unique definition. Generally the definition of the Business Rules Group is used: "A business rule is a statement that defines or constrains some aspect of the business. It is intended to assert business structure or to control or influence the behavior of the business" [http://www.businessrulesgroup.org].

It has been proved that using business rules increases the effectiveness and efficiency of business systems (Ross 2003). Business rules can be seen in several domains, but mainly known in software engineering (Ross 2003; von Halle 2001).

As there is no unique definition for business rules, there is also no unique classification scheme (von Halle 2001). For a very simple business rule structure, following classification can be made: comprising term, fact and a rule. An example can be given as "patient", "patient has pain" and "increase medication dose when patient has pain" respectively.

Scientific literature search for the ReMINE approach to RAPS prediction, detection and control based on Business Rules is done with the following restrictions:

- The medical domain is limited to the domains that are of interest to ReMINE project (obstetrics, treatment of stroke and treatment of Methicillin-resistant Staphylococcus aureus (MRSA) infections;
- Contributing factors are being defined as risk factors for the given medical domain that are not patient-related (age, smoking status, …) but related to the care personnel (workload of the staff, stress of nursing personnel, …) or within the organizational setup (few nurses during night shift, low qualified personnel, …).

2.2.1. Clinical Risk Management and Risk Contributing Factors

Clinical Risk Management is "organizational systems or processes that aim to improve the quality of health care and create and maintain safe systems of care" and it is important for ensuring patient safety. Moreover, organizational culture, learning from adverse events, risk assessment, training, induction, guidelines, communication, audit, claims and complaints are also included in clinical risk management (Scholefield, 2005).

With the traditional way of thinking, clinical risk assessment was following an event-based approach (Trucco et al., 2008). However, nowadays rather than individual factors, more attention is paid to organizational factors (Vincent et al., 1998). Vincent et al. used Reason's model of organizational risks to search for patient adverse events within different medical settings (Figure 10).

Decisions taken by the people at a higher level in the hierarchy (e.g. managers) can result in latent failures and these failures can provide the condition in which adverse events may occur (Vincent et al., 1998). Active failures are due to the actions of the frontline care personnel (e.g. nurses and physicians) (Vincent et al., 1998; Scholefield, 2005).

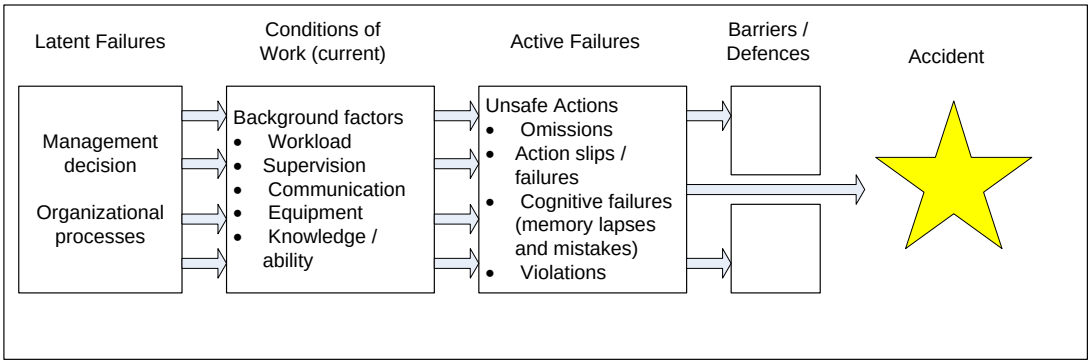

Figure 10: Reason's Model of Organizational Risks (source: Vincent et al., 1998)

Some of the conditions may not have an effect if an unsafe action is not combined with a dangerous situation which may result in an adverse event (Trucco et al., 2008). Anatomy of an accident by Trucco et al. is depicted in Figure 11.

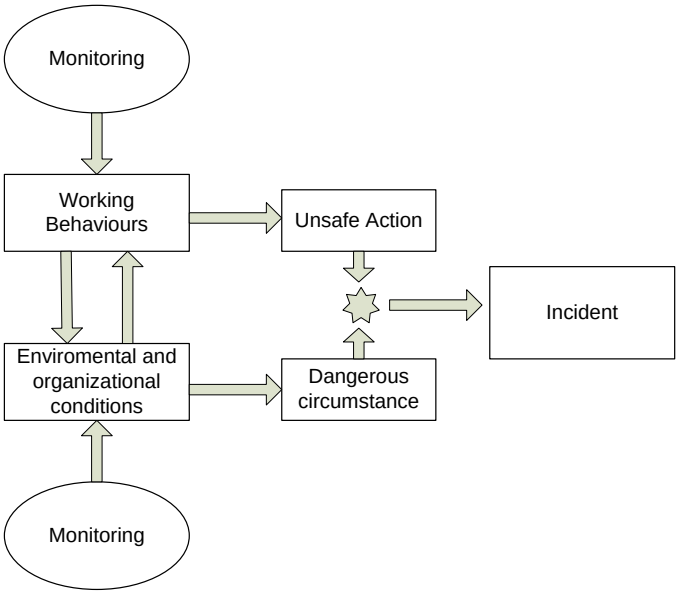

Figure 11: Anatomy of an accident (Trucco et al., 2008)

Numbers of factors that affect the clinical practice according to Vincent et al. are listed as follows:

- Institutional context
  - Economic and regulatory context
  - National Health Service Executive
  - Clinical negligence scheme for trusts
- Organizational and management factors
  - Financial resources and constraints
  - Organizational structure
  - Policy standards and goals
  - Safety culture and priorities
- Work environment
  - Staffing levels and skills mix
  - Workload and shift patterns
  - Design, availability and maintenance of equipment
  - Administrative and managerial support
- Team Factors
  - Verbal communication
  - Written communication
  - Supervision and seeking help
  - Team structure
- Individual (staff) factors
  - Task design and clarity of structure
  - Availability and use of protocols
  - Availability and accuracy of test results

- Patient characteristics
    - Condition (complexity and seriousness)
    - Language and communication
    - Personality and social factors

Patients' safety is mostly affected by medication errors (Brady et al., 2009). Medication errors form the one third of medical errors (Leape et al., 1991). %72 of the medication errors is due to the failure of the personnel to follow the policies and procedures (Long an Johnson, 1981).

According to Brady et al., factors that affect the medication errors are deviation from procedures, barriers to reporting, reconciling medical history and prescriptions, drug distribution systems and knowledge and skills (Brady et al., 2009). Higher workload results in higher rate of medication errors (Brady et al., 2009; Tissot et al., 2003). Possible reasons behind this are insufficient time to perform tasks, decreased motivation leading to lower quality of performance during job, more stress and burnout, decision making errors, violations in following rules and may lead to affecting the patient's safety of care. Moreover, working long shifts and working overtime may also increase the risk of medication error (Brady et al, 2009).

According to the study of Tang et al., most contributing factors to medication errors are personal neglect, heavy workload and new staff. This study is also coherent with the study of Beyea et al., where 30% of the medication errors are due to high workloads and inexperienced personnel (Beyea et al., 2003).

2.2.2. Limitations of Current Approaches and ReMINE Capabilities

Considering the medical area targets of ReMINE project, clinical risk management is mainly discussed within the domains of obstetrics and medication management.

Contributing factors are not providing a risk estimate. If a weighted fraction for each contributing factor or relative risk values or odds ratios were provided, this information could have been used for the development of predictive business rules in the ReMINE platform. Scholefield suggests "inexperience increases the risk of error four fold" and "unfamiliarity increases the risk of error by a factor of 17". However it is not clear what the author means by "risk of error" (Is this an adverse event occurring or deviation from the protocol and so on). Moreover, there is no information about if other variables are investigated or not, or at which department of the hospital these values are calculated. To sum up, more information on the quantification of the contributing factors should be provided.

To calculate probabilities of adverse events given the occurrence of certain contributing factors, Error and Risk Antecedent Statistical Monitoring (ERASMO) method is developed by Trucco et al. Providing the occurrence of a certain error, nurses were asked to estimate the conditional probability of certain factors the happen. Although this is a subjective approach, it is a useful method for prediction of adverse events because the objective data of contributing risk factors related to non-patient issues is very limited.

Moreover, in the hospitals collected data is mainly focused on patients (vital signs, medication and so on) but generally no information is kept on for example the inexperience of the staff or distractions.

2.2.3. Types and Functions of ReMINE Business Rules

In a programming way of thinking, ReMINE Business Rules (BRs) are expressed with if-then structure and specify what is done when specific conditions occur. BRs play a significant role as they generate two of the most important functionalities for the final users: the real time monitoring of the implementation of clinical protocols and procedures, and the prediction of risky situations that may cause adverse events to hospitalized patients. They are called "Real Time Business Rules" and "Predictive Business Rules" respectively.

Considering Reason's "Model of Organizational Risks" (Figure 10), it can be concluded that Predictive BRs try to identify latent factors and risky work conditions, whereas the Real Time BRs try to control active failures and adverse working conditions. **Real time business rules** can be defined as *they support real time management of a contingent risky situation for a specific patient, thus their affect on patient safety is immediate*. **Predictive business rules** can be defined as *they detect a potential future risky situation for a (group of) patient(s), thus their effect on patient safety is in the future*.

BRs can be grouped considering the following dimensions:

- The information type, timing and rationale on which risky situation detection is based:
  - Actual observations and measurements (Direct data acquired from the hospital information system are used to express conditions)
  - Forecast/simulation models (Previously processed data acquired from the hospital information system are used to apply conditions)
- The type of action that is triggered:
  - Patient handling (intervention on the activities of the patient's clinical pathway)
  - Organization/work environment change (intervention of the resources that are employed along the patient's clinical pathway.
  - Risk monitoring and control (activities that are not part of the standard clinical pathway but are carried out in order to mitigate the impact of a risky situation for a patient).

Actual observations and measurements are the basis of detection of a risky situation in Real Time BRs and the correspondent action is focused on patient handling and organization/work environment. In other words, Real Time BRs are built on clinical protocols and their effects are immediate.

Prediction of risky situations and simulation models of clinical processes are the basis of Predictive BRs. These rules can trigger actions on patient handling or organization/work environment change and risk monitoring/control. Moreover, a group of Predictive BRs can be defined for which the risky situation is detected using actual observations and measurements: the action affects organization/work environment and risk monitoring/control but not the patient handling. Main reason is that a future effect on a clinical pathway cannot be driven by the actual status of the patient. Business Rules specification can be seen in Table X.

Table X: Business Rules Classification

		Actions Type			
		Patient Handling	Organization/work environment change		Risk monitoring / control
Detection of Risky Situation	Actual observations and measurements	Real Time	Real Time	Predictive	Predictive
	Forecast / simulation models	Predictive	Predictive	Predictive	Predictive

2.3. Methodology

2.3.1. The Risk Assessment Methodology

In-depth analysis of risk related to the clinical processes selected as ReMINE Scenarios is the first step for designing ReMINE Business Rules. Criticality Risk Assessment (CRA) methodology is used for identifying criticalities in the process under analysis, the extension of their related risks and the main factors contributing to their occurrence. CRA method is based on SHEL model which describes the behavior of interactive systems with special regard to human factors and also representing systemic interactions and criticalities between Software, Hardware, Environment and Liveware components of the system.

"Criticality" is an event which has the possibility to cause a risk against patient safety and it is the outcome of an interaction among the system components.

CRA is based on a proactive methodology, namely Failure Modes and Effects Analysis (FMEA) for modes at which something may fail during the process. However CRA has 3 main differences from FMEA:

- The object of analysis is not the "failure mode" but "criticality". Although these terms can be similar as they both mean that something may go wrong during an activity, "criticality" is less tied to industrial domains respect to "failure modes".
- While performing the analysis both the effects and the main actual or potential trigger reasons of a specific criticality are addressed during the analysis.
- For each criticality, separate analysis is conducted for the contributing factors. Basis of the Contributing Factors Analysis (CFA) is Vincent's organizational risk analysis framework. Patient's

condition, skills and competences of caregivers, application of protocols, availability of devices, tools and instruments and so on can be related to contributing factors. CFA is conducted for correcting or eliminating the cause and preventing the problem from recurring which may result in a patient safety risk.

For the ReMINE project, risk analysis is performed in three pilots Niguarda Hospital, Sacco Hospital and Rotherdam NHS Foundation Trust on three clinical processes the reperfusion treatment process in stroke acute phase, the low risk labour management process and the infection early detection and management process respectively.

In order to perform a risk analysis, strong commitment by the hospital professionals is required. Therefore several focus groups have to be carried out (stakeholders: nurses, physicians, neurologists, obstetricians, midwifes, laboratory technicians, pharmacists and clinical risk managers and so on).

Analysis is conducted in two phases. In the first phase, stakeholders are requested to determine all the potential criticalities about the each step of scenario clinical process, main causes and effects and to rate the likelihood of occurrence and outcomes severity of criticality from 1 to 10 where 1 being very rare and 10 being all the time. Then, risk priority number (RPN) is calculated by the multiplication of Occurrence and Severity. Then, each criticality is placed into the risk level. Risk assessment matrix can be seen in Table XI.

Table XI Risk Assessment Matrix

Risk Class Legend	
Risk Level	RPN
Low	(1-4)
Moderate	(10-25)
Medium	(26-64)
High	(65-100)

2nd phase is the identification of Contributing Factors for each criticality determined in the first phase. Focus groups are requested to assign a weight for each Liveware, Software, Hardware and Environmental factors from 1 to 10 where 1 having no significant contribution and 10 to be the main trigger. Then, quantitative risk variables which might have an influence on the occurrence of an adverse event are identified. Output of the 2nd phase, the Contributing Factors Analysis Sheet (CFAS) can be seen in Table XII.

Table XII: CFAS Structure

ID:	Criticality:		(RPN:)
Type of Contributing Factors	**Description**	**Weight**	**Quantitative Risk Variables**
Liveware related to patient			
Liveware related to staff			
Software			
Hardware			
Environment			

2.3.2. ReMINE Business Rules Design

Although there are several contributing factors that may result in criticalities, not all of them are effectively covered by ReMINE. Therefore filtering is needed by taking the features of BRs and the functionalities of the platform within pilots' processes into account.

Table XIII shows the factors and their compatibility with ReMINE. Contributing factors with the "red" background are out of ReMINE scope as they are the decisions of the management. Contributing factors with the "yellow" background are partially covered by ReMINE. Some of these factors are managed during every execution of clinical processes, on the other hand, some others are considered only for organization improvement using data mining and knowledge inference tools. Contributing factors with "green" background are fully covered by ReMINE because their data can be easily acquired from the hospital information system.

Table XIII: Vincent's factors which influence clinical practice

Institutional context	- Economic and regulatory context - National Health Service Executive - Clinical negligence scheme for trusts
Organizational and management factors	- Financial resources and constraints - Organizational structure - Policy standards and goals - Safety culture and priorities
Work environment	- Staffing levels and skills mix - Workload and shift patterns - Design, availability and maintenance of equipment - Administrative and managerial support
Team factors	- Verbal communication - Written communication - Supervision and seeking help - Team structure
Individual (staff) factors	- Knowledge and skills - Motivation - Physical and mental health
Task factors	- Task design and clarity of structure - Availability and use of protocols - Availability and accuracy of test results
Patient characteristics	- Condition (complexity and seriousness) - Language and communication - Personality and social factors

Development of Real Time Business Rules is different than the Predictive Business Rules.

2.3.3. Methodology for Real Time Business Rules Design

Clinical protocols which are implemented in hospital processes are the basis of Real Time Business Rules. Thus, for designing Real Time Business rules which effectively monitor the criticalities and contributing factors that are selected from the Risk Assessment study, all the information gathered during the patient pathway is considered. As a result, “critical check points” are identified through the patient pathway. For each check point, there exists a condition concerning the patient, context or both for controlling a specific contributing factor. Moreover, physicians’ experience and scientific literature is also taken into account. The counter measures are limited to messages and alerts which are triggered by the conditions that are defined according to hospital staff’s indications in order to fulfill the user requirements.

For all the scenarios, a common template has been design including the following information:

- ID of the rule;
- Title of the rule;
- Brief description of the rule;
- Conditions of the rule (divided between patient related and context related factors);
- Action(s) triggered by the rule (usually it is a message/alert);
- Data required to implement the rule;
- Recipient and media for receiving messages/alerts.

If there is no automatic action applied by the ReMINE protocol, the recipient is responsible of applying an adequate operative countermeasure.

2.3.4. Methodology for Predictive Business Rules Design

The design of Predictive Business Rules is based on a deeper analysis of contributing factors that affect a specific criticality. Criticality Risk Assessment and Contributing Factors Analysis are the input for the identification of the phases along the clinical pathways which would most benefit from a proactive risk management approach. Predictive Business Rules are based on two logics:

- Risk assessment simulation
- Control charts

3. Impact Assessment Framework of ReMINE Platform

3.1. Introduction

Most of the e-Health for Safety Solutions resulted in disappointment in terms for reducing Risk against Patient Safety (RAPS) due to their inefficiency in the adaption in the healthcare systems. From this point of view, Impact Assessment Model along with the development of the technological solution is established. With comprehensive and on time recommendations, most of the failures can be prevented by appropriate assessment. E-Health success depends on changes of organizational, technological and individual levels. Within most of the models the focus is limited mostly to clinical outcomes and costs. Therefore, the theoretical basis of the Impact Assessment Model aims to achieve two goals:

- Supporting hospital managers in the decision regarding the adoption of ReMINE (effective decision making)
- Providing an early identification of the changes to the organization, to the technologies and/or to the individuals which might be required to adopt ReMINE in a cost-effective manner (effective change management)

These two goals address two diverse managerial dilemmas:

- Does ReMINE produce sufficient benefits that outweigh its costs and substantiate its adoption?
- Does the organization meet the pre-requisites which are necessary to exploit ReMINE potential to improve patient safety?

As a consequence, a conceptual model including a broad definition of the benefits of ReMINE that are not limited to clinical outcomes for patients, but also including consequences to providers, informal caregiver, hospital and the healthcare system and the sustainability of ReMINE was designed. Benefits and sustainability of ReMINE can be seen in Table XIV and Table XV.

Table XIV: Relevant dimensions to assess the impacts of ReMINE

BENEFITS			
INTERNAL		**EXTERNAL**	
Stakeholder	**Impact**	**Stakeholder**	**Impact**
HOSPITAL	Improved Choice of Treatment	**PATIENTS**	Reduced # of Adverse Events
	Reduced Length of Stay		Reduced Mortality
	Reduced Lead-Time		Better Clinical Evaluation
	Improved Image		Better Quality of Life
	Improved Patient Satisfaction		Less Productive Loss
PROVIDERS	Decreased Stress	**CAREGIVERS**	Better Quality of Life
	Decreased Fatigue	**SYSTEM**	Less Hospitalizations
	Increased Confidence		Less Operations
	Increased Learning		Less Re-admission
	Better Quality of Life		Less Litigation Costs

Table XV: Relevant dimensions to assess ReMINE sustainability

ECONOMIC SUSTAINABILITY	
COSTS FOR THE HOSPITAL	
RUNNING COSTS	**INVESTMENT COSTS**
Adverse events medical costs	Purchase costs
Adverse events non-medical costs	Implementation costs
Ordinary care medical costs	Training costs
Ordinary care non-medical costs	
Litigation costs	
Maintenance costs	
COSTS FOR PATIENTS and CAREGIVERS	
Opportunity costs	
Out-of-pocket costs	

SUSTAINABILTY
Safety issues
Organizational climate
Training and education
Ethical issues
Workload issues
Access to care

3.2. Assessment of Organizational Requirements

Success of ReMINE on patient safety depends on the combination of three factors:

- Inherent quality of the technological platform: e.g., in the case of ReMINE, the quality of the business rules to trigger proper alerts.
- ReMINE should produce changes if only it complies with legal and ethical requirements. Each pilot had to verify its compliance with EU laws of reference.
- ReMINE is more effective if it is applied to a system where three organizational requirements are already met
    - A positive orientation toward improving clinical risk management.
    - A positive acceptance of an ICT-based solution to improve patient safety.
    - A positive climate among practitioners who are required to collaborate in order to introduce and use ReMINE.

Pre-requisites will be based on questionnaires that will call for providers' perceptual measures of performance and context. Depending on 3 reasons, perceptual measures are strong enough to provide reliable information. These reasons are:

- The investigated traits are salient for the respondents and they are knowledgeable about them.
- Multiple terms are used to increase the reliability of measures.
- Questionnaires are based on validated scales in the literature.

3.2.1. Questionnaire #1: Orientation to Clinical Risk Management

Items which assess what practitioners' perception about the current state of clinical risk management are (i.e. before ReMINE). Items have been adapted from Linzer et al. (2009), Working Conditions in Primary Care: physicians' reactions and care quality, Annals of Internal Medicine, Vol. 151, pp. 28-36.

Three issues are explored in this section:

- Practitioners' satisfaction with the current manner in which patient safety is ensured. These items will provide information on whether ReMINE will be embedded in an hospital which is already attentive to Clinical Risk Management or in a context that requires urgent improvements;

1. My unit does an excellent job in managing risks to ensure patient safety
2. Members of my unit have a feeling of dissatisfaction with the ways available of delivering care
3. Members of my unit often have a driving need to address a clinical risk problem
7. Members of my unit often talk about clinical risk management issues

- Practitioners' assessment on the support to Clinical Risk Management provided by administrators and supervisors. It will provide information on whether ReMINE will be embedded in an environment where clinical risk management is envisioned as a priority not only by practitioners but also by administrator.

5. In my unit, the quality of each practitioner's work is closely monitored
6. In my unit, practitioners who develop inappropriate care practices are "talked to"
8. There is a high level of commitment to measuring clinical outcomes
9. Hospital has a strong commitment for the continuous improvement of practice

- Practitioner's perception of control over patient safety, in terms of their perception to have sufficient time, support, training and involvement in the decision process to translate their attention on Clinical Risk Management into an actual possibility to guarantee high-level safe performances.

4. I do not have enough time to complete patient care tasks safely
10. Hospital promotes periodic meetings to discuss Clinical Risk Management issues with the group
11. Hospital often provides timely feedbacks which are useful to solve patient safety issues
12. In my unit, admitting mistakes during practice would lead to hard consequences to reputation
13. Adequate training is provided to deal with quality of care issues
14. My workload is often excessive
15. There is broad involvement of physicians in most decisions.

3.2.2. Questionnaire #2: Technological Acceptance

In this section the existence of an organizational climate conducive to the introduction of new technologies are assessed since there is evidence that practitioners have frequently resisted the introduction of Information Systems in their practice. Moreover practitioners have proven to be peculiar information system users since they have to work in a very complex and dynamic environment and standardized solutions are heavily scrutinized to see in which way they can satisfy the very varying needs they have to deal with (Berg et al., 2003). The items have been adapted from Khoja et al. (2007), e-Health Readiness Assessment Tools for Healthcare Institutions in Developing Countries, Telemedicine and e-Health, Vol. 13, No. 4, pp. 425-431. Three issues are explored in this section:

- Whether practitioners are familiar to the use of Information Systems before ReMINE is adopted

1. In my hospital, using Information Systems has become a routine over the years
2. In my hospital, we often rely on Information Systems to provide care
4. There is general comfort in using Information Systems among members of my unit
8. Healthcare professionals have been largely involved in the implementation of Information Systems
10. Currently available Information Systems are easy to use

- Whether practitioners are satisfied with existing Information Systems and are aware of their potential to improve practice

3. Broad awareness of Information Systems role in healthcare exists among my members of my unit
6. There is general awareness among members in my unit in using Information Systems for the purpose of storing information
9. Members of my unit have a feeling of dissatisfaction with the current utilization of Information Systems tools

- Whether practitioners perceive that hospital managers are committed to the introduction of new Information systems for the purpose of data storage and supporting the provision of care

5. My hospital is extremely committed to introducing Information Systems for **data storage**
7. My hospital is extremely committed to introducing Information Systems for **supporting the provision of care**

3.2.3. Questionnaire #3: Organizational Readiness

This section is related to exploring the ease of introducing changes in the hospital environment. Selected items are adapted from Edmondson (1999), Psychological Safety and Learning Behavior in Work Teams, Administrative Science Quarerly, Vol. 4 No. 2, pp. 350-383 and Linzer et al. (2009), Working Conditions in Primary Care: physicians reactions and care quality, Annals of Internal Medicine, Vol. 151, pp. 28-36.

Three issues are explored in this section:

- The existence of a positive climate within the organizational unit that might facilitate the collaboration among co-workers, minimize stress and elicits a positive "citizenship behavior".

1. Members of my unit are always willing to help me if I needed
5. There have been recurrent cases of burnout in my unit over the years
6. My unit shares a strong sense of belonging

- The existence of "psychological safety" in the unit.

2. In my unit, if you make a mistake it is often held against you
7. No one in my unit would deliberately act in a way that undermines my efforts
9. Members of my unit often deliberately hide information which is useful for care

- Practitioners' perception that the unit where ReMINE will be used is populated with skilled individuals

3. My unique skills and talents are valued and utilized by members of my unit
4. My unit can achieve its task without requiring us to put in unreasonable time or efforts
8. All members of my unit have more than enough training and capability for the kind of work

3.2.4. Methodology

Questionnaires will be applied before and after the implementation of ReMINE. They are applied before the ReMINE implementation to control the prerequisites and applied after the ReMINE implementation to get information on the organizational impacts of ReMINE.

The questionnaires will be applied to practitioners such as physicians, nurses, risk managers and technology managers who will use ReMINE and to practitioners that belong to a comparable Control Group. The units involved in the three pilot sites are described in the Table XVI.

Table XVI: Involved Units

Pilot Site	ReMINE Unit	Control Group
NIGUARDA	A&E Department	Cardiology Department
SACCO	Obstetric and Gynaecologic Department	Pediatrics Department
TRFT	Infection Control	To be disclosed (at the moment no control group is notified for TRFT

The questionnaires have a 7-point Likert scale where each item stands for a level of agreement (Table XVII).

Table XVII: Likert scale

1	2	3	4	5	6	7	
I completely disagree	I mostly disagree	I moderately disagree	Indifferent	I moderately agree	I completely agree	I completely agree	I don't know

"I don't know" cell was added to address cases where the respondents are not confident with their answer. To reduce acquiescence problems, some of the items are reverse scored (Lindell, Whitney, 2001). Moreover some items are meant for identifying possible differences in the answer in accordance to the control variables such as Age, Gender, Profession and Work Experience and so on.

By performing a data analysis, potential issues in organizational pre-requisites will be identified and the evolution of requirements before and after ReMINE adoption and the differences between adopters and non-adopters will be observed. Firstly, internal consistency of the measurement variables will be determined by calculating Cronbach's alpha. This analysis is performed to see whether different measurement items can be grouped into a single variable or not. Secondly, means and variances will allow the identification of items which are located below the acceptability threshold (value = 4) and cause some concern.

3.3. Assessment of Patient Safety Improvements

With the ReMINE protocol, improved provision of care to patients through an improved management of Risk against Patient Safety (RASP) is aimed. It should be kept in mind that the clinical outcomes are affected by multiple factors which go beyond ReMINE's direct support. In fact, clinical outcomes are related to protocols and guidelines. ReMINE is not designed or supposed to change the protocols and/or guidelines that the hospital is referring to, but aimed at improving and supporting them.

ReMINE directly impacts the process of care and has an indirect impact on clinical outcomes. Therefore the evaluation protocol for each pilot distinguishes between two objectives:

- A primary objective which fosters indicators that are related to adherence and compliance to protocols
- A secondary objective which fosters indicators that are related to clinical outcomes.

All in all, the assessment would show if ReMINE is more effective in detecting and signaling RAPS than AS-IS processes and facilitates the adherence of daily clinical practice to the clinical protocol or guidelines adopted by the organization. More details about each pilot scenario is explained in the following parts.

3.3.1. Evaluation Protocol for Niguarda Pilot

3.3.1.1. Introduction

In this section validation and evaluation of ReMINE platform at the Niguarda Hospital from patient safety perspective will be described.

The Niguarda Hospital is the biggest hospital in Milan and it has more than 4.000 employees, 1.305 beds and 48.253 inpatients, 3.051.211 outpatient services, 82.394 accesses to A&E in 2008.

At Niguarda Hospital, ReMINE will be working on the management of stroke acute phase in the A&E. Risks due to late stroke diagnosis and lack of early information assessment are considered since "door to needle" is the most important factor for stroke patients as they should have an access to medical assessment quickly to determine whether they are eligible for thrombolytic therapy or not. ReMINE will be responsible of monitoring the time left for starting effective therapies taking into account the clinical protocol for the management of stroke acute stage. The maximum time for administering fibrinolitic treatment to stroke patients is set to 90 minutes from the triage.

3.3.1.2. Baseline Procedures

At the Niguarda Hospital, following activities are performed in the A&E.

1) The responsible nurse for triage starts the admission procedure
2) The nurse assesses the patient and fills in the electronic A&E report (PIESSE) with his/her personal data and description of symptoms
3) If the inclusion criteria are met the "yellow-stroke" code is assigned to the patient
4) The patient is transferred in an intensive care bed in the Emergency Room (ER)
5) Triage nurse calls the on-call neurologist
6) The on-call neurologist arrives in ER
7) The neurologist performs a preliminary evaluation of the patient and takes in charge the patient opening the PIESSE program
8) The neurologist fills in the PIESSE program with the patient data (clinical history and physical examination)
9) The neurologist fills in the request form for blood examinations and calls the urgency lab to order an immediate analysis of the samples
10) The neurologist fills in the request form for cerebral CT scan
11) Patient's blood samples are taken and sent to laboratory by the A&E nurse through the internal pneumatic system
12) The nurse performs ECG
13) The neurologist administrates the NIH Stroke Scale and verifies the inclusion/exclusion criteria to the thrombolytic treatment
14) The neurologist evaluates the cerebral CT imaging and lab results on PC
15) The neurologist reports clinical evaluation in the PIESSE program
16) The neurologist asks for evaluation by internist (emergency physician) if needed
17) If the indication to thrombolysis is confirmed the neurologist obtains the informed consent both for the fibrinolytic treatment, transfers the patient on a monitored bed and administrates the fibrinolytic treatment
18) If the indication to thrombolysis is not confirmed, the patient is excluded from thrombolytic treatment and is transferred in charge to emergency physician

3.3.1.3. Objectives

The primary objective is to determine if the clinical pathway which is supported by ReMINE returns better patient outcomes or not. Below, the considered indicators are listed for evaluating the result of the study.

1. % of fibrinolitic treatments on "yellow stroke" patients
2. % of missed fibrinolitic treatments
3. % of recovered on-time fibrinolitic patients
4. % of hospitalized yellow stroke patients
5. % of patients gone out of Diagnosis and Therapy Protocol (DTP)

The secondary objective is to determine if ReMINE provides a higher degree of compliance of the clinical pathway to the protocol. Below, the considered indicators are listed for evaluating the result of the study.

6. % of overall diagnosis of ischemic stroke from ER on admitted yellow stroke patients
7. % of overall diagnosis of ischemic stroke from ER on patients gone out of DTP stroke
8. Average number of alerts per patient

% of patients with a specific alert associated

9. % of patients coded as “Yellow Stroke” at triage for which the first assessment is carried out by an A&E physician
10. Average time
11. Time standard deviation

Detailed explanations of the indicators can be found in the appendix.

3.3.2. Evaluation Protocol for Sacco Pilot

3.3.2.1. Introduction

In this section validation and evaluation of ReMINE platform at the Sacco Hospital from patient safety perspective will be described.

Sacco Hospital is one of the most significant public hospitals in Milano and it has more than 500 inpatient beds. It consists of 4 management departments with 19 administrative and technical units and 9 healthcare departments made up to 43 clinical units.

At Sacco Hospital, ReMINE will be working on the patient assistance during labour. It will deal with the risk for patient safety due to a delayed execution of the clinical protocol which provides medical staff with important information for the correct assessment and selection of the best clinical pathway. ReMINE platform will control the execution of the clinical protocol (both during admission and labour assistance) and it will alert in case of non compliance of the key roles.

In addition, ReMINE can support the correct match of Fetal Heart Rate (FHR) tracings with patients through the timestamp of activities. It could also prevent risks caused by non-compliance of the clinical protocol. ReMINE can define the expected needs of Electronic Fetal Monitoring (EFM) devices and midwife/obstetrician assistance by using the data from A&E report and patient health records. These data can be used to anticipate potential critical situations that could quickly lead to an adverse event. Lastly, ReMINE can also support the management of EFM devices. With this property, it will be possible to provide an alert in case of an “inappropriate” way of EFM usage and to plan its availability in the short/medium term for answering to ward’s or ambulatories’ requests whenever possible.

3.3.2.2. Baseline Procedures

At the Sacco Hospital, following activities are performed by the ward personnel during the testing of ReMINE:

1. Diagnosis of active and low risk labor

- The midwife fills in the A&E report ("Isolabella") with patient's anagraphic data
- The midwife creates the barcode bracelet in a specific ReMINE form and applies it on the patient
- The obstetrician assesses the patient and checks if the inclusion criteria are met
- The obstetrician fills in the forms for admission in ReMINE
- If needed for diagnosis a first FHR monitoring or obstetric evaluation are carried out
- The obstetrician makes the diagnosis and decided about hospitalization, filling in the A&E report with these data
- The obstetrician collects the signed standard informed consent and the authorization to use and disclose health information
- At the time of the admission, the obstetrician performs an obstetric evaluation
- The patient is transferred in the delivery room

2. FHR monitoring execution

- For a patient with an active low-risk labor the FHR monitoring has to be performed every two hours and last 30 minutes. If the characteristics of the FHR tracing are not satisfied, the monitoring could last longer than the average duration
- The midwife activates the FHR monitoring through a specific form in ReMINE
- When FHR monitoring is finished, the midwife stops the task through a specific form in ReMINE
- Either the midwife or obstetrician registers the evaluation of the tracing in a specific ReMINE form

3. Obstetric evaluation

- For a patient with an active low-risk labor the obstetric evaluation has to be performed every two hours
- Either the midwife or obstetrician registers the findings of the obstetric evaluation in a specific ReMINE form
- If a slowdown of the labor occurs, amniorexis or oxiticin perfusion are used according to internal protocols: the prescription is registered in the "Obstetric evaluation" form in ReMINE
- If the epidural anesthesia is asked by the patient and administered to her, the obstetrician registers the prescription in the "Epidural" form in ReMINE

4. "Exit"

- The patient exits from ReMINE after delivery or discharge
- The obstetrician fills in the "exit" form in ReMINE, reporting the outcome of the clinical pathway, the conditions of the newborn in case of delivery and the indications to a caesarean section if this occurred.

5. EFM device reservation

- In order to predict effectively the availability of EFM devices in a time period, ReMINE needs to know how many working devices are in the Obstetrics ward
- Every time an EFM device is needed in advance for an external usage or for maintenance, a reservation has to be entered in a specific form in ReMINE
- When an EFM device is taken from or returned to the Obstetrics ward, the check in/out data have to be entered in a specific form in ReMINE

3.3.2.3. Objectives

The primary objective is to determine if the clinical pathway which is supported by ReMINE returns better patient outcomes or not. Below, the considered indicators are listed for evaluating the result of the study.

1. Average delay of the main activities of labor assistance
2. Average number of alerts per patient
3. % of patients with a specific alert associated
4. Average number of alerts per context risk level
5. % of patients with "N" alerts associated

The secondary objective is to evaluate the clinical outcome. The list of indicators that will be considered to evaluate the secondary objectives of the study is reported below:

1. % of unplanned caesarean sections
2. % of women admitted as active low-risk labor who have other complications (different than caesarean sections).

Detailed explanations of the indicators can be found in the appendix.

3.3.3. Evaluation Protocol for TRFT Pilot

3.3.3.1. Introduction

In this section validation and evaluation of ReMINE platform at the The Rotherdam NHS Foundation Trust (TRFT) from patient safety perspective will be described.

TRFT is a publicly funded NHS hospital which is modern and progressive. The trusts works with local general practitioners and the trust have around 3500 employees. Each clinical director is responsible for the service quality and performance within the area. Each clinical area is supported by several teams which also contains risk management and infection control.

At TRFT, ReMINE's target is the infection control program due to following reasons:

- Infection control is a major risk to patient safety for all hospitals.
- All hospital patients are affected by the infection control.

- Infection control protocols are relatively well developed in logical orders and can be easily translated into machine rules.

3.3.3.2. Baseline Procedures

Rank coding of possible infected patients and notification to ward managers:

1. Gathering the admitted patient list from PAS:

- Patients' previous infections and residential status are controlled by ReMINE. For flagged patients, further information is gathered about MRSA screening from the LIS.
- An alert is sent to the infection control team by ReMINE for patients who are found positive according to the defined rule for a possible infected patient

2. Considering the following rules, ReMINE ranks every patient in the list with a risk code:

- If a patient is flagged for previous MRSA within less than 3 weeks ago
    - If positive for MRSA in sputum, high risk code is assigned
    - If positive for MRSA in skin site, high risk code is assigned
    - If positive for MRSA in nasal:
        - And if the patient is transferred to a surgical specialist ward, high risk code is assigned
        - And if the patient is transferred to a medicine specialist wards, medium risk code is assigned
    - If previous positive covered with no leakage:
        - And if the patient is transferred to a surgical specialist ward, high risk code is assigned
        - And if the patient is transferred to a medicine specialist wards, medium risk code is assigned
- If a patient has a flag for previous MRSA occurring more than 3 weeks ago (risk alerts can be lowered only after one negative screen)
    - If positive for MRSA in sputum, high-risk code is assigned
    - If positive for MRSA in skin site, high-risk code is assigned
    - If positive for MRSA in nasal:
        - And if the patient is transferred to a surgical specialist ward, high risk code is assigned
        - And if the patient is transferred to a medicine specialist wards, medium risk code is assigned
    - If previous positive covered wound with no leakage:
        - And if the patient is transferred to a surgical specialist ward, high risk code is assigned
        - And if the patient is transferred to a medicine specialist wards, medium risk code is assigned
        - If the last repeat screen was performed more than 4 weeks ago, high risk code is assigned

- If patient comes from nursing/residential homes and has an alert of previous MRSA infection, high-risk code is assigned
- If patient comes from nursing/residential homes and has no alert of previous MRSA infection, medium-risk code is assigned

3. Risk Manager Interface (RMI) is opened by the infection control team and ReMINE provides the infection control daily report
4. By using RMI, infection control team can:

- Confirm the list of possible infected patients automatically generated by REMINE;
- Manually enter other patients in the list if they are reported as suspicious by ward managers
- Assign an alert code to each patient manually entered in the list or change the code to a patient automatically coded by REMINE
- Add free text comments for each patient

5. Once the list is confirmed by the infection control team, a daily report is created about all patients with an infection code who:

- Stay in that particular ward
- Are going to be transferred there soon
- Have been transferred over last 24 hours

6. ReMINE creates a similar report for the patient flow team, but with visibility on the whole hospital for keeping track of patient transfers.

Deep cleaning of cubicles

1. As soon as a red or yellow coded patient leaves a cubicle, ward manager rings the infection control team as the cubicle needs to be cleaned and disinfected by specialized staff.
2. The infection control team uses an electronic form of ReMINE to input which cubicles needed for cleaning and the kind of the cleaning.
3. According to the kind of the cleaning, ReMINE notifies the terminal cleaning team or external cleaning team.
4. After the cleaning, the cleaning team provides the time information and it is input to the ReMINE through an electronic form.
5. ReMINE informs the infection control team about the status of the cubicle every time a cleaning is completed and registered in the list.
6. The control team is daily reported by ward managers about the cleaning of green coded patients who do not require specialized treatments. As a consequence, the infection control team has an overall map of free cubicle and the team is notified as a cubicle becomes available.

Monitoring of MRSA screening:

1. If screening of a patient treated for MRSA is not carried within a week, ReMINE sends an alert to the infection control team.
2. If the results of the MRSA screening for a patient are positive, ReMINE sends an alert to the infection control team and the related infection code is green.

3.3.3.3. Objectives

The primary objective of the study is to determine if ReMINE allows achievement of better performance in the care process. The indicators that will be considered to evaluate the result of the study are:

1. Number of times in which a specific alert is triggered.
2. Quickness to trigger a specific alert.
3. Completeness of a specific alert.
4. Average time from room vacancy to completion of a routine ward clean of a bed.
5. Average time from room vacancy to completion of a routine ward clean followed by hydrogen peroxide disinfection of a bed.
6. Average time from room vacancy to completion of a terminal clean followed by hydrogen peroxide disinfection of a bed.
7. Average time between two screenings of a red/yellow coded patient.
8. Standard deviation of the time between two screenings of a red/yellow coded patient.
9. % of late screenings on the total number of screenings

Secondary objective is to determine whether the clinical pathway is supported by ReMINE returns better patient outcome or not. The indicators that will be considered to evaluate the result of the study are:

1. % of patients infected.
2. % of red/yellow coded patients in the hospital on the total hospitalized patients.
3. % of red/yellow coded patients at admission to the hospital.
4. % of red/yellow coded patients in “ReMINE wards” on patients hospitalized in “ReMINE wards”.
5. Average number of contacts that the red/yellow coded patient has.

Detailed explanations of the indicators can be found in the appendix.

3.4. Assessment of Long Term Impacts

Benefits in terms of patients, providers, informal caregivers and society are the potential of ReMINE which cannot be covered by the clinical protocols and/or by questionnaires. In this sub-section these benefits will be explained briefly.

Patients: Adverse events can be reduced and ordinary care can be improved by the implementation of ReMINE in terms of:

- Incidence and prevalence of adverse events
- Incidence and prevalence of mortality
- Reduction of disability case
- Increase in the quality of everyday life (mobility, self-care, everyday activities, pain and anxiety/depression)

Providers: Namely physicians, nurses and any other healthcare professionals who are supported in their daily clinical practice by ReMINE. Possible benefits in terms of providers are

- Improved job satisfaction and self efficacy
- Reduced job stress and burnout cases
- Increased possibility and ability to learn from experience

Informal Caregivers: People (most often family members) who suggest informal care to patients. By the implementation of ReMINE, adverse events are likely to be reduced as a consequence, resulting in:

- Improvements in the quality of life, in terms of reduced psychological and physical distress
- Increased productivity due to a reduction in the time they spend to provide care to patients

Society: Reduced adverse events have the potential of reducing the number and duration of litigations which affects the costs for the insurers, the public image of the hospital and the providers' attitude.

Benefits explained above can be only measured and assessed in a mid-long term. However, assessment of ReMINE at the pilots will be done within a short period of time after the implementation of ReMINE. As a result, there will not be sufficient time to gather data to evaluate such benefits. Therefore, no quantitative measures for the long term benefits will be collected. However, these benefits can be assessed through a more qualitative approach by collecting the experts' perceptions, recommendations and consensus about long term impacts.

4. Assessment of ReMINE Impact on Process Safety

In the first part, assessment of pre-requisites of the 3 pilot will be made. Although there have been 3 pilots where the ReMINE platform is being tested, due to technical problems, the implementation of ReMINE platform at Sacco and TRFT Hospitals are not yet fully completed. As a result, the assessment of process indicators could only be evaluated with the data of the Niguarda Hospital. In the second part, evaluation of the Niguarda Hospital in terms of process indicators will be made.

Gathered data from the Niguarda Hospital is simulated as if the ReMINE system was adopted and with the generation of delay alert messages, assessment of the ReMINE impact on process safety is done. In other words, graphs with time duration is the actual data gathered from the hospital, whereas the generated alert messages are obtained after a simulation.

4.1. Assessment of Pre-Requisites of the Pilots

Within the evaluation process of ReMINE, first step is the assessment of pre-requisites before the implementation of ReMINE. This evaluation would help to understand the hospital status in terms of different point of views In other to achieve the pre-requisites, a 7 point Likert Scale questionnaires are applied to practitioners (physicians, nurses, risk managers, technology managers) who are going to use (or be affected directly by) ReMINE and to practitioners who belong to a comparable control group.

With these questionnaires, orientation to clinical risk management, orientation to information systems and organizational readiness is evaluated from different point of views. Table XVIII shows the 7 point Likert Scale questionnaire applied for the orientation to clinical risk management.

Table XVIII: Questionnaire for the orientation to clinical risk management

	1	2	3	4	5	6	7	Don't know
1. My unit does an excellent job in managing risks to ensure patient safety	Perception of Quality							
2. Members of my unit have a feeling of dissatisfaction with the ways of delivering care	Perception of Quality							
3. Members of my unit often have a driving need to address a clinical risk problem	Culture of CRM							
4. I do not have enough time to complete patient care tasks safely	Organizational Support							
5. In my unit, the quality of each practitioner's work is closely monitored	Quality monitoring							
6. In my unit, practitioners who develop inappropriate care practices are "talked to"	Quality monitoring							
7. Members of my unit often talk about clinical risk management issues	Culture of CRM							
8. There is a high level of commitment to measuring clinical outcomes	Quality monitoring							
9. Hospital has a strong commitment for the continuous improvement of practice	Culture of CRM							
10. Hospital promotes periodic meetings to discuss Clinical Risk Management with the group	Culture of CRM							
11. Hospital often provides timely feedbacks which are useful to solve patient safety issues	Organizational Support							
12. In my unit, admitting mistakes during practice lead to harsh consequences to reputation	Organizational Support							
13. Adequate training is provided to deal with quality-of-care issues	Organizational Support							
14. My workload is often excessive	Organizational Support							
15. There is broad involvement of physicians in most decisions	Culture of CRM							

From Figure 12 to Figure 14 the evaluation results of the orientation to clinical risk management from different point of views are depicted for each pilot.

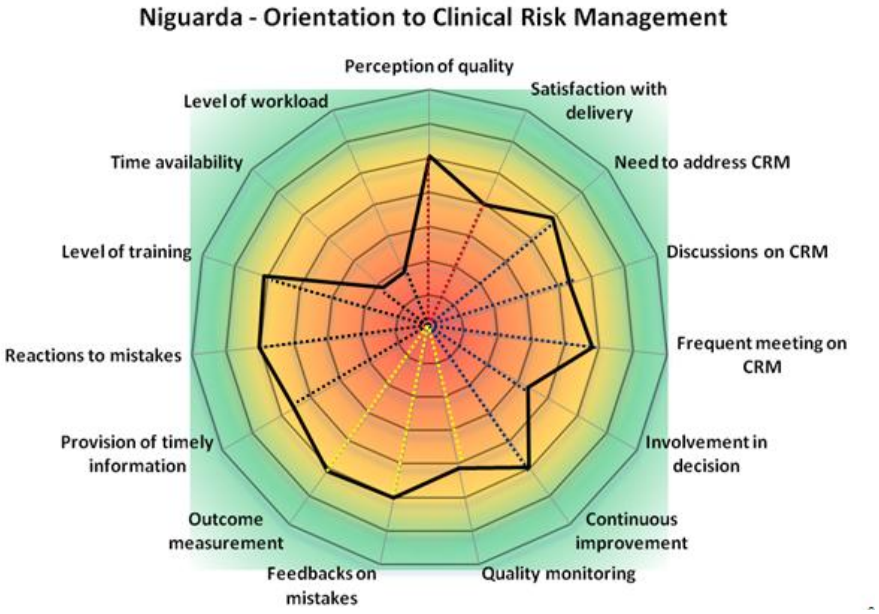

Figure 12: Evaluation results of the orientation to clinical risk management at Niguarda Hospital

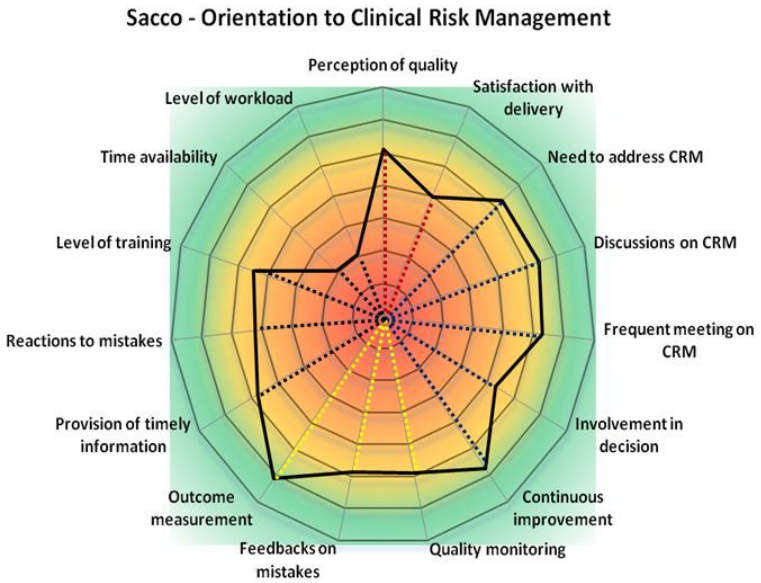

Figure 13: Evaluation results of the orientation to clinical risk management at Sacco Hospital

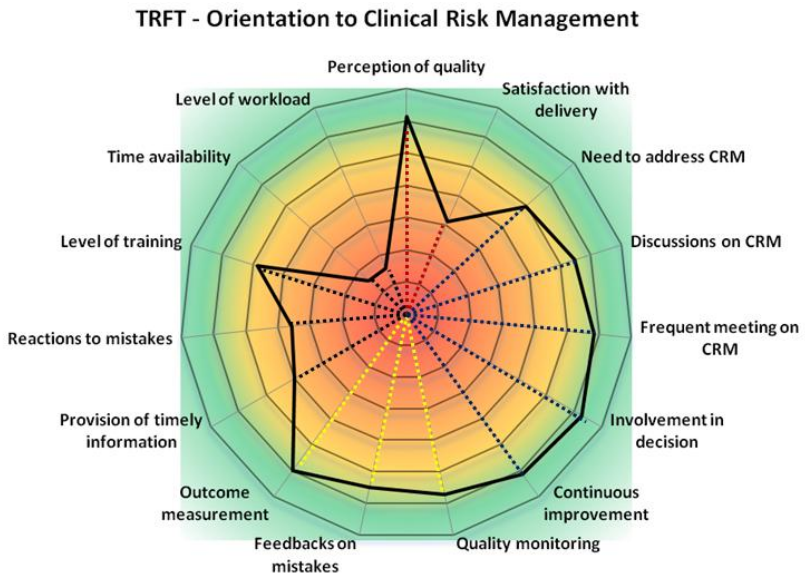

Figure 14: Evaluation results of the orientation to clinical risk management at TRFT Hospital

It is obviously seen that for each hospital, the satisfaction with available way of delivering care is average. This partial un-satisfaction leads to a high level of discussion in CRM in Sacco and TRFT and it might be to well understanding of its importance. Although the level of discussion in CRM in less in Niguarda, seeing that the need to address to CRM is high in each hospital, one can state that the importance of CRM is well understood in every case with a high perception of quality.

The assessment on the support of CRM is measured by the quality monitoring, reaction to mistakes, outcome measurement and continuous improvements to understand the level of understanding by administrators. The quality monitoring, outcome measurement and continuous improvements are less than the others for Niguarda but the reaction to mistakes is higher in Niguarda and less in TRFT. This is not contradictory because one can see that in Niguarda, the reaction of mistakes and outcome measurement are balanced whereas in Sacco and TRFT, although the availability of a good monitoring and outcome measurement the reaction to mistakes is not well established. Each hospital intends to have a continuous improvement which shows how well the administrations perceive the importance of a CRM but they lack of the knowledge of the right implementation in order to react accordingly. ReMINE can help them in this point.

Practitioners' perception control over patient safety is measured in terms of time, support, training, involvement in decision and keeping attention on CRM. The time availability's being low means that the practitioners have enough time, because the question #4 is negative. For each hospital the workload is low which explains the availability of practitioners. They are not hurried and patient care can be done safely. Additionally this indicates that practitioners have time to enter data to the system and check it often which facilitates the implementation of ReMINE which will further increase the safety of the treatment. In TRFT the level of training is high, physicians are highly involved in decisions, feedback on mistakes is considered but this hospital is not very efficient to provide timely feedbacks to patients. This means that TRFT is strong in involvement in decision; training but they have weaknesses in terms of

patient support. Niguarda has a more balanced profile; its values are average in terms of support, involvement and training but it still needs improvements to have better control over the patient safety. The frequency of CRM meeting should be improved which will also affect the other indicators for the patient safety. Sacco hospital is weaker in training, giving information decision involvement and feedbacks on mistakes, maybe due to a lack of CRM implementation or a lack of right organization and this is also the reason of the rare meetings on CRM.

Table XIX shows the 7 point Likert Scale questionnaire applied for the orientation to information systems.

Table XIX: Questionnaire for the orientation to information systems

	1	2	3	4	5	6	7	Don't know
1. In my hospital, using Information Systems has become a routine over the years	Use of Information Systems							
2. In my hospital, we often rely on Information Systems to provide care	Use of Information Systems							
3. Broad awareness of Information Systems role in healthcare exists among members of my unit	Awareness of IS relevance							
4. There is general comfort in using Information Systems among members of my unit	Comfort in using IS							
5. My hospital is extremely committed to introducing Information Systems for **data storage**	Commitment to IS							
6. There is general awareness among members in my unit in using Information Systems for the purpose of storing information	Awareness of IS relevance							
7. My hospital is extremely committed to introducing Information Systems for **supporting the provision of care**	Commitment to IS							
8. Healthcare professionals have been largely involved in the implementation of Information Systems	Commitment to IS							
9. Members of my unit have a feeling of dissatisfaction with the current utilization of Information Systems tools	Use of Information Systems							
10. Currently available Information Systems are easy to use	Comfort in using IS							

From Figure 15 to Figure 17 the evaluation results of the orientation to information systems from different point of views are depicted for each pilot.

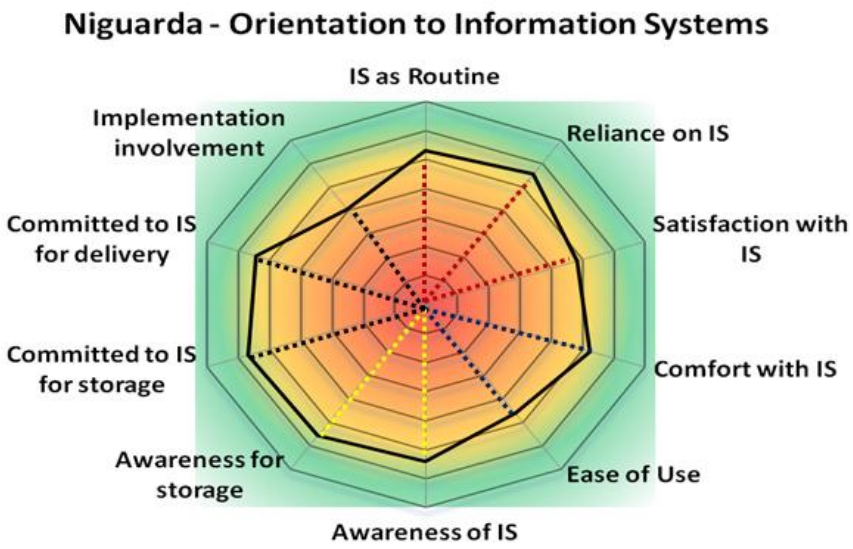

Figure 15: Evaluation results of the orientation to information systems at Niguarda Hospital

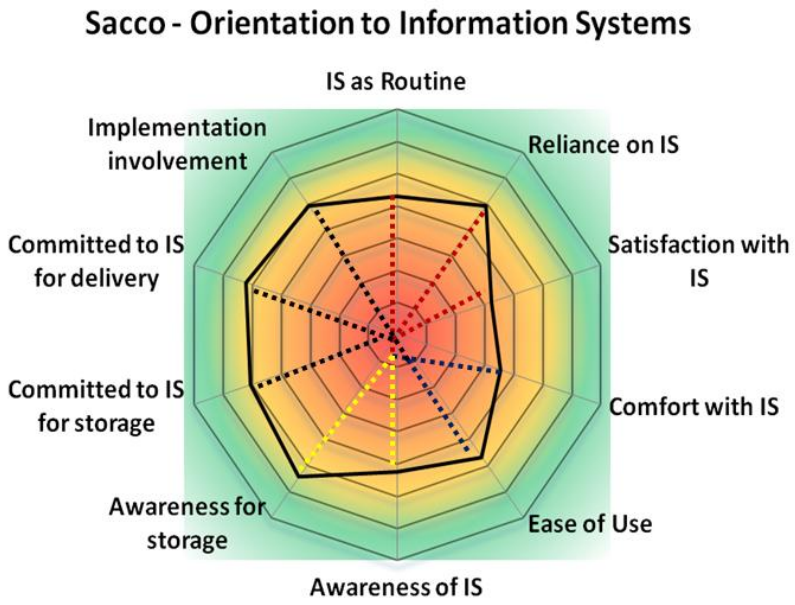

Figure 16: Evaluation results of the orientation to information systems at Sacco Hospital

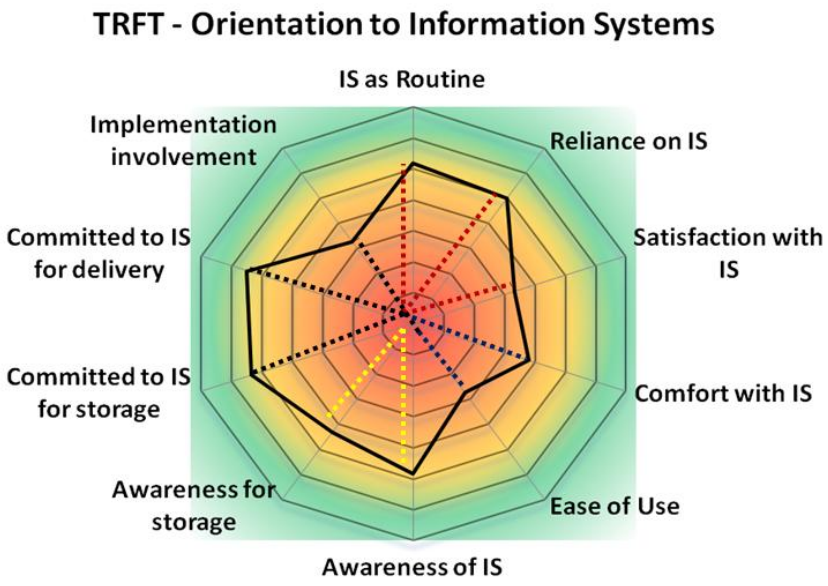

Figure 17: Evaluation results of the orientation to information systems at TRFT Hospital

Assessment results of the Niguarda and TRFT pilots show that using information systems have become a routine over the years. For Sacco Hospital using information systems is more recent. At all pilots, reliance on information systems is high. Niguarda Hospital is very comfortable with using information systems whereas Sacco and TRFT Hospitals are not. Main reason for being not very comfortable with IS systems for TRFT practitioners could be the difficulties in the usage of the IS. For Sacco practitioners, easiness of usage of information systems is above average, but this hospital is using information systems more recently than the other hospitals, this might be the main reason of being not very comfortable. These indicators helped to understand whether the practitioners are familiar to the use of information systems before ReMINE is adopted.

When the awareness of information systems within the pilots is compared, at Niguarda and TRFT pilots where the usage of information systems has become a routine, the awareness is also high as expectedly. For Sacco Hospital, the awareness is above average. Niguarda Hospital has a high satisfaction with the recent information systems; however TRFT and Sacco Hospitals are not very satisfied with their current information systems. For TRFT, difficulties in the usage must be the main reason for the dissatisfaction.

All three pilots have high commitment to introducing information systems for data storage and supporting the provision of care. It can be concluded that all these pilots are using information systems for some years, already aware if importance of IS and more importantly they rely on IS. Easiness of using also seems to have an effect on the satisfaction.

Table XX shows the 7 point Likert Scale questionnaire applied for the organizational readiness.

Table XX: Questionnaire for the organizational readiness.

	1	2	3	4	5	6	7	Don't know
1. Members of my unit are always willing to help me if I needed	Internal climate							
2. In my unit, if you make a mistake it is often held against you	Internal climate							
3. My unique skills and talents are valued and utilized by members of my unit	Human Capital							
4. My unit can achieve its task without requiring us to put unreasonable time or efforts	Pressures/Stress							
5. There have been recurrent cases of burnout in my unit over the years	Pressures/Stress							
6. My unit shares a strong sense of belonging	Internal climate							
7. No one in my unit would deliberately act in a way that undermines my efforts	Internal climate							
8. All members of my unit have more than enough training and capability for the kind of work they have to do	Human Capital							
9. Members of my unit often deliberately hide information which is useful for care	Human Capital							
10. It has often happened that members of my unit often were not aware of possessing relevant information for critical care	Human Capital							

From Figure 18 to Figure 21 the evaluation results of the organizational readiness from different point of views are depicted for each pilot.

Figure 18: Evaluation results of the organizational readiness at Niguarda Hospital

Figure 19: Evaluation results of the organizational readiness at Sacco Hospital

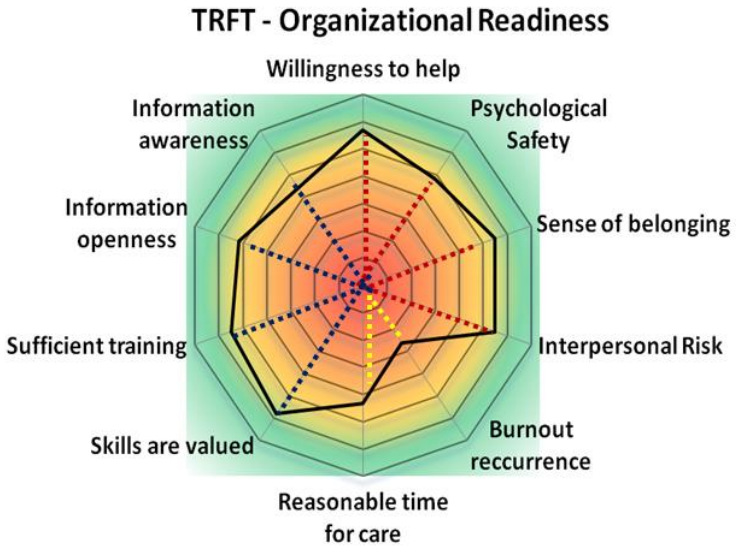

Figure 20: Evaluation results of the organizational readiness at Sacco Hospital

To evaluate the positive climate existence within the pilots, practitioners are asked whether other practitioners are being helpful, if any burnouts occurred and if a strong sense of belonging is shared. Within all pilots, practitioners are likely to help each other whenever needed and one can conclude that there is positive collaboration among co-workers. Occurrence of burnouts is less than

average at TRFT, around average on Niguarda and above average at Sacco. Burnouts are one of the main reasons of stress within the pilots. Sense of belonging at the pilots is above average.

Psychological safety is high for Niguarda and TRFT Hospitals but it is on average for Sacco Hospital. Practitioners believe that the time for delivering care is reasonable in TRFT. However for Sacco and Niguarda, tasks are completed with unreasonable time and efforts. This might show that there is a need of development within the care delivery for these pilots. At Niguarda and Sacco Hospitals practitioners are aware of possessing relevant information for critical care and they are sharing information with each other which is useful for care. On the other hand at TRFT awareness of information is less but the level of sharing of information is acceptable. With the improved information systems, awareness of information for delivering care can be improved.

At all pilots, practitioners seem to have a good training and capability for the work they are doing. Unique skills and talents are valued by the other practitioners. One can conclude that, the users of ReMINE will be skilled individuals at every pilot.

4.2. Assessment of Process Indicators of Niguarda Hospital

In this section, indicators that are explained as the primary and secondary objectives in section 3.3.1.3 are examined. Due to missing information within the data of Niguarda Hospital following indicators cannot be evaluated: Percentage of missed fibrinolitic treatments, percentage of hospitalized "yellow coded" patients, percentage of patients gone out of DTP, percentage of overall diagnosis of ischemic stroke from ER on admitted yellow stroke patients, percentage of overall diagnosis of ischemic stroke from ER on patients gone out from DTP Stroke and percentage of patients coded as "Yellow stroke" at triage for which the first assessment is carried out by an A&E physician. Evaluation of the other indicators can be found below.

Percentage of fibrinolitic treatments on "yellow stroke" patients, missed fibrinolitic treatments, recovered on-time fibrinolitic treatments and patients gone out of DTP are depicted in Figure 21. Fibrinolitic treatment is applied to 12.5% of the patients that are coded as "yellow stroke". In addition, recovered on-time fibrinolitic treatment is 9.88%. Fibrinolitic treatment is a very crucial treatment as it provides higher chances of saving lives. Therefore, although the amount might seem to be low, 9.88% should not be underrated. With the implementation of ReMINE Protocol, around 10% patients were better off with the fibrinolitic treatment with the help of delay alerts of ReMINE.

Percentage of missed fibrinolitic treatments is 77.78 according to the data of the hospital when ReMINE was not implemented. This indicator is one of the primary objectives of ReMINE at Niguarda Hospital and it seems very high. Once the ReMINE is implemented, this value would tend to decrease with the warning messages of ReMINE whose effects are explained below.

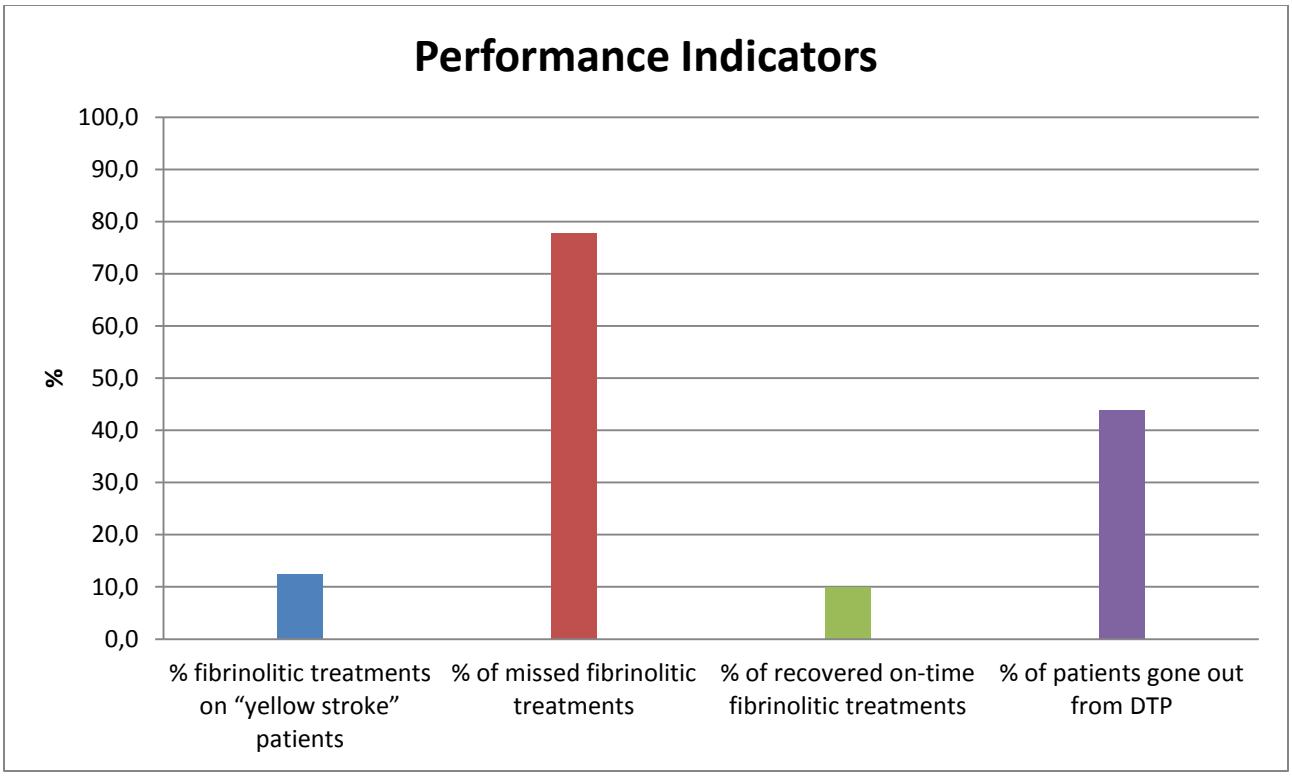

Figure 21: Percentage of fibrinolitic treatments, missed fibrinolitic treatments, recovered on-time fibrinolitic treatments and patients gone out from DTP

ReMINE would affect the priority order of the patient's blood samples in the laboratory. When the laboratory request alert occurs, it means that patient's blood sample is still not being examined at the laboratory although it has been in the waiting list. Since treatment of stroke patients are highly dependent on time, these patients should have a higher priority in terms of laboratory tests even though they are not on top of the waiting list. With the help of the alert, practitioner at the laboratory would be informed that this patient has a higher priority over the other patients on the list. Therefore, he/she might start the examination of the sample immediately and as a result can avoid time losses on the waiting list.

Laboratory examination check in alert occurs when a patient's result is not received within a pre-defined time period. Practitioner will be informed with this alert so that he/she might check the status of the examination and avoid the time loss due to an omission in the laboratory.

Laboratory result alert is provided by ReMINE when the practitioner has not checked the results of the sample within a defined period of time. With the generation of this alert, ReMINE would prevent the unnecessary time losses due to late control of the laboratory results.

The patient's treatment starts with a neurologic assessment after the patient record is added to the system by the responsible nurse. If the neurologic assessment is late, then the alert is sent to the related practitioner to start the neurologic assessment as soon as possible and therefore overcoming time losses.

CT Scan alerts are similar as laboratory examine check in alerts. If the define time is exceeded and the CT Scan results are not received, related practitioner is warned with a message to prevent losses.

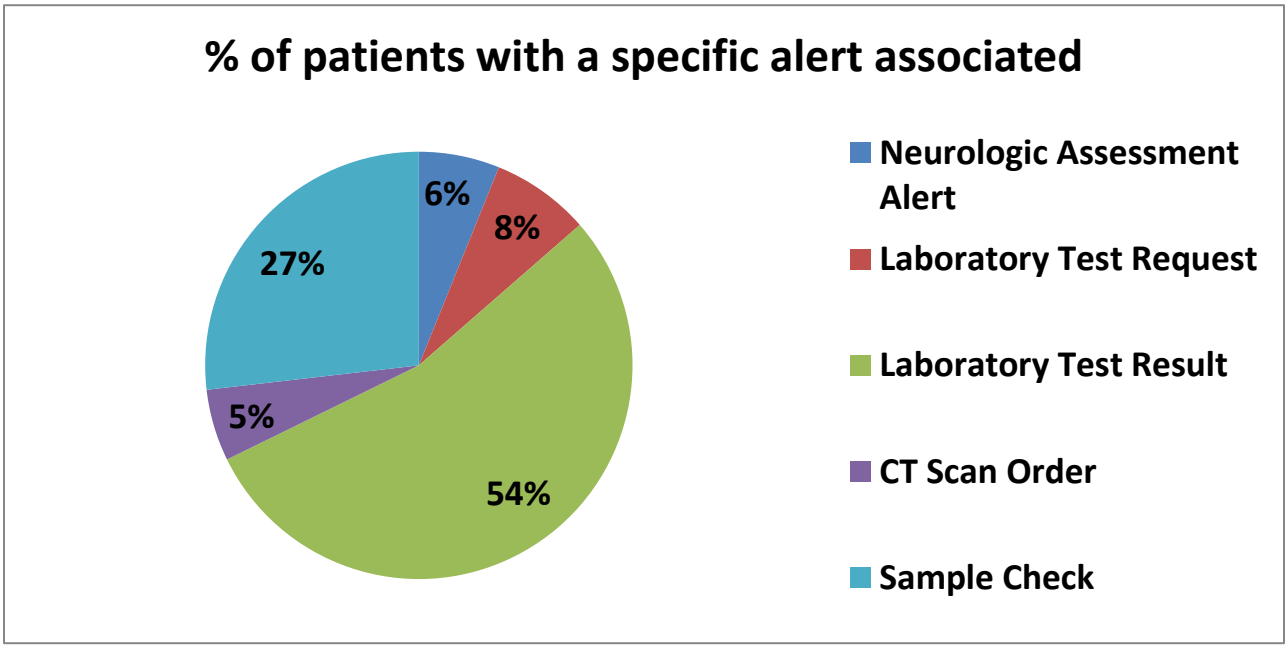

Figure 22: Comparison of the occurrence frequency of different alerts

In Figure 22, specific alerts provided by ReMINE are depicted showing their frequency of occurrence. Laboratory test result alerts occupy the biggest pie with 54%. It means that the pre-defined time for the laboratory test results is most frequently exceeded. 2nd biggest pie is occupied by the sample check alerts with %27 which occurs when the patient's blood sample is still not started to be examined at the laboratory. Remaining pies are occupied by neurologic assessment, laboratory test request and CT scan order with 6%, 8% and 5% respectively.

Total number of alerts generated by ReMINE is 589 and the total number of patients with at least one "delay alert" is 162. Therefore, number of alerts generated per patient is found to be:

$$\frac{Total\ number\ of\ alerts}{Total\ number\ of\ patients\ with\ at\ least\ one\ "delay\ alert"} = 3.64$$

Approximately 4 delay alerts per patient shows that ReMINE has informed the relevant practitioner with 4 different tasks in which the time limit is exceeded. As stated previously, time is a key factor for fibrinolitic treatment. For each patient, ReMINE would speed up the treatment decision process with the warnings. Obviously 3.64 messages on average per patient is very high. This shows that there are more than one bottleneck points within the treatment. Since ReMINE foresees these bottlenecks it avoids the delays and therefore decreases the total task duration. ReMINE does not affect the treatment time, but with the help of the alerts, the unnecessary time losses are prevented.

With the total of 589 delay alerts and 3.64 average delay alerts per patient, ReMINE surely increases the patient care and controls the treatment not in terms of the changing health procedure but supporting it.

The average task duration is calculated by the ratio of total task duration over number of patients. The total task duration is measured for different tasks which will be introduced in different bar charts from Figure 23 to Figure 29.

The total task durations from admission to first assessment for different patients are plotted and shown in Figure 23. The graph shows the time period from the patient's admission to the end of the patient's neurologic assessment. The red line indicates the average task duration which is 20 minutes for this task with a standard deviation of 25.96 minutes. It can be clearly seen from the graph that there are very sharp peaks and high deviation from the average. The defined time would have been exceeded several times and as a result ReMINE would provide a neurologic assessment alert and warn the related practitioner. With the implementation of ReMINE, the task duration would be standardized as much as possible, reducing time losses and providing a low standard deviation.

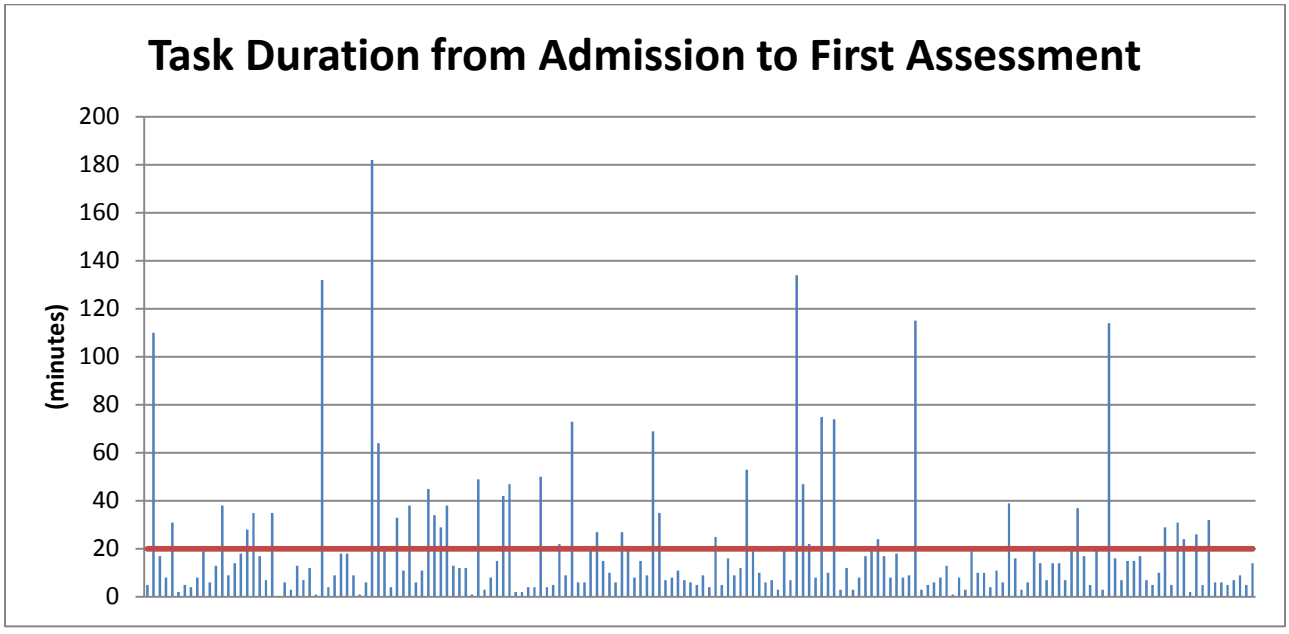

Figure 23: Task duration from admission to the end of the assessment

Next indicator is the time measured from the admission to laboratory examination request and it is depicted on the Figure 24. The average task duration is 28 minutes and the standard deviation is 31.73 minutes. The graph shows sharp peaks which would have been avoided or at least shortened by ReMINE protocol.

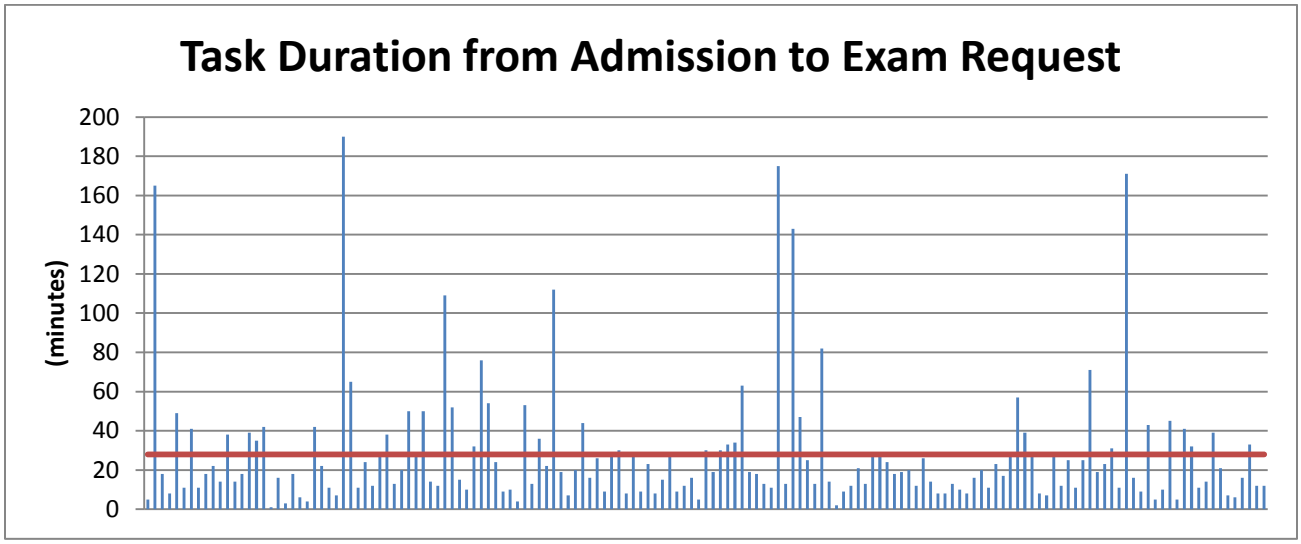

Figure 24: Task duration from the start to the end of lab request

The Figure 25 depicts the task duration from admission to sample check for each patient and the average task duration which is 47.38 minutes. The standard deviation for this task data is 12.83 minutes and as seen in on the bar chart high peaks don't exist, each patient's value is located near the red average line, which explains the standard deviation's being low. However, ReMINE would have generated 27% of the total alert delays for the sample check in. Although the deviation is not very high and the task duration seemed to be almost the same for all patients, with that amount of messages generated by ReMINE, improvement is needed for this period by the hospital which is beyond the scope study. Implementation of ReMINE does not directly affect the treatment policy, however it points out where an improvement is needed within the treatment process. As a result, it helps to improve the overall health care given by the hospital.

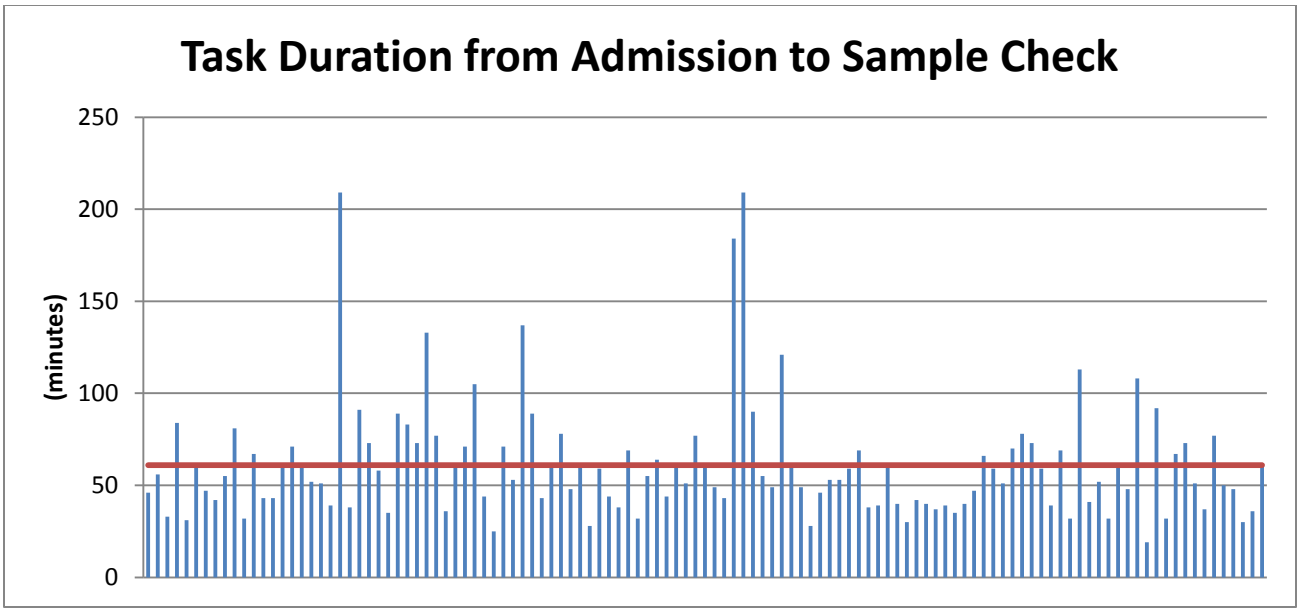

Figure 25: Task duration from the admission to the start of the examination of patient's blood sample

The task duration from admission to exam results for each patient and the average value are shown in Figure 26. The mean average for this task duration is 79 minutes with a standard deviation of 38.31 minutes. Within this period, ReMINE would have generated a total of 35% of the delay alerts (Laboratory request delay alert 8% and sample check in delay alert 27%) Moreover, 79 minutes on average for this task duration seems to be high as within the next step results have to be evaluated and patient's fibrinolitic treatment should start 90 minutes after the admission. This leaves around 11 minutes for the evaluation of the result and makes an important decision for the patient. With this amount of delay alerts, ReMINE would surely help to decrease the total task duration, therefore improving the total health care indirectly.

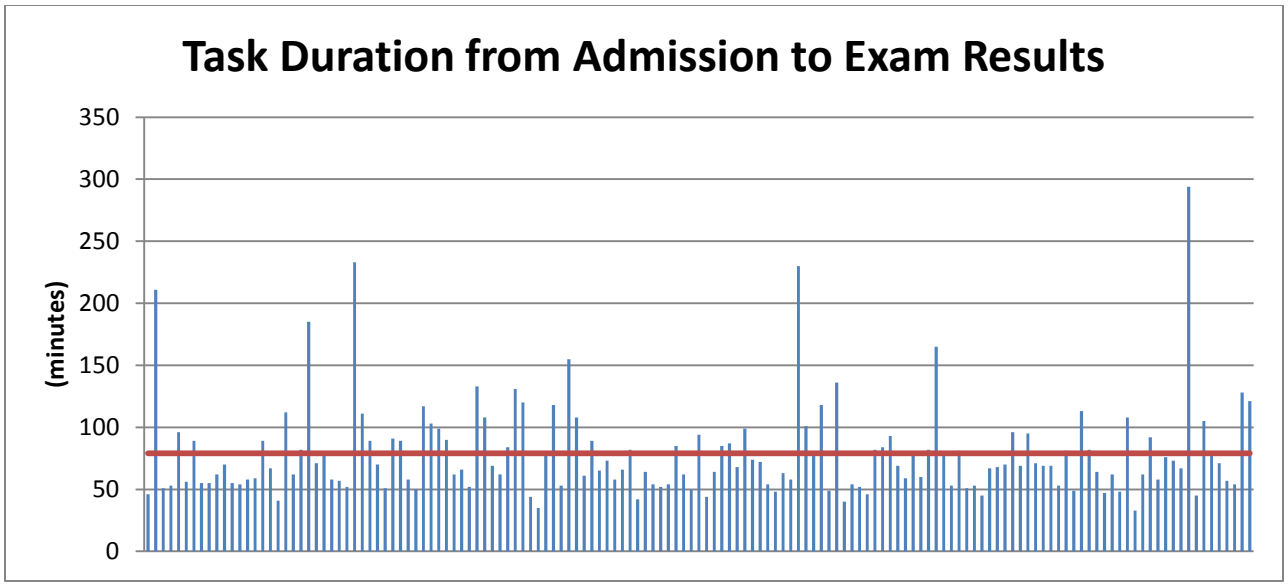

Figure 26: Task duration from the admission to the end of laboratory request

Figure 27Figure 27 depicts the task durations from assessment to exam request. The duration is the time from the end of the practitioner's assessment to the reception of the exam request. The average task duration is 10 minutes with a standard deviation of 16.24 minutes. The standard deviation is high due to the peak values seen on the bar chart. ReMINE would provide laboratory examine check in delay alert and laboratory request delay alert depending on the situation whether the blood sample examination is not started or the blood sample results are not arrived respectively.

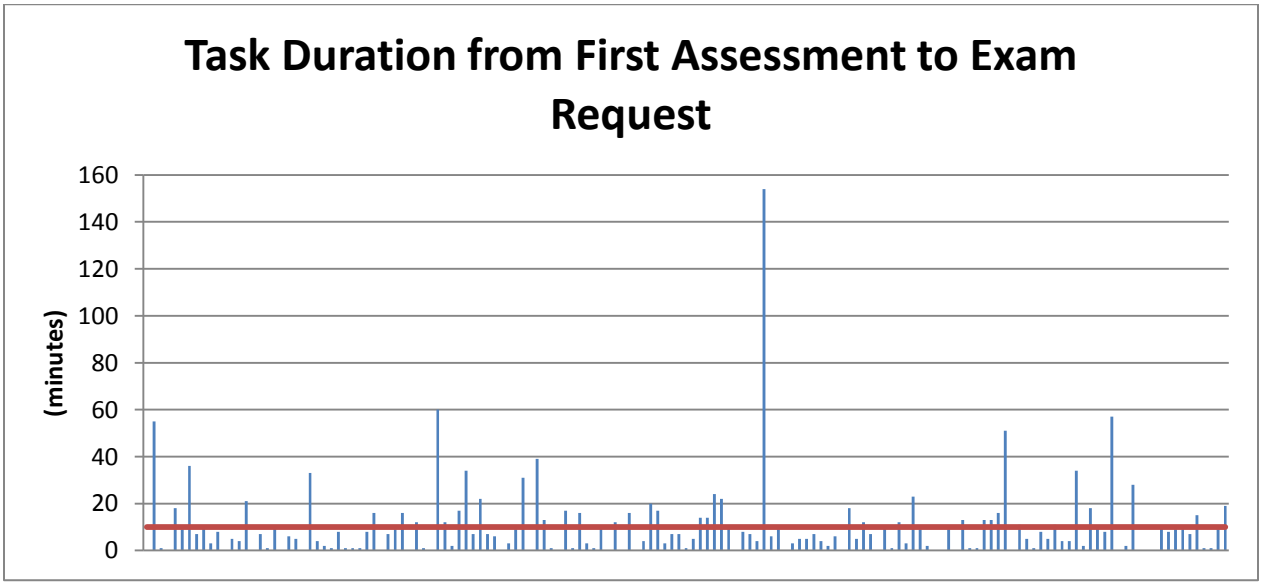

Figure 27: Task duration from the end of first assessment to the end of laboratory request

Next task duration is from the exam request to the exam results; the data for each patient is plotted in Figure 28. The mean average of the task duration is 50 minutes with a standard deviation of

25.92 minutes. All the data is distributed around the average red line with a few exceptions. Although the deviation is not very high, it is previously seen that 54% of the delay alerts are generated by ReMINE for this task duration. This implies that the average time duration of this task is high and it should be improved. Although this duration is more related to the hospital's health treatment, ReMINE shows that it is necessary to have an improvement for this task.

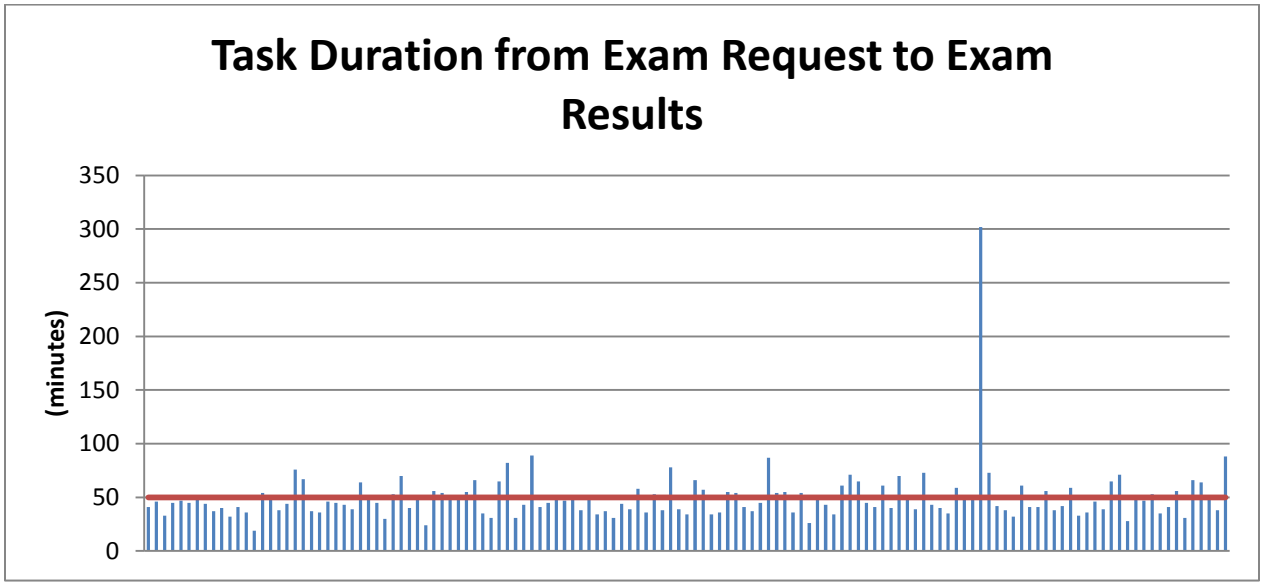

Figure 28: Task duration from the end of laboratory request to the end of laboratory result

Figure 29 shows the task duration from the exam results to treatment for each patient and the mean average duration. The average is 83 minutes and the standard deviation is 41.31 minutes. As the duration is from the lab result to the end of fibrinolitic treatment, it includes many evaluations made by neurologists and a decision period for the availability of the fibrinolitic treatment. Therefore the average task duration for this indicator is high. This task is more specific and changes according to the patient's status. The obtained data contains very few information about this task, however, unexpectedly there has been no observation of fibrinolitic treatment alert although for some patients even this task exceeds 90 minutes.

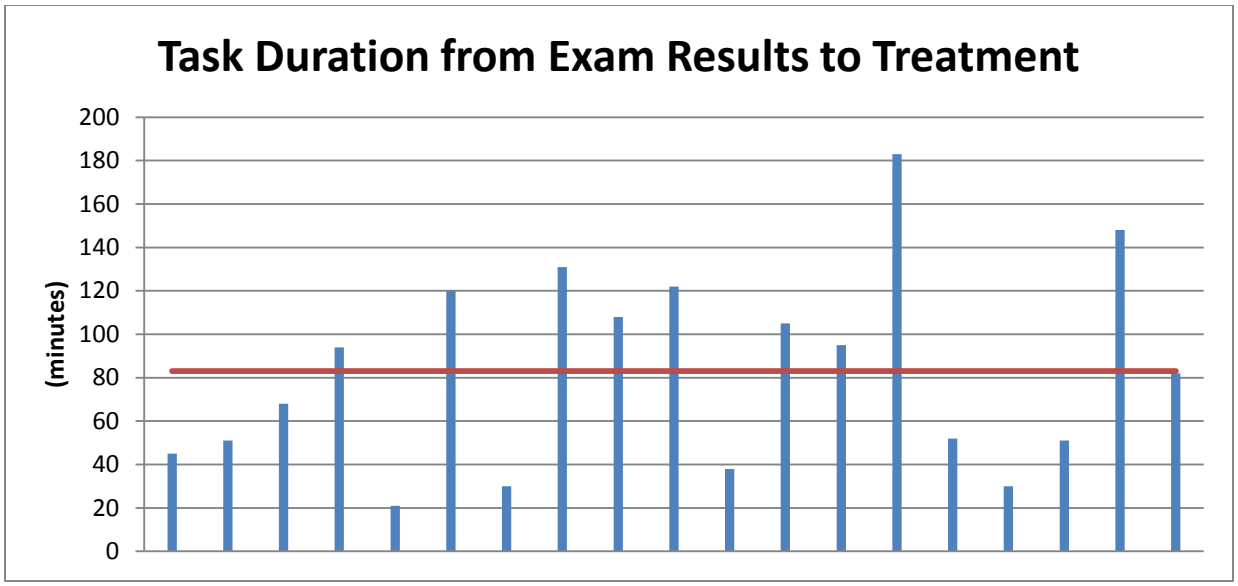

Figure 29: Task duration from the end of laboratory result to the end of treatment decision

5. Assessment of Costs

The cost involved or saved with the technologies in Healthcare is crucial in terms of hospital benefits. Therefore a good choice between such technologies is dependent on the economic evaluations. This assessment impact model introduces such economic evaluations for ReMINE costs in four clinical scenarios: stroke, drug administration, labor monitoring and infection control. This study shows both the costs of clinical scenarios with ReMINE adoption and the cost of hospitals' initial technological scenario when ReMINE is implemented.

In this study, Subramanian et al.'s (2007) assessment for Computer Physician Order Entry (CPOE) systems is applied and ReMINE costs are examined in terms of adoption costs, running costs and productivity saves and wastes.

5.1. Adoption Costs

The technological platform including the hardware purchase and software licensing, the implementation of it including preliminary analysis, configuration, installation and testing and the preparation for its use including initial training arise an investment which is studied under adoption costs.

There exist five functionalities depending on the investment of ReMINE adoption:

(i) Capturing data of patients and organizational states

(ii) Data persistence through databases

(iii) Management and orchestration of data and processes

(iv) Production of alert through business rules

(v) Analysis of RAPS events

For each functionality mentioned above a special investment is necessary (e.g. adopt a Meta Database to guarantee data persistence, or Work Flow Engines to guarantee data management).

The adoption cost can be examined for two different categories: the initial technological scenario and ReMINE adopted clinical scenario.

The initial technological level of the hospital affects a lot the adoption cost. If for example in the hospital it already exits Meta Databases or Work Flow Engines, the adoption cost of ReMINE is lowered. In other words, higher the initial technological state of the hospital is, lower the investment will be to apply the functionalities mentioned above.

Regarding the clinical scenarios where ReMINE will be implemented, the adoption cost is dependent on the clinical scenarios because the investment required for each scenario is different from each other. For example considering five functionalities each time, the adoption cost for the scenario of stroke management and that of labor monitoring are not same. Not only the implementation of which clinical

scenario is important but also the number of clinical scenarios chosen under the ReMINE adoption plays role for the investment.

5.2. Running Costs

Proper functioning of the adoption with continuous maintenance and updates in case of need and with supervision, trainings and assistance services to support the user should be ensured. The costs involved due to this fact after the implementation of ReMINE are called as running costs. Contrary to the adoption cost, the running cost is similar for each clinical scenario but it doesn't vary regarding the initial technological scenario.

5.3. Productivity Return

Instead of actual monetary returns or expenditures, productivity return considers money and time saved in three ways:

1. Decreasing the time used for a task and obviously reducing direct costs of that task or the employee

2. Avoiding the inappropriate tests and obviously reducing the total test cost

3. Discharging not required technologies.

Similar to return costs, different clinical scenarios and the initial technological scenario don't change the productivity returns.

To summarize the assessment cost, adoption and running costs can be called as monetary costs whereas the productivity returns are non-monetary costs. Data registration and collections for monetary costs are easier as the non-monetary costs are the opportunity costs measured by time, activity and productivity.

6. Further Developments

Data analysis of Niguarda Hospital and simulation of this data with ReMINE showed interesting results in terms of ReMINE's support of the treatment in positive manner even though it was a simulation. However, with the provided data, it was not possible to evaluate all the primary and secondary objectives. Analysis showed that ReMINE had an effect on the treatment on which the evaluation could be done. If the hospital would able to record and provide more information about the objectives, ReMINE's more powerful sides can be figured out.

Moreover, the analysis could only be done with Niguarda's data set. If the technical problems can be solved with other pilots, it would be an interesting study to examine these data sets as well since ReMINE will be working on different sections and has different objectives. Also, the initial status of the hospital might change the benefits of ReMINE. ReMINE should also be tested on a pilot with high work load.

A comparison of a data set with ReMINE implementation and another without ReMINE implementation could be another starting point. By doing such a study, one should have better chances to see the benefits. For example, comparison average task durations with and without ReMINE might provide interesting results.

In addition, the benefits in terms of cost analysis are also a nice point to consider. Although it is not a vey easy task to calculate such an indicator, one possible way of performing an analysis could be the reduction in the task durations of the practitioners as their effective working time would be reduced. As previously stated, benefits in patient safety is can only be measured in terms of absence of adverse events.

7. Conclusion

Applications of wrong plans for the treatment and medical errors which are defined as failure of a planned action to be applied during the treatment process are the main problems of healthcare systems. Besides being unacceptable, incident rate of these unwanted events are very high and they result in losing high amount of money due to clinical negligence claims. Therefore, patient safety has taken great attention within the last ten years and information and communication technologies are implemented in the patient safety area.

Main aim of this study was the evaluation of E-health solution for patient safety application to the ReMINE protocol. ReMINE was to be implemented to 3 different pilots, namely Niguarda, Sacco and TRFT Hospitals. ReMINE worked on management of stroke acute phase in the A&E at Niguarda, patient assistance during labour at Sacco and infection control program at TRFT. ReMINE is not designed or supposed to change the protocols and/or guidelines that the hospital is referring to, but aimed at improving and supporting them. ReMINE directly impacts the process of care and has an indirect impact on clinical outcomes. Therefore the evaluation protocol for each pilot distinguishes between two objectives. Primary objectives are related to adherence and compliance to protocols, whereas secondary objectives are related to clinical outcomes. However, it should be kept in mind that the clinical outcomes are affected by multiple factors which go beyond ReMINE's direct support. In fact, clinical outcomes are related to protocols and guidelines.

Although ReMINE was supposed to be tested and evaluated at 3 pilots, due to technical problems, ReMINE could not fully implemented to the pilots, however a data set from Niguarda Hospital was simulated with ReMINE and delay alerts of ReMINE and initial data of the hospital for the task durations were examined. 7 point Likert Scale questionnaires that are applied to practitioners who are going to use ReMINE also helped to evaluate the data sets as they contain good information about the orientation to clinical risk management, orientation to information systems and organizational readiness.

At Niguarda Hospital, simulation showed that ReMINE would generate 589 delay alerts (3,64 delay alert per patient) to support the treatment process. Examination of the task durations show that there is not a standard time for each task as they show high standard deviation for each patient. To apply a fibrinolitic treatment, time plays a significant role. A "yellow coded" patient's examination has to be completed within 90 minutes after the admission to the hospital to apply fibrinolitic treatment. Therefore unnecessary time losses should be avoided. Data from the Niguarda hospital showed that 77,78% of the yellow coded patients are missed for the fibrinolitic treatment due to lapse of time. Pre-assessment results showed that time work load is not high at Niguarda Hospital; however there are so high standard deviations for the task durations within the treatment protocol. If these durations can be standardized by avoiding unnecessary time delays, overall health care could be improved and more patients would be able to receive fibrinolitic treatment. Delay alerts were spread into several task durations within the treatment protocol. This shows that all these tasks can be supported by ReMINE and the durations can be lowered.

8. References

Bates D. W. 2008. Global priorities for patient safety research, *BM Journals BMJ 2009; 338:b1775*

Brennan T, 1991. *The Harvard Medical Practice Study*

Casolari L., Grilli R., 2004. *Il governo clinico del sistema sanitario. In Cinotti R. (a cura di). La gestione del rischio nelle organizzazioni sanitarie. Il Pensiero Scientifico Editore*, Roma, pp. 3-14.

Donabedian A. 1989. Institutional and Professional Responsibilities in Quality Assurance, *Int J Qual Healthcare 1(1): 3-11.*

Helmreich R. L., 2000. Error, stress and teamwork in medicine and aviation: cross sectional surveys, *BMJ 320: 745.*

Hollnagel E., Woods D. D. & Leveson N. 2006. *Resilience Engineering: concepts and precepts*, Cornwall: TJ International Ltd.

Kohn L. T., Corrigan J. & Donaldson M. S. 2000. *To err is human: building a safer health system*, Washington: National Academy Press

Leape L. L., 2008. Scope of Problem and History of Patient Safety, *Boston: Harvard School of Public Health*

Lorenzo F., 2010. A Systems Safety Engineering approach to the implementation of e-Health solutions for Patient Safety

Naessens et al., 2009. A comparison of hospital adverse events identified by three widely used detection methods, *Int J Qual Health Care(2009) 21 (4): 301-307.*

Runyon B et al., 2008. *Hype Cycle for Healthcare Provider Applications and Systems*, Gartner Industry Research

Stelfox H.T. et al., 2006 The “To Err is Human” report and the patient safety literature, *Qual Saf Health Care 2006; 15: 174-178,* Boston

Stroetmann K. A., Jones T, Dobrev A & Stroetmann V N 2006. *eHealth is Worth it,* UK: European Commission.

Thomas E.J. et al., 2000. *Costs of medical injuries in Utah and Colorado* Texas: PMID: 10570659

Pronovost P. J. et al., 2004. Improving Sepsis Care: An Evidence Based Approach, *VHA*

Tamburini E. et al., 2010 eHealth Strategies, Country Brief: England, *European Commission ICT for Health Unit.*

Valeri L. et al., 2010. Business Models for eHealth

Vincent C., 2003. Understanding and Responding to Adverse Events, *N Engl J Med 348; 11, March 2003.*

Wachter R. M., 2004. The End of the Beginning: Patient Safety Five Years After 'To Err is human', *Health Affairs no. (2004)*

Wachter R. M., 2010. Patient Safety at Ten: Unmistakable Progress, Troubling Gaps, *Health Affairs (2010) vol. 29 no. 1: 165-173.*

Wears R. L. & Leveson N. G. 2008. *"Safeware": Safety-Critical Computing and Health Care Information Technology* Florida: Massachusetts Institute of Technology.

Whitehouse D. et al., 2010 eHealth Strategies, Country Brief: England, *European Commission ICT for Health Unit.*

Wilson R. M et al., 1995. *The Quality in Australian Health Care Study* North Sydney: PubMed

APPENDIX

Niguarda Hospital - Tables of indicators

Table A 1: % fibrinolitic treatments on "yellow stroke" patients

# 1	**% fibrinolitic treatments on "yellow stroke" patients**
Type of variable	Ratio
Rationale	To measure the ratio of fibrinolitic treatments to patient admitted at triage as "yellow stroke". A better adherence to the protocol is expected to increase this ratio
Data definition	Patient ID; triage code; fibrinolitic treatment execution
Numerator description	Number of patients that receive the fibrinolitic treatment
Denominator description	Number of patients coded as "yellow stroke" at triage
Data source	ReMINE, PIESSE
Stratification	None

Table A 2: % of missed fibrinolitic treatments

# 2	**% of missed fibrinolitic treatments**
Type of variable	Ratio
Rationale	To measure the incidence of patients that do not receive the fibrinolitic treatment although they would have been eligible from the clinical perspective
Data definition	Patient ID; patients conditions (exam results, CT scan results, …); fibrinolitic treatment execution
Numerator description	Number of patients that do not receive fibrinolitic treatment
Denominator description	Number of "yellow stroke" patients that do not exit from clinical pathway for their own clinical conditions (i.e. number of patients inside DTP STROKE until the end of protocol (90' from triage)
Data source	ReMINE, PIESSE, LIS
Stratification	None

Table A 3: % of recovered on-time fibrinolitic treatments

# 3	**% of recovered on-time fibrinolitic treatments**
Type of variable	Ratio
Rationale	To measure the likelihood that the fibrinolitic treatment is administered to a patient for which at least an alert due to a delay has been triggered
Data definition	Patient ID; alert ID associated to patient; fibrinolitic treatment execution
Numerator description	Number of patients that receive the fibrinolitic treatment after at least one "delay-alert"
Denominator description	Number of patients with at least one "delay-alert"
Data source	ReMINE, PIESSE, LIS
Stratification	None

Table A 4: % of hospitalized yellow stroke patients

# 4	**% of hospitalized yellow stroke patients**
Type of variable	Ratio
Rationale	To measure the ratio of hospitalized patients between the ones admitted at triage as "yellow stroke".
Data definition	Patient ID; triage code; hospitalization
Numerator description	Number of hospitalized patients coded as "yellow stroke" at triage
Denominator description	Number of yellow stroke patients
Data source	ReMINE, PIESSE
Stratification	None

Table A 5: % of patients gone out from DTP

# 5	**% of patients gone out from DTP**
Type of variable	Ratio
Rationale	To measure the ratio of patients gone out from DTP to patients admitted at triage as yellow stroke.
Data definition	Patient ID; triage code; coming out from DTP
Numerator description	Number of patients gone out from DTP STROKE
Denominator description	Number of yellow stroke patients
Data source	ReMINE, PIESSE
Stratification	None

Table A 6: % of overall diagnosis of ischemic stroke from ER on admitted yellow stroke patients

# 6	**% of overall diagnosis of ischemic stroke from ER on admitted yellow stroke patients**
Type of variable	Ratio
Rationale	To measure the ratio of ischemic stroke from ER to patients admitted at triage as “yellow stroke”.
Data definition	Patient ID; triage code; type of admission disease
Numerator description	Number of patients with a diagnosis of ischemic stroke from ER
Denominator description	Number of patients coded as “yellow stroke” at triage
Data source	ReMINE, PIESSE
Stratification	None

Table A 7: % of overall diagnosis of ischemic stroke from ER on patients gone out from DTP STROKE

# 7	**% of overall diagnosis of ischemic stroke from ER on patients gone out from DTP STROKE**
Type of variable	Ratio
Rationale	To measure the ratio of ischemic stroke from ER to patients gone out from DTP STROKE
Data definition	Patient ID; triage code; type of admission disease
Numerator description	Number of patients with a diagnosis of ischemic stroke from ER
Denominator description	Number of patients gone out from DTP STROKE
Data source	ReMINE, PIESSE
Stratification	None

Table A 8: Average number of alerts per patient

# 8	**Average number of alerts per patient**
Type of variable	Ratio
Rationale	To measure the average number of alerts generated per patient
Data definition	Patient ID; Alert ID; triage code
Numerator description	Number of alerts generated
Denominator description	Number of patients for which at least an alert was generated
Data source	ReMINE, PIESSE
Stratification	None

Table A 9: % of patients with a specific alert associated

# 9	**% of patients with a specific alert associated**
Type of variable	Ratio
Rationale	To measure the ratio of patients with a specific alert to the total number of patients with any alert
Data definition	Patient ID; Alert ID; triage code
Numerator description	Number of patients with a specific alert
Denominator description	Number of patients for which at least an alert was generated
Data source	ReMINE, PIESSE
Stratification	Type of alert

Table A 10: % of patients coded as "Yellow Stroke" for which the first assessment is carried out by an A&E physician

# 10	**% of patients coded as "Yellow Stroke" at triage for which the first assessment is carried out by an A&E physician**
Type of variable	Ratio
Rationale	To measure the ratio of patients with ER physician's first assessment (instead neurologist) to patients coded as "yellow stroke" at triage
Data definition	Patient ID; triage code; doctor ID (for the first assessment)
Numerator description	Number of patients coded as "Yellow Stroke" at triage for which the first assessment is carried out by an A&E physician (instead of the neurology consultant)
Denominator description	Number of patients coded as "yellow stroke" at triage
Data source	ReMINE, PIESSE
Stratification	None

Table A 11: Average task duration

# 11	**Average task duration**
Type of variable	Rate
Rationale	To measure the average time between two hospital tasks
Data definition	Patient ID; triage code; task duration
Numerator description	Total task duration
Denominator description	Number of patients
Data source	ReMINE, PIESSE
Stratification	Period from task to task: * from admission to first assessment * from admission to exam request * from admission to sample check * from admission to exam results * from first assessment to exam request * from exam request to exam results * from exam results to treatment

Table A 12: Task duration standard deviation

# 12	**Task duration standard deviation**
Type of variable	Standard deviation
Rationale	To calculate the mean time‟s standard deviation between two hospital tasks
Data definition	Patient ID; triage code; task duration
Numerator description	Standard deviation of the task duration
Denominator description	None
Data source	ReMINE, PIESSE
Stratification	Period from task to task: o from admission to first assessment o from admission to exam request o from admission to sample check o from admission to exam results o from first assessment to exam request o from exam request to exam results o from exam results to treatment

Sacco Hospital - Tables of indicators

Table A 13: Average delay of the main activities of labour assistance

# 1	Average delay of the main activities of labour assistance
Type of variable	Mean
Rationale	To measure the average delays of the labour assistance main activities
Data definition	Alert ID; alert time; activity execution time
Numerator description	Total delays of labour assistance main activities
Denominator description	Number of labour assistance main activities
Data source	ReMINE (most of data are acquired through forms)
Stratification	Main activities monitored by ReMINE: o Start of FHR monitoring; o End of FHR monitoring; o Evaluation of FHR monitoring; o Obstetrician assessment.

Table A 14: Average number of alerts per patient

# 2	Average number of alerts per patient
Type of variable	Mean
Rationale	To measure the average number of alerts triggered per patient, assessing if there is any correlation with the type of activity and with the resource saturation11
Data definition	Patient ID; alert ID; resource saturation
Numerator description	Number of alerts triggered by ReMINE
Denominator description	Number of patients
Data source	ReMINE
Stratification	Type of alert; Resource saturation level: o EFM devices; o Obstetricians; o Labour rooms; o Delivery room.

Table A 15: % of patients with a specific alert associated

# 3	% of patients with a specific alert associated
Type of variable	Ratio
Rationale	To measure the ratio of patients with a specific alert to the total number of patients
Data definition	Patient ID; alert ID;
Numerator description	Number of patients with a specific alert
Denominator description	Number of patients
Data source	ReMINE
Stratification	Type of alert

Table A 16: Average number of alerts per context risk level

# 4	Average number of alerts per context risk level12
Type of variable	Mean
Rationale	To measure a possible correlation between the number of alerts and the context risk level when the alerts are triggered
Data definition	Alert ID; context risk level; risk level of a specific risk contributing factor
Numerator description	Number of alerts triggered by ReMINE within a specific range of context risk level
Denominator description	Number of occurrences of a specific range of the context risk level
Data source	ReMINE
Stratification	Type of alert; Risk level of a specific risk contributing factor: o EFM device saturation; o midwives saturation; o obstetrician saturation; o labour room saturation; o delivery room saturation; o time of the day; o obstetrician experience.

Table A 17: % of patients with "N" alerts associated

# 5	% of patients with "N" alerts associated
Type of variable	Ratio
Rationale	To measure the frequency of non-compliances with the clinical protocol for labour assistance
Data definition	Patient ID; alert ID; labour risk level
Numerator description	Number of patients with "N" alerts associated
Denominator description	Number of patients included in the study
Data source	ISOLABELLA, ReMINE
Stratification	Labour risk level: o low risk labour; o non-low risk labour. Number of alerts "N"; Type of alert.

Table A 18: % of unplanned Caesarean Sections

# 6	% of unplanned caesarean sections
Type of variable	Ratio
Rationale	To measure the incidence of caesarean sections among patients admitted to the Obstetrics A&E Room with a diagnosis of active low-risk labour
Data definition	Patient ID; admission diagnosis; delivery type
Numerator description	Number of patients admitted to the Obstetrics A&E Room with a diagnosis of active low-risk labour who have caesarean sections
Denominator description	Number of patients admitted to the Obstetrics A&E Room with a diagnosis of active low-risk labour
Data source	ReMINE
Stratification	Labour risk level (during the labour assistance, not at the admission): o low risk labour; o non low risk labour.

Table A 19: % of women admitted as active low-risk labour who have other complications

# 7	% of women admitted as active low-risk labour who have other complications (different than caesarean sections)
Type of variable	Ratio
Rationale	To measure the incidence of other complications than caesarean section among patients admitted to the Obstetrics A&E Room with a diagnosis of active low-risk labour
Data definition	Patient ID; admission diagnosis; delivery type
Numerator description	Number of patients admitted to the Obstetrics A&E Room with a diagnosis of active low-risk labour who have other complications (different than Caesarean Sections)
Denominator description	Number of patients admitted to the Obstetrics A&E Room with a diagnosis of active low-risk labour
Data source	ReMINE, patient health record
Stratification	Labour risk level (during the labour assistance, not at the admission): o low risk labour; o non low risk labour.

TRFT Hospital - Tables of Indicators

Primary Indicators (Process Performance)

Table A 20: Number of times in which a specific alert is triggered

RTHPRM 1	**Number of times in which a specific alert is triggered**
Type of variable	Rate
Rationale	To measure the effectiveness of ReMINE in detecting specific events
Data definition	Alert ID
Numerator description	Number of alerts triggered by ReMINE
Denominator description	None
Data source	ReMINE, PAS, LIS
Stratification	Alerts due to: o rank coding (red/yellow) of a patient; o coded red/yellow patient sharing a bay with non-coded patients; o late screening for MRSA.

Table A 21: Quickness to trigger a specific alert

RTHPRM 2	**Quickness to trigger a specific alert**
Type of variable	Proportion
Rationale	To measure the quickness of ReMINE to detect specific events
Data definition	Alert ID; alert time
Numerator description	Number of alerts triggered by ReMINE before the ones triggered by the existing HIS
Denominator description	Number of alerts triggered by ReMINE
Data source	ReMINE, PAS, LIS
Stratification	Alerts due to: o rank coding (red/yellow) of a patient; o coded red/yellow patient sharing a bay with non-coded patients; o late screening for MRSA.

Table A 22: Completeness of a specific alert

RTHPRM 3	**Completeness of a specific alert**
Type of variable	Proportion
Rationale	To measure the completeness of the alerts triggered by ReMINE
Data definition	Alert ID; alert time; quality assessment (Boolean variable)
Numerator description	Number of alerts triggered by ReMINE that have a better quality than the ones triggered by the existing HIS [for each couple of alerts (ReMINE-existing HIS) the infection control team evaluates the most complete one]
Denominator description	Number of alerts triggered by ReMINE
Data source	ReMINE, PAS, LIS
Stratification	Alerts due to: o coded red/yellow patient sharing a bay with non-coded patients; o late screening for MRSA.

Table A 23: Average duration of a routine ward clean of a bed

RTHPRM 4	**Average duration of a routine ward clean of a bed**
Type of variable	Average Rate
Rationale	To measure the average time from room vacancy to completion of a routine ward cleaning of a bed
Data definition	Patient ID; Cleaning Duration; Cleaning Type
Numerator description	Total duration of ward cleaning of beds
Denominator description	Number of routine ward cleaning of beds
Data source	ReMINE, PAS, LIS
Stratification	Place: o bay o cubicle

Table A 24: Average duration of a routine ward clean followed by hydrogen peroxide disinfection of a bed

RTHPRM 5	**Average duration of a routine ward clean followed by hydrogen peroxide disinfection of a bed**
Type of variable	Average Rate
Rationale	To measure the average time from room vacancy to completion of a ward cleaning of a bed followed by its hydrogen peroxide disinfection
Data definition	Patient ID; Cleaning Duration; Cleaning Type
Numerator description	Total duration of ward cleaning followed by hydrogen peroxide disinfection of beds
Denominator description	Number of ward cleaning followed by hydrogen peroxide disinfection of beds
Data source	ReMINE, PAS, LIS
Stratification	Place: o bay o cubicle

Table A 25: Average duration of a terminal clean followed by hydrogen peroxide disinfection of a bed

RTHPRM 6	**Average duration of a terminal clean followed by hydrogen peroxide disinfection of a bed**
Type of variable	Average Rate
Rationale	To measure the average time from room vacancy to completion of a terminal cleaning of a bed followed by its hydrogen peroxide disinfection
Data definition	Patient ID; Cleaning Duration; Cleaning Type
Numerator description	Total duration of terminal cleaning followed by hydrogen peroxide disinfection of beds
Denominator description	Number of terminal cleaning followed by hydrogen peroxide disinfection of beds
Data source	ReMINE, PAS, LIS
Stratification	Place: o bay o cubicle

Table A 26: Average time between two screenings of a red/yellow coded patient

RTHPRM 7	**Average time between two screenings of a red/yellow coded patient**
Type of variable	Average Rate
Rationale	To measure the average time occurring between two screenings of a red/yellow coded patient
Data definition	Alert ID; Patient ID; Screening date
Numerator description	Total time between screenings of red/yellow coded patients
Denominator description	Number of screenings of red/yellow coded patients
Data source	ReMINE, PAS, LIS
Stratification	Type of screening: o consecutive screenings o consecutive late screenings

Table A 27: Standard deviation of the time between two screenings of a red/yellow coded patient

RTHPRM 8	**Standard deviation of the time between two screenings of a red/yellow coded patient**
Type of variable	Ratio
Rationale	To measure the variability of the time occurring between two screenings of a red/yellow coded patient
Data definition	Alert ID; Patient ID; Screening date
Numerator description	Square root of the sum of the squares of the differences of each time between screenings of red/yellow coded patients from the mean time
Denominator description	Square of the number of screenings of red/yellow coded patients
Data source	ReMINE, PAS, LIS
Stratification	Type of screening: o consecutive screenings o consecutive late screenings

Table A 28: % of late screenings on the total number of screenings

RTHPRM 9	% of late screenings on the total number of screenings
Type of variable	Ratio
Rationale	To measure the number of late screening that occur to the total number of screenings
Data definition	Alert ID; Patient ID; Screening date
Numerator description	Number of late screenings
Denominator description	Total number of screenings
Data source	ReMINE, PAS, LIS
Stratification	None

Secondary Indicators (Clinical Outcome)

Table A 29: % of patients infected

RTHSEC 1	% of patients infected
Type of variable	Ratio
Rationale	To measure the percentage of patients infected to the total number of patients
Data definition	Patient ID, type of infection
Numerator description	Number of infected patients
Denominator description	Number of admitted patients
Data source	ReMINE, PAS, LIS
Stratification	None

Table A 30: % of red/yellow coded patients in the hospital on total hospitalized patients

RTHSEC 2	% of red/yellow coded patients in the hospital on total hospitalized patients
Type of variable	Ratio
Rationale	To measure the percentage of red/yellow coded patients to the total number of patients
Data definition	Patient ID, type of infection
Numerator description	Number of red/yellow coded patients
Denominator description	Number of admitted patients
Data source	ReMINE, PAS, LIS
Stratification	Infection code: - red - yellow

Table A 31: % of red/yellow coded patients at admission to the hospital

RTHSEC 3	**% of red/yellow coded patients at admission to the hospital**
Type of variable	Ratio
Rationale	To measure the percentage of red/yellow coded patients at admission to the total number of patients admitted
Data definition	Patient ID, type of infection
Numerator description	Number of patients already red/yellow coded at admission
Denominator description	Number of admitted patients
Data source	ReMINE, PAS, LIS
Stratification	Infection code: - red - yellow

Table A 32: %of red/yellow coded patients in “ReMINE wards” on patients hospitalized in “ReMINE wards”

RTHSEC 4	**% of red/yellow coded patients in "ReMINE wards" on patients hospitalized in "ReMINE wards"**
Type of variable	Ratio
Rationale	To measure the percentage of red/yellow coded patients in “ReMINE wards” to the total number of patients in “ReMINE wards”
Data definition	Patient ID, type of infection
Numerator description	Number of red/yellow coded patients in “ReMINE wards”
Denominator description	Number of patients hospitalized in “ReMINE wards”
Data source	ReMINE, PAS, LIS
Stratification	Infection code: - red - yellow

Table A 33: Average number of contacts that the red/yellow coded patients has

RTHSEC 5	**Average number of contacts that the red/yellow coded patient has**
Type of variable	Average Rate
Rationale	To measure the average number of contacts that a red yellow coded patient has during his hospitalization both before and after being coded
Data definition	Patient ID; Patient Code; Contacts
Numerator description	Number of contacts red/yellow code patients have
Denominator description	Number of red/yellow coded patients
Data source	ReMINE, PAS, LIS
Stratification	period of hospitalization o during hospitalization o during hospitalization before being coded o during hospitalization after being coded