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Master of Science in Mechanical Engineering

E-HEALTH FOR PATIENT SAFETY: QUANTITATIVE PERFORMANCE ASSESSMENT OF THE REMINE PLATFORM

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Abstract

According to recent studies, Risks Against Patient Safety (RAPS) represent one of the most important factors of dead in hospitals: during therapy, more than 8% of patients recovered in hospitals suffer for additional disease that in almost 50% of the cases produce either dead or significant additional health problems. RAPS occur in any stage of the patient care process.

REMINE project idea originates from the common difficulty in conducting the analysis, early identification and effective prevention on RAPS when there are significant mass of inhomogeneous data sources, stored in multimedia databases, as well as distributed environments with different care professionals contemporary involved. To contrast the RAPS trends and the malpractices diffusion, REMINE prosecutes a number of main objectives. a new technological platform, new care process organizational requirements. Main elements are: mining of multimedia data; modelling, prediction, detection of RAPS, RAPS management support system and info broker patient safety framework.

Main outcomes of REMINE will be: time reduction in collecting data, time reduction in RAPS analysis, standardization of common language, evolution in the interaction model, reference framework, patient safety improvement, health-care cost saving

ReMINE has been tested on 2 pilot hospitals in Italy, namely stroke management (Niguarda, Italy) and labor monitoring (Sacco, Italy) and the assessment of ReMINE impacts in these pilots has been completed in this thesis. ReMINE is not designed to change clinical pathways but to better support them. At each hospital, ReMINE's impact assessment has been 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 is discussed.

ReMINE does not affect directly to protocols to change them ,but aim to improve and support them. ReMINE directly impacts the process of care and has an indirect impact on clinical outcomes.

All in all, the assessment showed that 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.

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1. ICT for Patient Safety

1.1. Introduction

"To err is human"

"Crossing the quality chasm"

Together, the above phrases—titles of reports—catalyzed a revolution in American health care to ensure patient safety and improve quality of care. To Err Is Human estimated that 44,000 98,000 lives are lost in hospitals every year due to medical errors and led to the widespread recognition that health care is not as safe as it should be (IOM, 1999). With an emphasis on improving quality,1 better results were thought to be achievable (IOM, 2001).

Subsequent research further documented the deficiencies in the quality and safety of American health care. Early work found evidence-based practice is only followed 55 percent of the time (McGlynn et al., 2003) and ensuing studies have reconfirmed that medical errors continue to be prevalent, as more than 1.5 million preventable adverse drug events occur annually (IOM,2006). Adverse events can result from almost any type of interaction with the care system, at any point during care delivery, and in all care settings. Events can be the result of human, technological, and systems errors and can be classified as errors of commission (a direct consequence of treatment) or errors of omission (failure to undertake an action that should have been completed). Specific to safety, there has been a tendency to assume that a focus on quality will of necessity result in improved safety. This assumption may have delayed awareness of the need for a robust framework focused on safety alone.

Perhaps more important, these studies brought to light the critical concept of systemness, which recognizes that health care is a collection of disparate fragmented parts with many individual actors, each seeking to do their best by the patient instead of health professionals within a comprehensive "system." This lack of systems to improve coordination in part fostered the promulgation of poor-quality, unsafe health care. While the attention to systems of care have increased greatly, many of the efforts in the 10 years since To Err Is Human and Crossing the Quality Chasm have focused on processes of care as a first step, with the end goal of creating a comprehensive system of high quality and safe care. These studies and those in the next section focused on quality and safety in health care overall. This background is needed to understand the context for discussing patient safety related to health information technology (health IT).

1.2. Patient Safety İssue

More than 10 years since these landmark patient safety reports, there is considerable controversy about how much improvement in safety has actually occurred. Clearly some progress has been made with respect to specific processes, such as high rates of prescribing beta-blockers at discharge to patients presenting with an acute myocardial infarction (Chassin et al., 2010), and significantly reduced surgical mortality rates (Neily et al., 2010). Nationwide efforts were undertaken to reduce the number of medical errors in all care settings and campaigns were developed to increase awareness, reduce risk factors, and develop a framework for high-quality care.

Despite these efforts, quality improvement throughout much of the U.S. health care system is still proceeding at a glacial pace. The National Healthcare Quality Report by the Agency for Healthcare Research and Quality (AHRQ) revealed that while nearly two-thirds of 179 measures of health care quality did show improvement, the median annual rate of change was only 2.3 percent. Several quality measures relating to cancer screening and diabetes management actually worsened during this time (AHRQ, 2010).

In terms of safety, several new studies have recently been published suggesting that patients continued to experience high rates of safety problems during hospital stays. Indeed, one study found adverse events continue to occur in as many as one-third of hospital patients (Classen et al., 2011). These adverse events occur in hospitalized patients even in regions where there has been a heavy programmatic focus on improving patient safety in hospitals (Landrigan et al., 2010). Safety problems also plague Medicare beneficiaries—a study suggests that more than 27 percent of Medicare beneficiaries will experience an adverse event during their hospitalizations, with half of these patients suffering more severe adverse events (HHS, 2010a).

These patient safety problems are not just limited to inpatient care. To Err Is Human recognized that more patients could be harmed by errors in ambulatory settings, since more medical care is delivered outside of hospitals than inside. A recent review of malpractice claims concluded that 52 percent of all paid malpractice claims for all physician services involved ambulatory services and almost two-thirds of these claims involved a major injury or death (Bishop et al., 2011).

Important differences exist between the inpatient and ambulatory settings regarding patient safety, including the types of errors seen (IOM, 1999), the relative importance of patient responsibility for following through on care decisions, and the different organizational and regulatory structures in place (Gandhi and Lee, 2010). As a result, it cannot be assumed that interventions to improve hospital safety will be applicable in the ambulatory setting, which deserves focused attention of its own. In recognition of this, an expert consensus conference to establish an agenda for research in ambulatory patient safety

recognized that knowledge of ambulatory patient safety was lacking (Hammons et al., 2001). A recent 10-year review of ambulatory patient safety literature concluded that some progress has been made in understanding ambulatory safety, major gaps remain, and virtually no experiments or demonstrations have been done that show how to improve it (AMA, 2011).

This new refocus on patient safety as a specific system priority is best exemplified by a new Department of Health and Human Services (HHS) initiative with a sole focus on patient safety. Policy makers have recently recognized the significant challenges in improving patient safety across the continuum of care and the lack of progress over the past decade. HHS recently announced a national initiative called the Partnership for Patients, aimed at reducing preventable hospital-acquired conditions and complications, that would result in about 1.8 million fewer injuries to patients and would save more than 60,000 lives over 3 years. The partnership also aims to reduce preventable complications during care transitions, thereby cutting hospital readmissions by 20 percent from 2010 levels (HHS, 2011). This may herald a new national focus on patient safety over the next decade in the United States.

As these findings indicate, the opportunity to continue to improve is great, with many tools yet to be developed and effectively implemented. In virtually every report on patient safety summarized above, health IT has been identified as a critical tool to both measure and improve patient safety. Yet despite the possibility that health IT can enhance the safety and effectiveness of care, the widespread adoption and safe use of health IT products is still relatively immature. Technical and organizational limitations exist that can make health IT difficult to use effectively to improve the safety and quality of care.

1.2.1. 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 1).

The first Minimum Standard (1917)
1) Each hospital should have a medical staff.
2) The members of the medical staff should be chosen basen 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 ve written and filed for all cases.
5) Each hospital should have a clinical laboratory and radiologu section.

Table 1: Minimum Standard for Hospitals, 1917 (Source: Mallon, 2007)

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 were published that considers all dimensions that play a role in the quality of care, when there is a trade-off between costs and effectiveness. 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, in 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.

1.2.2. 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 1: The Secretary of Health and Human Services (HHS) should publish an action and surveillance plan within 12 months that includes a schedule for working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use. The plan should specify:

a. The Agency for Healthcare Research and Quality (AHRQ) and the National Library of Medicine (NLM) should expand their funding of research, training, and education of safe practices as appropriate, including measures specifically related to the design, implementation, usability, and safe use of health IT by all users, including patients.

b. The Office of the National Coordinator for Health IT (ONC) should expand its funding of processes that promote safety that should be followed in the development of health IT products, including standardized testing procedures to be used by manufacturers and health care organizations to assess the safety of health IT products.

c. ONC and AHRQ should work with health IT vendors and health care organizations to promote postdeployment safety testing of EHRs for high-prevalence, high-impact EHR-related patient safety risks.

d. Health care accrediting organizations should adopt criteria relating to HER safety.

e. AHRQ should fund the development of new methods for measuring the impact of health IT on safety using data from EHRs.

Recommendation 2: The Secretary of HHS should ensure insofar as possible that health IT vendors support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details (e.g., screenshots) relating to patient safety.

Recommendation 3: ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available.

Recommendation 4: The Secretary of HHS should fund a new Health IT Safety Council to evaluate criteria for assessing and monitoring the safe use of health IT and the use of health IT to enhance safety. This council should operate within an existing voluntary consensus standards organization.

Recommendation 5: All health IT vendors should be required to publicly register and list their products with ONC, initially beginning with EHRs certified for the meaningful use program.

Recommendation 6: The Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.

Recommendation 7: The Secretary of HHS should establish a mechanism for both vendors and users to report health IT–related deaths, serious injuries, or unsafe conditions.

a. Reporting of health IT–related adverse events should be mandatory for vendors.

b. Reporting of health IT–related adverse events by users should be voluntary, confidential, and nonpunitive.

c. Efforts to encourage reporting should be developed, such as removing the perceptual, cultural, contractual, legal, and logistical barriers to reporting.

Recommendation 8: The Secretary of HHS should recommend that Congress establish an independent federal entity for investigating patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT. This entity should also monitor and analyze data and publicly report results of these activities.

Recommendation 9:

a. The Secretary of HHS should monitor and publicly report on the progress of health IT safety annually beginning in 2012. If progress toward safety and reliability is not sufficient as determined by the Secretary, the Secretary should direct the FDA to exercise all available authority to regulate EHRs, health information exchanges, and PHRs.

b: The Secretary should immediately direct the FDA to begin developing the necessary framework for regulation. Such a framework should be in place if and when the Secretary decides the state of health IT safety requires FDA regulation as stipulated in Recommendation 9a above.

Recommendation 10: HHS, in collaboration with other research groups, should support cross-disciplinary research toward the use of health IT as part of a learning health care system. Products of this research should be used to inform the design, testing, and use of health IT. Specific areas of research include

a. User-centered design and human factors applied to health IT,
b. Safe implementation and use of health IT by all users,
c. Sociotechnical systems associated with health IT, and
d. Impact of policy decisions on health IT use in clinical practice.

“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).

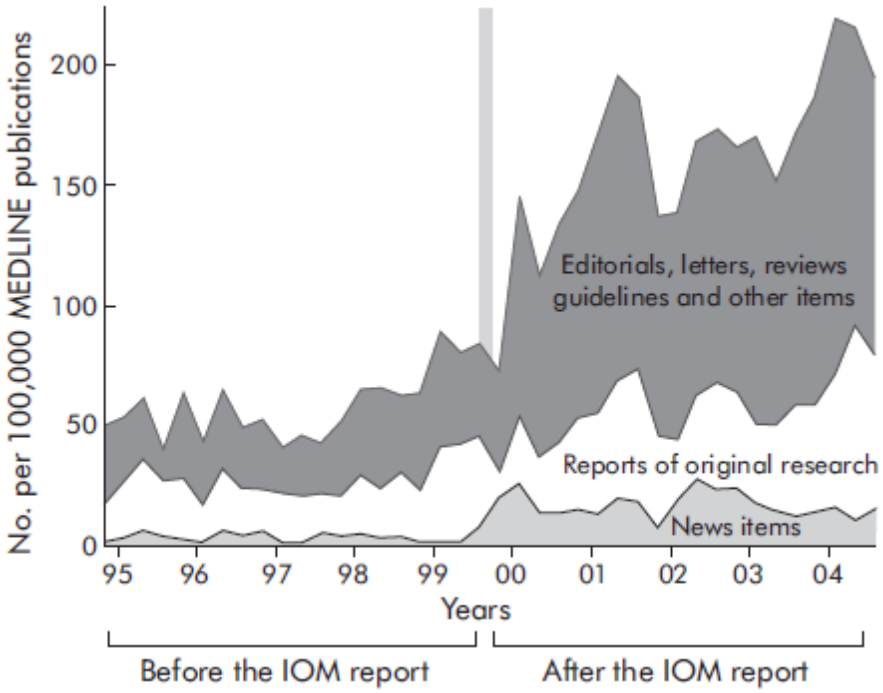

Figure 1: Patient safety publications before and after the publication of the "To Err is Human" report (Source: Stelfox et al., 2006)

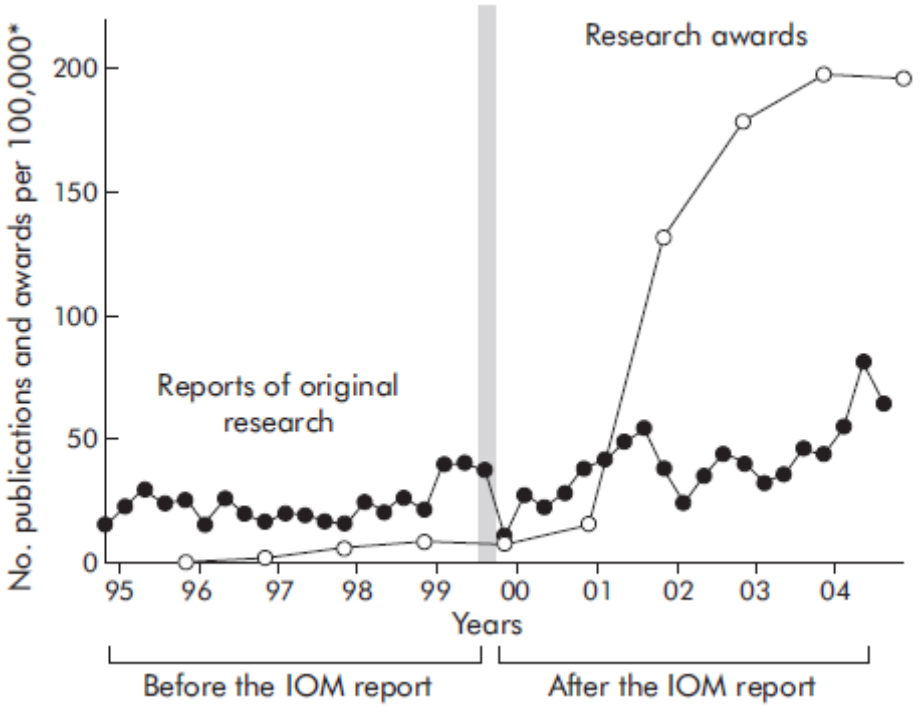

Figure 2: Patient safety research and awards before and after the publication of the "To Err is Human". (Source: Stelfox et al., 2006)

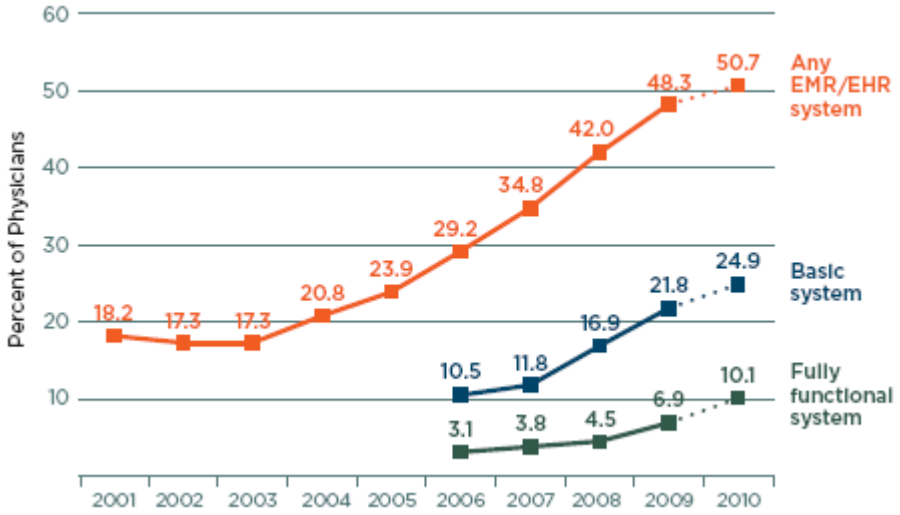

Figure 1-1: Percentage of offi ce-based physicians with electronic medical records/electronic health records: United States, 2001–2009 and preliminary 2010.

Any EMR/EHR is a medical or health record system that is either all or partially electronic (excluding systems solely for billing). The 2010 data are preliminary estimates (as show by dotted lines), based only on the mail survey. Estimates through 2009 include additional physicians sampled from community health centers; prior 2008 combined

estimates were revised to include those physicians (4). Estimates of basic and fully functional systems prior to 2006 could not be computed because some items were not collected in the survey. Fully functional systems are a subset of basic systems. Some of the increase in fully functional systems between 2009 and 2010 may be related to a change in survey instruments and defi nitions of fully functional systems between 2009 and 2010 (see Table for more details). Includes nonfederal, offi ce-based physicians. Excludes radiologists, anesthesiologists, and pathologists.

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.

1.3. Priority Matrix and Hype Cycle Analysis for Health Care

1.3.1. The Priority Matrix

The priority matrix (Table) accompanies the Hype Cycle graph. It represents a technology's benefit to its time to maturity. Table 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 2: 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 (Healtcare 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 Deparment 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 (Acess and Financial Transactions) * Personal Health Management Tools - Healthcare Providers	* Remote ICU
Low			* Perioperative Charting and Anesthesia *Documentation within the CPR	* Patient Deciosion Aids - Healthcare Provider

1.3.2. Hype Cycle

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 is 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.

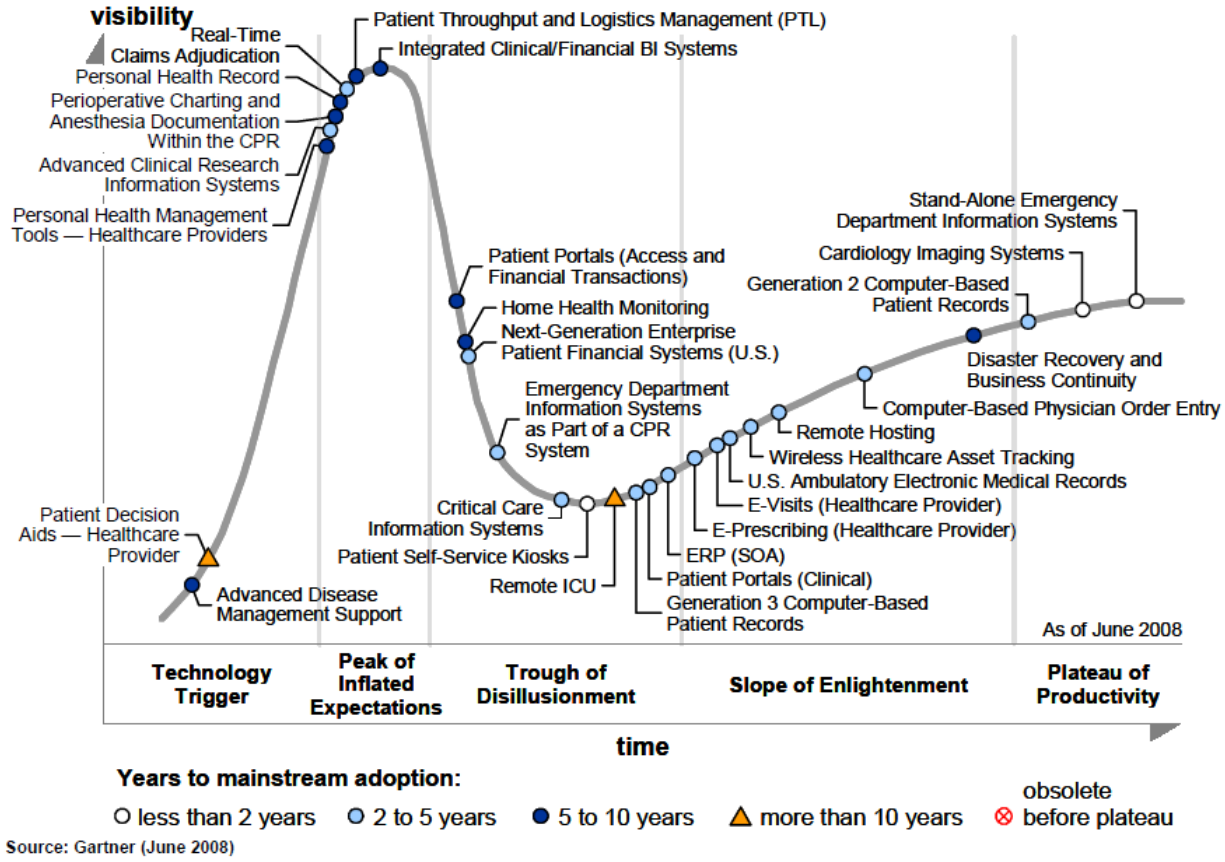

Figure 3: The Hype Cycle for Healthcare

1.3.3. Detailed Analysis of the Technologies on 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 3 and Table 4.

Table 3: 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 4: 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

1.3.4. On the Rise

1.3.4.1. 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.

1.3.5. At the Peak

1.3.5.1. 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.

1.3.5.2. 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.

1.3.5.3. 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.

1.3.5.4. 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.

1.3.5.5. 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 is 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.

1.3.6. Climbing the Slope

1.3.6.1. 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, 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.

1.3.6.2. 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.

1.4. Information Technology and Patient Safety

Health IT is not one specific product that, once implemented, can automatically result in highly safe and effective health care. It encompasses a technical system of computers, software, and devices that operate in the context of a larger sociotechnical system—a collection of hardware and software working in concert within an organization that includes people, processes, and workflow. It is widely believed that, when designed and used appropriately, health IT can help create an ecosystem of safer care while also producing a variety of benefits such as reductions in administrative costs, improved clinical performance, and better communication between patients and caregivers. In this view, it can be a positive, transformative force for delivering health care. However, the assumption that the aforementioned benefits are highly correlated with health IT has not been adequately tested and there are some indications that the features needed to acquire one benefit may actually frustrate efforts to achieve another. In particular, there is a growing concern that health IT designs that maximize the potential for administrative and economic benefit may be creating new paths to failure. Reports of health IT becoming a distraction or cause of miscommunication raise the possibility that health IT may cause harm if it is poorly designed, implemented, or applied. Poorly designed, implemented, or applied, health IT can create new hazards in the already complex delivery of health care, requiring health care professionals to work around brittle software, adding steps needed to accomplish tasks, or presenting data in anonintuitive format that can introduce risks that may lead to harm. Risks to patient safety also arise as a result of great heterogeneity in health IT products. As health IT products have become more intimately involved in the delivery of care, the potential for health IT–induced medical error, harm, or death has increased significantly. Examples of health IT–induced harm that can result in serious injury and death include dosing errors, failing to detect fatal illnesses, and delaying treatment due to poor human–computer interactions or loss of data (Aleccia, 2011; Associated Press, 2009; Graham and Dizikes, 2011; Schulte and Schwartz, 2010; Silver and Hamill, 2011; U.S. News, 2011).

The portfolio of research on health IT has included little regarding the general impact of health IT on safety of clinical care. The evidence in the literature about the impact of health IT on patient safety is mixed but shows that the challenges facing safer health care and safer use of health IT involve the people and clinical implementation as much as the technology. The literature does reflect improvements in some areas in well-established health care institutions, notably medication administration through use of computerized prescribing and bar-coding systems. But the evidence of health IT's impact on patient safety beyond medication safety and across the health care system is lacking. Although evidence suggests improvements in safety can be made, some studies have found health IT to have no effect on patient safety, and case reports such as those cited above show that it can also contribute to harm.

Advanced technology can create some new paths to failure at the same time that it blocks others. These new forms of failure are often hard to anticipate and may go unnoticed or be misidentified until the introduction of the new technology is well advanced. The resulting shift in the locus of failure can make the evaluation of the impact of technology on safety difficult, especially if the contribution of technology to the new forms of failure is not appreciated (Woods et al., 2010). Given the large investments being made in health IT, there is a great need to ensure that the new technology is actually improving safety of care.

1.4.1. 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 healthcare 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).

1.4.2. 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)

1.5. Clinical Risk Management and ICT Application Due to IOM Report 2011

The ONC's Health IT Policy Committee held a hearing on patient safety and health IT in February 2010 and recommended ONC "commission a formal study to thoroughly evaluate health IT patient safety concerns, and to recommend additional actions and strategies to address those concerns" (HHS, 2010b). In September 2010, ONC asked the IOM to make recommendations about how public and private actors can maximize the safety of health IT–

assisted care (see Box 1-1). In response, the IOM established the Committee on Patient Safety and Health Information Technology.

The committee's report comes at a point in time characterized by a number of rather dramatic changes relating to health care in addition to major national health insurance and financial reforms. First, the HITECH legislation provides substantial incentives to accelerate the adoption of EHR systems. Second, there is an ongoing movement away from the historical model of physician autonomy to one focused on adherence to evidence-based guidelines and best practices that promote safe, high-quality care. Finally, the practice of medicine is inexorably moving from being based primarily upon knowledge of organs and organ systems to being based upon genomics and proteomics, which has major implications for data management capabilities. The aggregate impact of these tectonic shifts beneath health care and its related technologies and treatments is one that requires development of more complex yet reliable systems to assure high performance in the midst of great baseline challenges to achieving excellent outcomes.

Clinical risk management is also 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 of 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 there is 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.

1.6. Chapter Review

In this chapter, information computer technology for patient safety issue was described briefly. Effect of the "To Err is Human" report by Institute of Medicine and the Hype Cycle were examined in details. Models and Methods which are developed in recent years are explained with their benefits and limitations. The effects of Information technology on patient safety also described. Lastly, clinical risk management and ICT applications due to 2011 IOM report are stated.

2. The "ReMINE" Project and 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 5).

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).

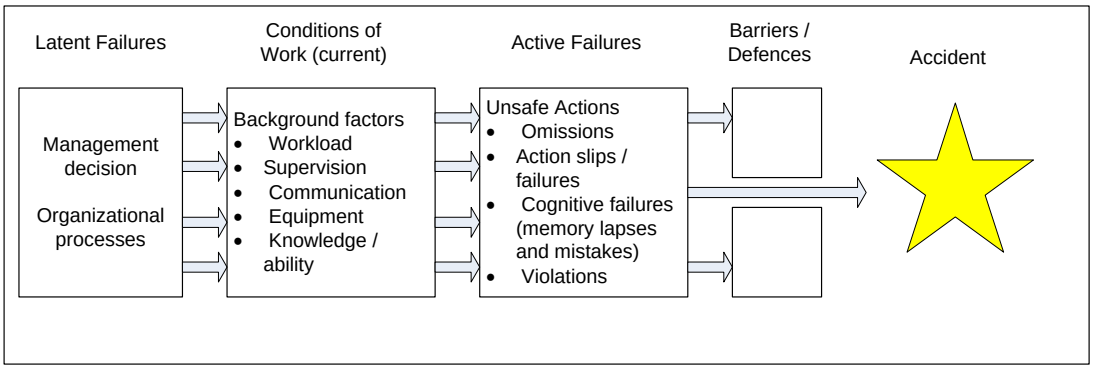

Figure 5: Reason's Model of Organizational Risks (source: Vincent et al., 1998)

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 6.

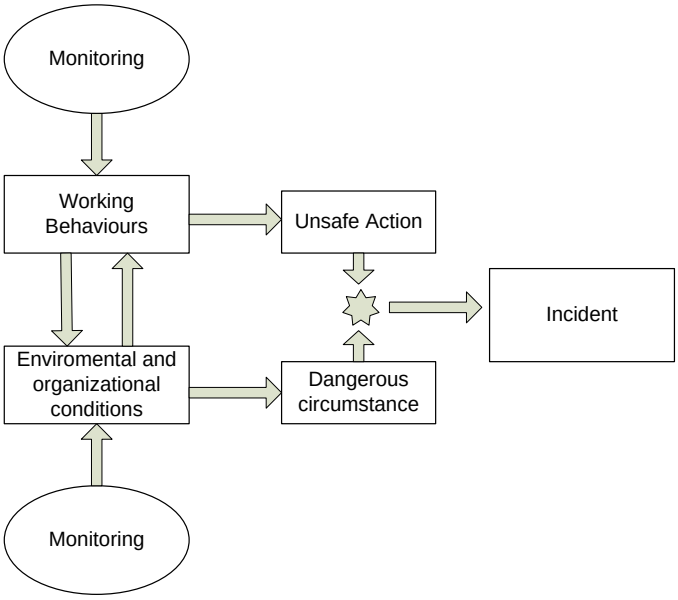

Figure 6: Anatomy of an accident (Trucco et al., 2008)

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 5), 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 5 Table .

Table 5: 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, 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 number (RPN) is calculated by the multiplication of Occurrence and Severity. Then, criticality is placed into the risk level. Risk assessment matrix can be seen in Table 6Table

Table .

Table 6 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 7.

Table 7: 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 8 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 8: Vincent's factos 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

2.4. Competitors of Remine Platform and ''Soarian'' Clinical Workflow Tool by Siemens

Whether you run, own or operate a hospital, a group practice, a private physician practice, or a rehabilitation clinic, you all pursue a common objective: the most efficient and patient-oriented health care possible. Meeting this objective requires close cooperation among all of the participants. Soarian Integrated Care from Siemens is a solution that provides you key support with an optimized flow of information across sectors. Soarian Integrated Care is an application that enables integration of new communication media into your existing treatment workflows and systems.

In complex treatment processes, patients are often treated by various health care providers, for example, a general practitioner, specialists in private practice, and a hospital. To ensure a smooth treatment process without unnecessarily repeating examinations, patient data has to be exchanged, such as information regarding treatments and therapies, diagnoses, and images. Often, the treating physician wants to obtain the opinion of a colleague or another institute, especially in the case of a difficult diagnosis. With Soarian Integrated Care, all of this occurs easily via a secure common network, enabling all participants to view the relevant information with a click of the mouse. This can help you lower treatment costs and increase treatment quality, particularly when dealing with chronic diseases.

Soarian Integrated Care supports communication between various health care facilities. This is enabled through the exchange of diagnostic reports and images between the participants, and through the administration of a common patient file. As a result, the facilities participating in the treatment have easy access to all relevant information entered in the treatment network and provided in the patient file.

All classic hospital information systems (HIS) from Siemens, such as medico//s, Clinicom, and the innovative workflow management system Soarian Clinicals, are compatible with Soarian Integrated Care. The HIS systems of other manufacturers as well as physician information systems can be linked to Soarian Integrated Care amongst others via HL7. This openness to various IT systems makes Soarian Integrated Care a universal telemedicine platform for integrated health care.

Close cooperation between inpatient and outpatient care is a general requirement in health care, because it results

in improved treatment. But it is mandatory to ensure the efficient provision of services in this area. Soarian Integrated Care is an important component for reaching this objective – thanks to significantly improved communication between participating physicians, treatment quality increases while at the same time, administrative expenditures decrease.

By synchronizing the service providers involved in patient care and the corresponding information, workflows are simplified across all sectors, existing relationships, e.g. between

referring physicians and hospitals, are strengthened, and new relationships are established. Soarian Integrated Care provides this integration in a simple, web-based manner.

The modular design of Soarian Integrated Care enables optimal adaptation to the individual needs of users. Depending on the application scenario, existing and newly added modules can be utilized and the system design can be adapted to an increasing number of users.

2.5. Benchmark of Remine Platform

Remine platform and project is not alone in its market. There are some other platforms which are competitors of Remine project are also exist. In this chapter Remine will be compared with its competitors.

REMINE:

According to recent studies, Risks Against Patient Safety (RAPS) represent one of the most important factors of dead in hospitals: during therapy, more then 8% of patients recovered in hospitals suffer for additional disease that in almost 50% of the cases produce either dead or significant additional health problems. RAPS occur in any stage of the patient care process.

REMINE project idea originates from the common difficulty in conducting a analysis, early identification and effective prevention on RAP when there are significant mass of inhomogeneous data sources, stored in multimedia databases, and a distributed environments with different care professionals contemporary involved.

To contrast the RAPS trends and the malpractices diffusion, REMINE prosecutes a number of main objectives. a new technological platform, new care process organizational requirements. Main elements are: mining of multimedia data; modelling, prediction, detection of RAPS, RAPS management support system and info broker patient safety framework.

Main outcomes of REMINE will be: time reduction in collecting data, time reduction in RAPS analysis, standardization of common language, evolution in the interaction model, reference framework, patient safety improvement, health care cost saving (within an estimated RAPS reduction between 6% to 9% of RAPS.

ALERT:

Serious adverse effects resulting from the treatment with thalidomide prompted modern drug legislation more than 40 years ago. Post-marketing spontaneous reporting systems for suspected adverse drug reactions (ADRs) have been a cornerstone to detect safety signals in pharmacovigilance. It has become evident that adverse effects of drugs may be detected too late, when millions of persons have already been exposed.

In this project, an alternative approach for the detection of ADR signals will be developed. Rather than relying on the physician's capability and willingness to recognize and report suspected ADRs, the system will systematically calculate the occurrence of disease (potentially ADRs) during specific drug use based on data available in electronic patient records. In this project, electronic health records (EHRs) of over 30 million patients from several European countries will be available. In an environment where rapid signal detection is feasible, rapid signal assessment is equally important. To rapidly assess signals, a number of resources will be used to substantiate the signals: causal reasoning based on information in the EHRs, semantic mining of the biomedical literature, and computational analysis of biological and chemical information (drugs, targets, anti-targets, SNPs, pathways, etc.).

The overall objective of this project is the design, development and validation of a computerized system that exploits data from electronic healthcare records and biomedical databases for the early detection of adverse drug reactions. The ALERT system will generate signals using data and text mining, epidemiological and other computational techniques, and subsequently substantiate these signals in the light of current knowledge of biological mechanisms and in silico prediction capabilities. The system should be able to detect signals better and faster than spontaneous reporting systems and should allow for identification of subpopulations at higher risk for ADRs.

AVERT-IT:

Intensive Care patients can experience Adverse Events associated with sudden episodes of low blood pressure. These Adverse Events may impact all of the main organs resulting in longer lengths of stay, increased care costs and reducing quality of outcomes. Existing technologies enable to clinicians to know when these events have occurred and treat the effects.

Medical techniques for avoiding Adverse Events currently exist, but clinicians don#t have a reliable way to predict the occurrence, so there is no opportunity for intervention.

Research indicates average lengths of stay can be reduced by up to 30%, and outcomes improved for a similar proportion of patients, if these Adverse Events can be avoided through prediction and intervention. Potential savings across the EU exceed 5 billion euros, annually.

A model for predicting Adverse Events offers potential for improving outcomes across a wide range of conditions and or illnesses.

The main objectives of the project are:

Understanding the association between multiple patient parameters and arterial hypotension (sudden drop in blood pressure)

Development of a software application to predict the occurrence of arterial hypotension based on recognition of the associations described above

Validation of the solution in clinical trials

Exploitation model for the commercialisation of the software in product/service sales across international markets

PSIP:

Adverse Drug Events (ADE) due to product safety problems, and medication errors due to human factors (HF) are a major Public Health issue. They endanger the patients¿ safety and originate considerable extra hospital costs. Healthcare ICT applications should help reducing the prevalence of preventable ADE, by providing healthcare professionals and patients with relevant knowledge (guidelines, recommendations, etc.).

But their efficiency is impeded by two major drawbacks:

lack of reliable knowledge about ADE

poor ability of ICT solutions to deliver contextualised knowledge focused on the problem at hand, aggravated by a poor consideration of causative HF.

The objective of the project Patient Safety through Intelligent Procedures in Medication (PSIP) is (1) to facilitate the systematic production of epidemiological knowledge on ADE and (2) to ameliorate the entire medication cycle in a hospital environment.

The first sub-objective, SO, is to innovatively produce knowledge on ADE: to know, as exactly as possible, per hospital, their number, type, consequences and causes, including HF. Data Mining of the structured hospital data bases, and Semantic Mining of Data Collections of free-texts (letters, reports), will give a list of observed ADEs, with frequencies and probabilities, thus giving a better understanding of potential risks.

The second SO is to develop a set of innovative knowledge based on the mining results and to deliver a contextualised knowledge fitting the local risk parameters, in the form of alerts and decision support functions. This knowledge will be implemented in a PSIP-

platform independently of existing ICT applications. These applications will connect to the platform to access and integrate the knowledge in their local system. The design and development cycle of the PSIP solution will be HF oriented.

Dissemination plans will be developed taking into account other uses (medical devices, primary and tertiary Healthcare).

Table 9: Remine vs others

	REMINE	ALERT	AVERT-IT	PSIP
WHY	• Early identification • Inhomogeneous data source • Multimedia database • Distributed environment • Different care professionals	• Adverse drug effect may be detected too late • Millions of people can be exposed • Design, develop and validate a computerized system • Early detection of ADR	• Sudden expose of low blood pressure • Adverse events impact main organs • Clinicians can not predict occurence	• ICT applications should guide and recommend to professionals • Facilitate systematic production • Ameliorate medication cycle
HOW	• Mining of multimedya data • Modeling • Prediction • Detection of RAPS • RAPS management support	• Semantic mining of biomedical literature • Computational analysis of biomedical and chemical info • Systematically calculation of the occurence of desiase	• Understading association between multiple patient parameter-arterial hypotension • Predicting occurence of arterial hypotension	• Data mining of the structured hospital data bases • Semantic mining of data collections of free-texts (letters, reports) • Alerts • Decision support function
OUTCOME	• Time reduction • Standardization of common language • Patient safety improvement • Health care cost saving	• Better and faster signal detecting from spontaneous reporting systems.	• Prediction and intervention • Reducing length of stay • İmproved outcome quality • Cost saving	• Better understanding of potential risks • Human factor reduced • Health care cost saving

There are many commercial platforms which are used for e-health record, early identification and managing clinical workflow. As the human factor is very important on health issues, those type of IT applications develop better health care and minimize human factor.

Remine ,Alert ,Avert-IT, PSIP platforms are compared at the table above. While Alert, Avert-IT and PSIP are focused on specific subjects such as; adverse drug effect and sudden expose of low blood pressure, REMINE can be used for different specifications such as; acute stroke and labour assistance. The working principles of all platforms are based on data mining, data examining and giving alerts as a results. They all improve health care quality, cost saving and negative effect of human factor.

2.6. Chapter Review

In this chapter the ReMINE protocol is briefly introduced by explaining its capabilities, limitations, business rules and risk assessment methodology. Differences of Predictive and Real Time business rules are discussed. Detailed description of the business rules can be seen in the appendix.

Competitors of Remine platform such as Soarian by Siemens, Alert, Avert-IT and Psip are examined thus strongness and weakness of remine platform in e-health market can be described. Finally a benchmark study is done for Remine project.

3. Socio-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 10 and Table 11.

Table 10: 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 11: 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

- 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 12.

Table 12: 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 13).

Table 13: 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. Remine Platform Validation in Pilot 1 – Acute Stroke Patients

In the first part, assessment of pre-requisites of the Niguarda pilot will be made and the assessment of process indicators will 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 Niguarda Hospital

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 14 shows the 7 point Likert Scale questionnaire applied for the orientation to clinical risk management.

Table 14: 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							

Figure 7 depicts the evaluation results of the orientation to clinical risk management from different point of views. Results show that the work load is not very high, the training level of the practitioners are good. Moreover discussions and meetings are done about clinical risk management.

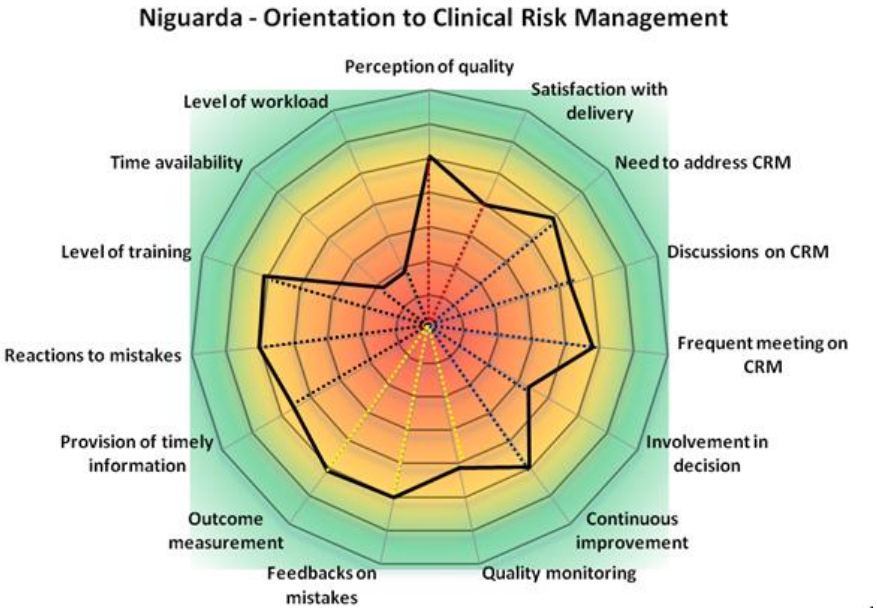

Figure 7: Evaluation results of the orientation to clinical risk management at Niguarda Hospital

Table 15 shows the 7 point Likert Scale questionnaire applied for the orientation to information systems.

Table 15: 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							

Figure 8 depicts the evaluation results of the orientation to information systems from different point of views. Results show that the hospital is committed rely on information systems. Moreover, information systems are satisfactory for the hospital.

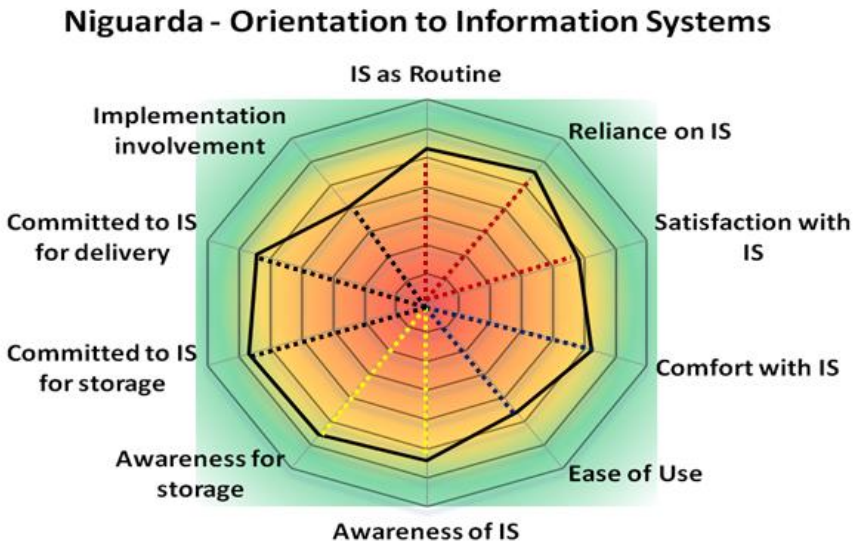

Figure 8: Evaluation results of the orientation to information systems at Niguarda Hospital

Table 16 shows the 7 point Likert Scale questionnaire applied for the organizational readiness.

Table 16: 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							

Figure 9 depicts the evaluation results of the organizational readiness from different point of views. The general climate of the hospital is good. Practitioners are willing to help each other, have a strong sense of belonging and are well trained and have the capability for the kind of work they have to do.

Figure 9: Evaluation results of the organizational readiness at Niguarda Hospital

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 10. 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.

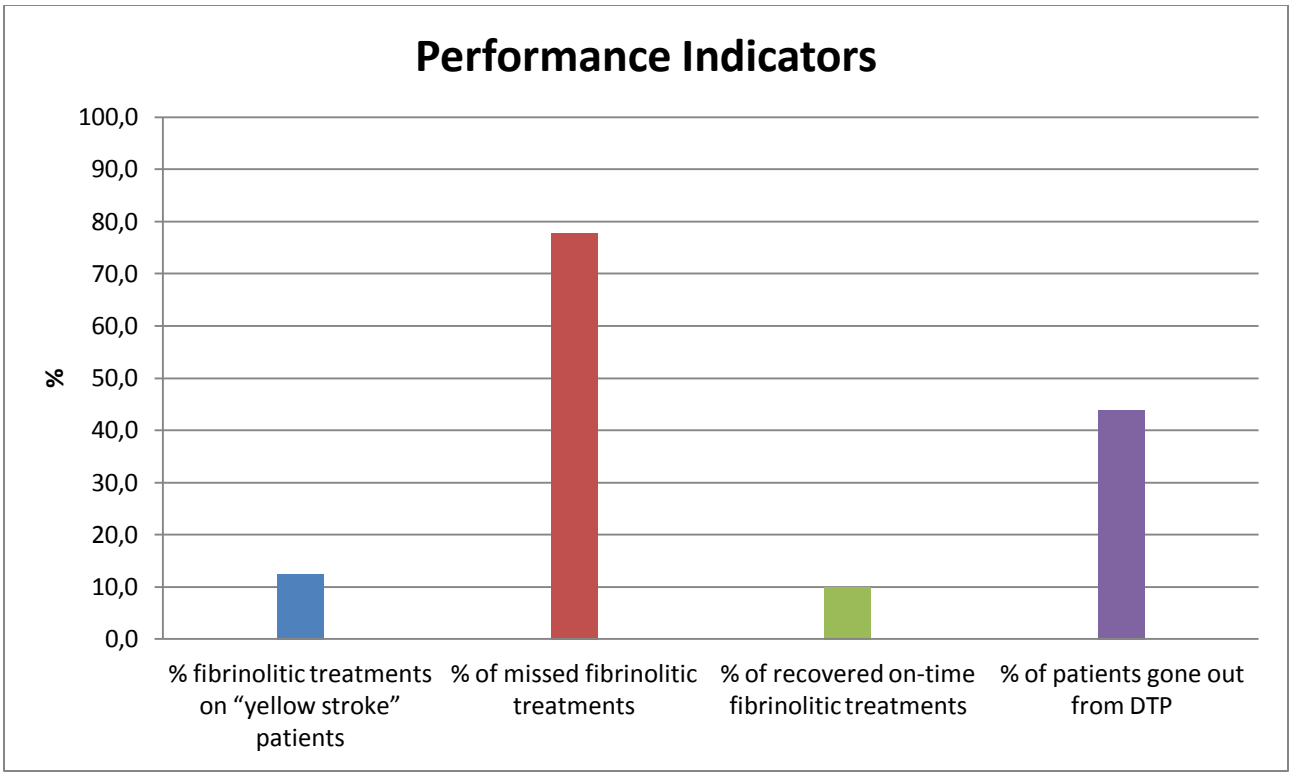

Figure 10: Percentage of fibrinolitic treatments, missed fibrinolitic treatments, recovered on-time fibrinolitic treatments and patients gone out from DTP

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.

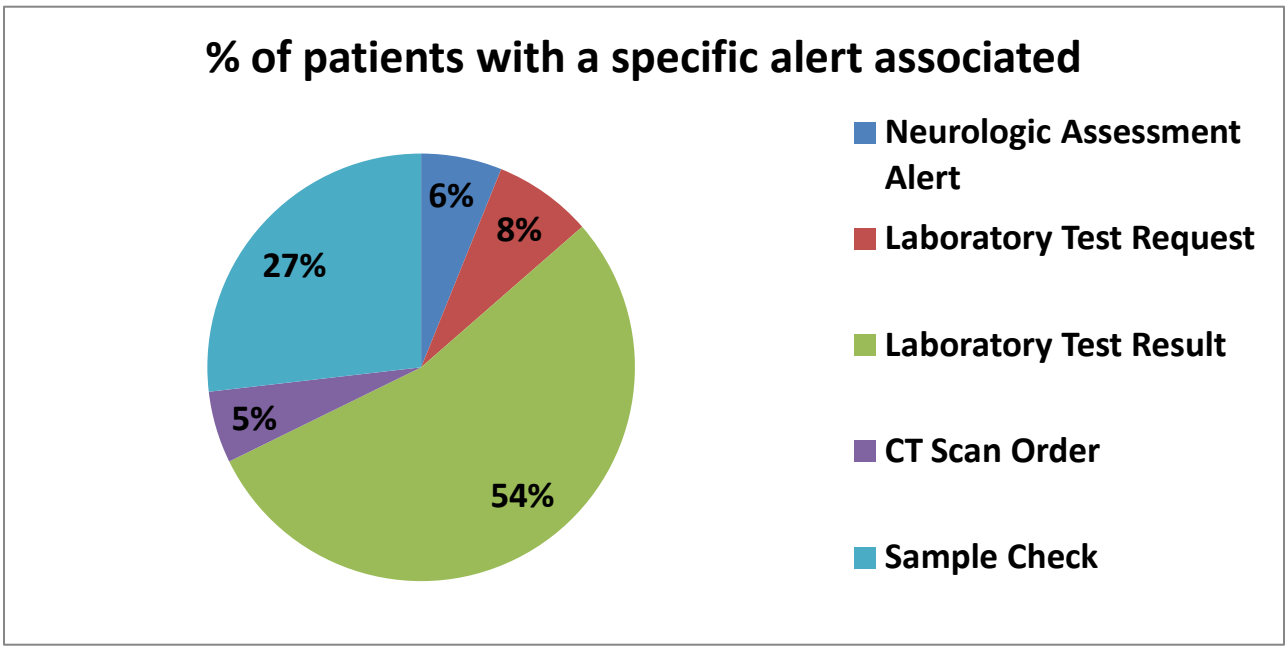

Figure 11: Comparison of the occurrence frequency of different alerts

In Figure 11, 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 12 to Figure 18.

The total task durations from admission to first assessment for different patients are plotted and shown in Figure 12. 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.

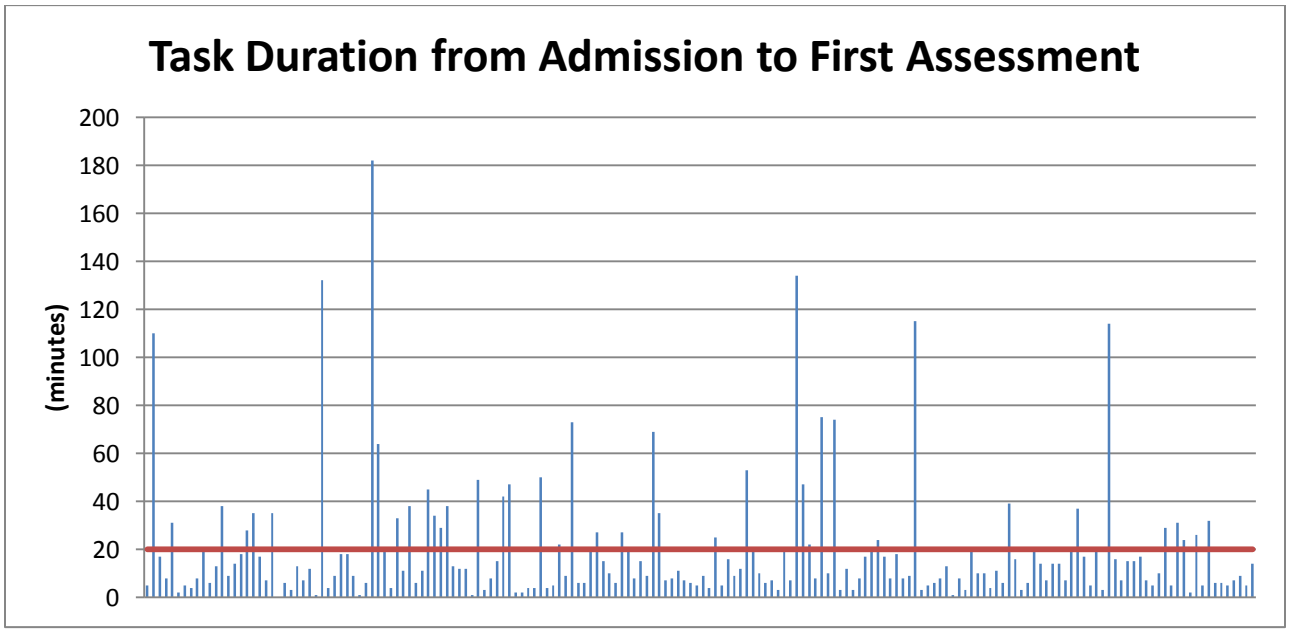

Figure 12: Task duration from admission to the end of the assessment

Next indicator is the time measured from the admission to laboratory examination request and it is depicted on the Figure 13. 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.

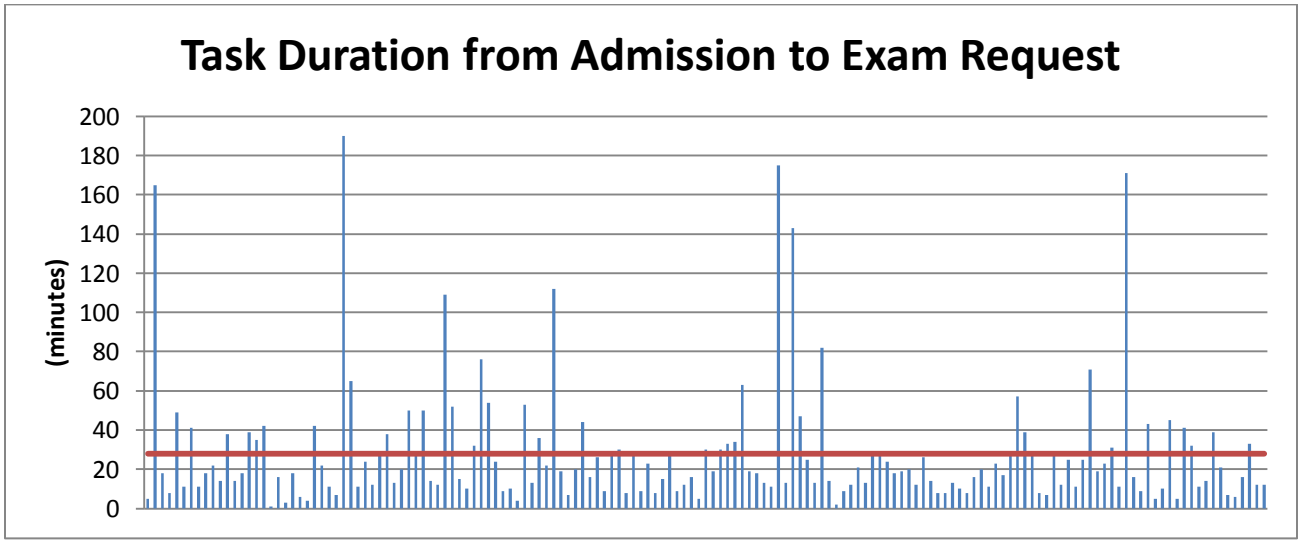

Figure 13: Task duration from the start to the end of lab request

The Figure 14 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.

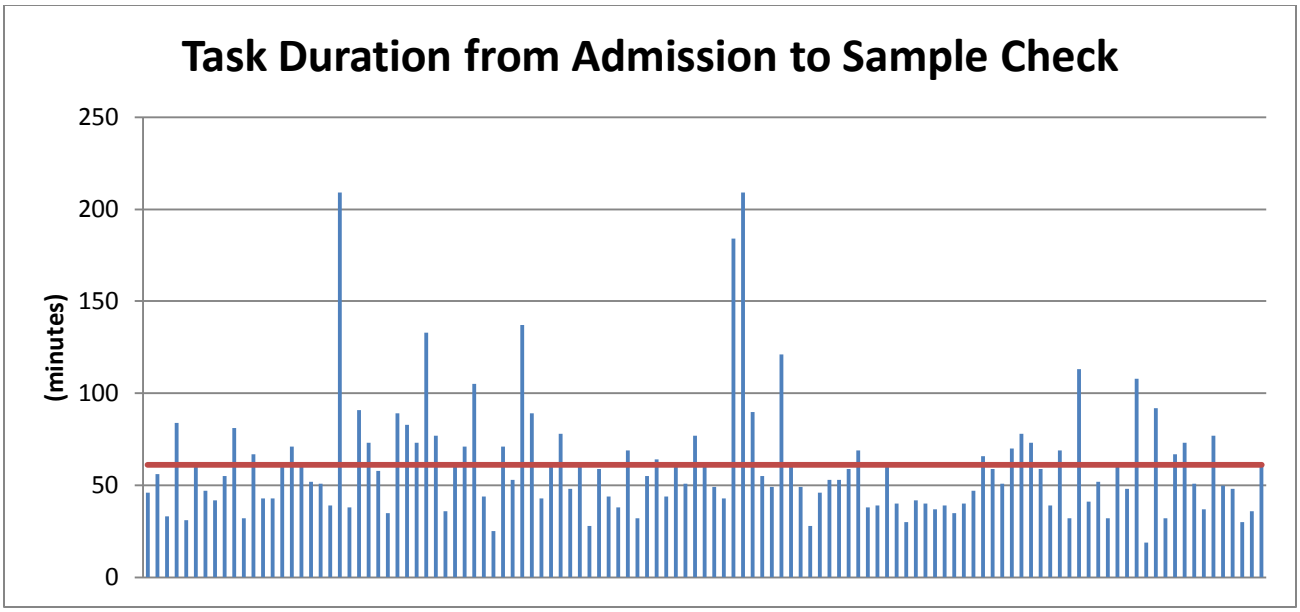

Figure 14: Task duration from the admission to the start of the examination of patient's blood sample

The task duration from admission to exam results for each patient and the average value are shown in Figure 15. 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.

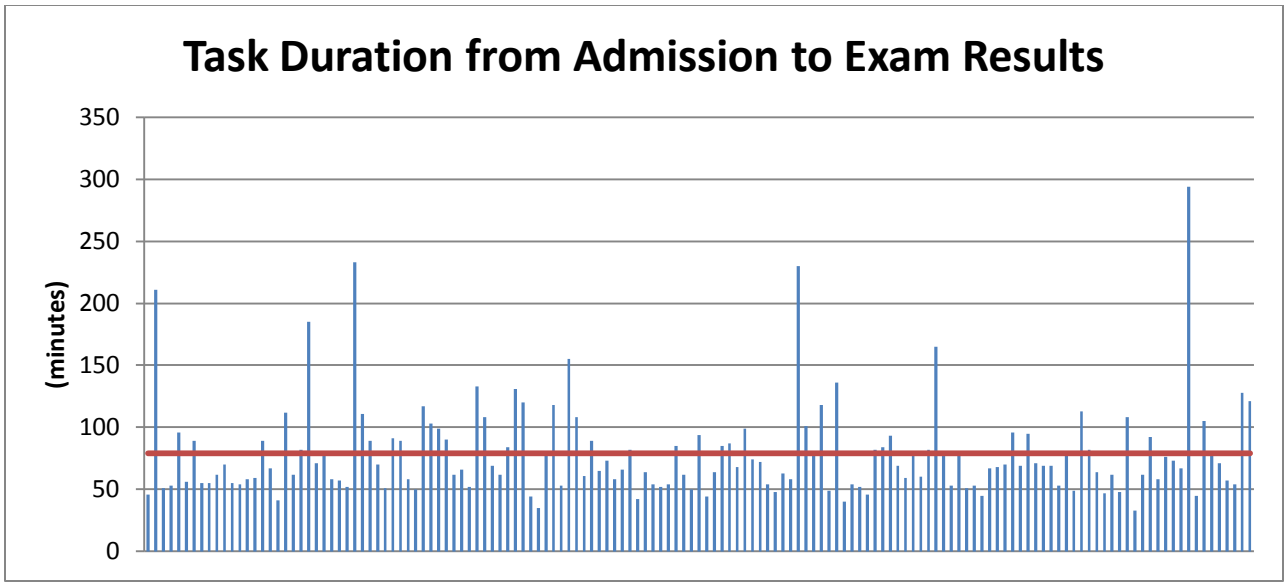

Figure 15: Task duration from the admission to the end of laboratory request

Figure 16 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.

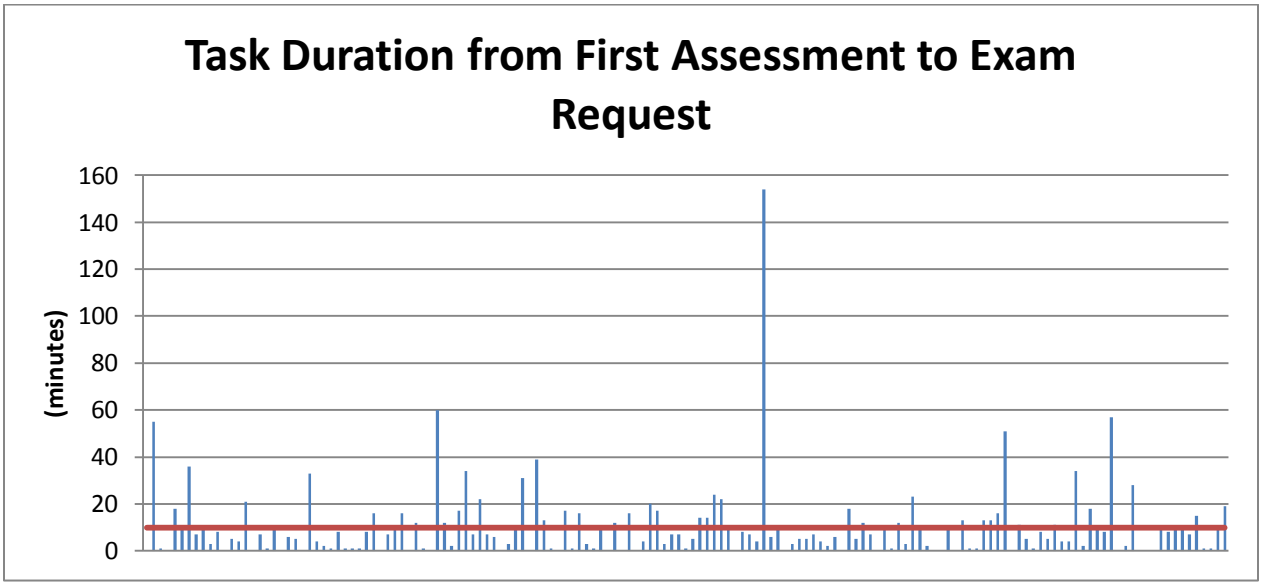

Figure 16 Task duration from the end of first assessment to the end of laboratory request

Next task duration is from the exam request to the exam results; the data for each patient is plotted in Figure 17. 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.

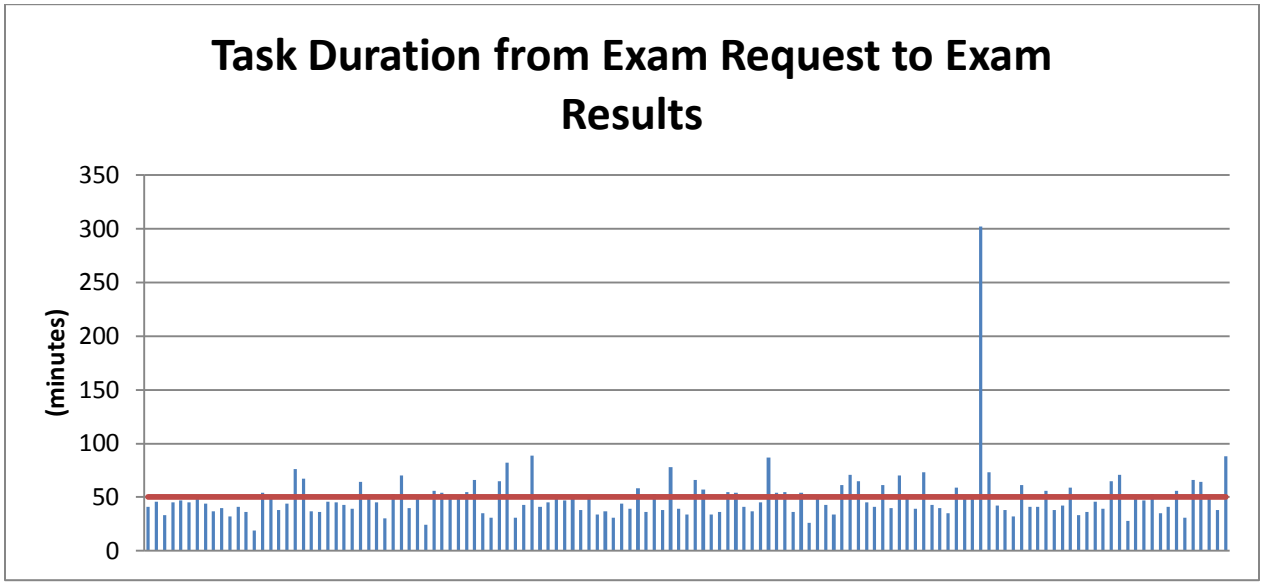

Figure 17: Task duration from the end of laboratory request to the end of laboratory result

Figure 18 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.

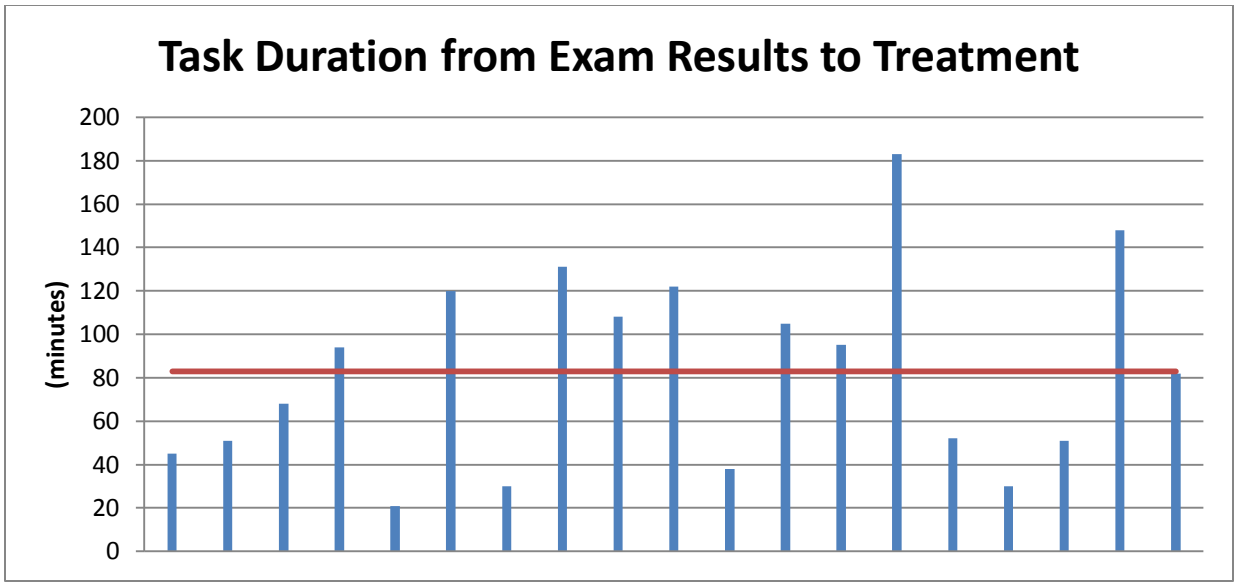

Figure 18: Task duration from the end of laboratory result to the end of treatment decision

5. Remine Platform Validation in Pilot 2 – Labour Asistance

In the first part, assessment of pre-requisites of the Sacco pilot will be made and the assessment of process indicators will be evaluated with the data of the Sacco Hospital. In the second part, evaluation of the Sacco Hospital in terms of process indicators will be made.

Gathered data from the Sacco 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.

5.1. Assessment of Pre-Requisites of Sacco Hospital

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 17 shows the 7 point Likert Scale questionnaire applied for the orientation to clinical risk management.

Table 17: 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							

Figure 19 depicts the evaluation results of the orientation to clinical risk management from different point of views. Results show that the work load is not very high, the training level of the practitioners are good. Moreover discussions and meetings are done about clinical risk management.

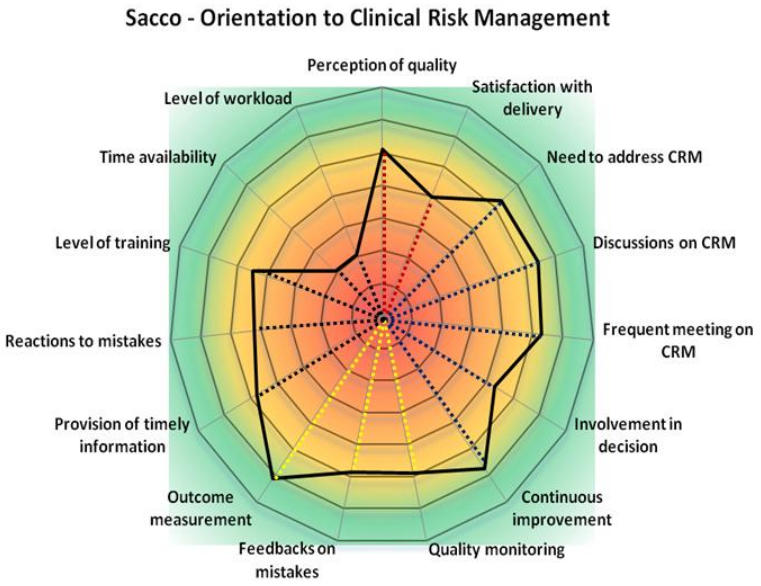

Figure 19: Evaluation results of the orientation to clinical risk management at Sacco Hospital

Table 18 shows the 7 point Likert Scale questionnaire applied for the orientation to information systems.

Table 18: 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							

Figure 20 depicts the evaluation results of the orientation to information systems from different point of views. Results show that the hospital is committed rely on information systems. Moreover, information systems are satisfactory for the hospital.

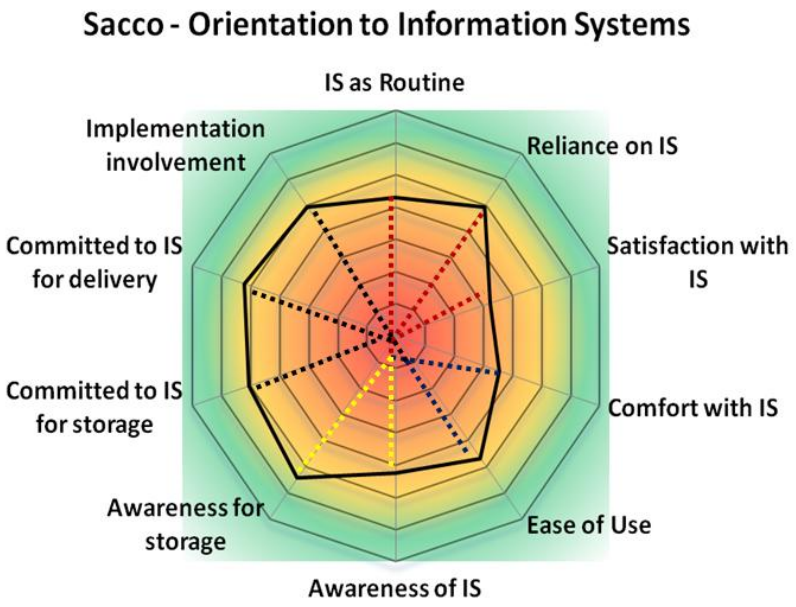

Figure 20: Evaluation results of the orientation to information systems at Sacco Hospital

Table Table 19 shows the 7 point Likert Scale questionnaire applied for the organizational readiness.

Table 19: 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							

Figure 21 depicts the evaluation results of the organizational readiness from different point of views. The general climate of the hospital is good. Practitioners are willing to help each other, have a strong sense of belonging and are well trained and have the capability for the kind of work they have to do.

Figure 21: Evaluation results of the organizational readiness at Sacco Hospital

5.2. Assessment of Process Indicators of Sacco Hospital

In this section, indicators that are explained as the primary and secondary objectives in section 3.3.1.3 are examined. Evaluation of the other indicators can be found below.

Table 20 : Total number of alerts,patients and average number alerts per patient

Historical data	
Total number of alerts	155
Total number of patients	118
Average number of alerts per patient	1,31
Batch 1&2	
Total number of alerts	377
Total number of patients	117
Average number of alerts per patient	3,22

Total number of alerts generated by ReMINE is 377 and the total number of patients with at least one “delay alert” is 117. Therefore, number of alerts generated per patient is found to be:

$$\frac{\text{Total number of alerts}}{\text{the total number of patients}} = 3{,}22$$

Approximately 4 delay alerts per patient shows that ReMINE has informed the relevant practitioner with 4 times in which the time limit is exceeded. Time is a key factor for labour assistance. For each patient, ReMINE would control the clinical pathway with the warnings. Obviously 3.22 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 supports avoiding delays when enough resources are available. Indeed, ReMINE does not affect the delivery time, but with the help of the alerts, the unnecessary time losses are prevented.

While comparing batch 1&2 with historical data, average number of alerts are increased more than %200 in batch 1&2. The reason of this increase is caused by active usage of REMINE in batch 1&2 period.

With the total of 377 delay alerts and 3.22 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.

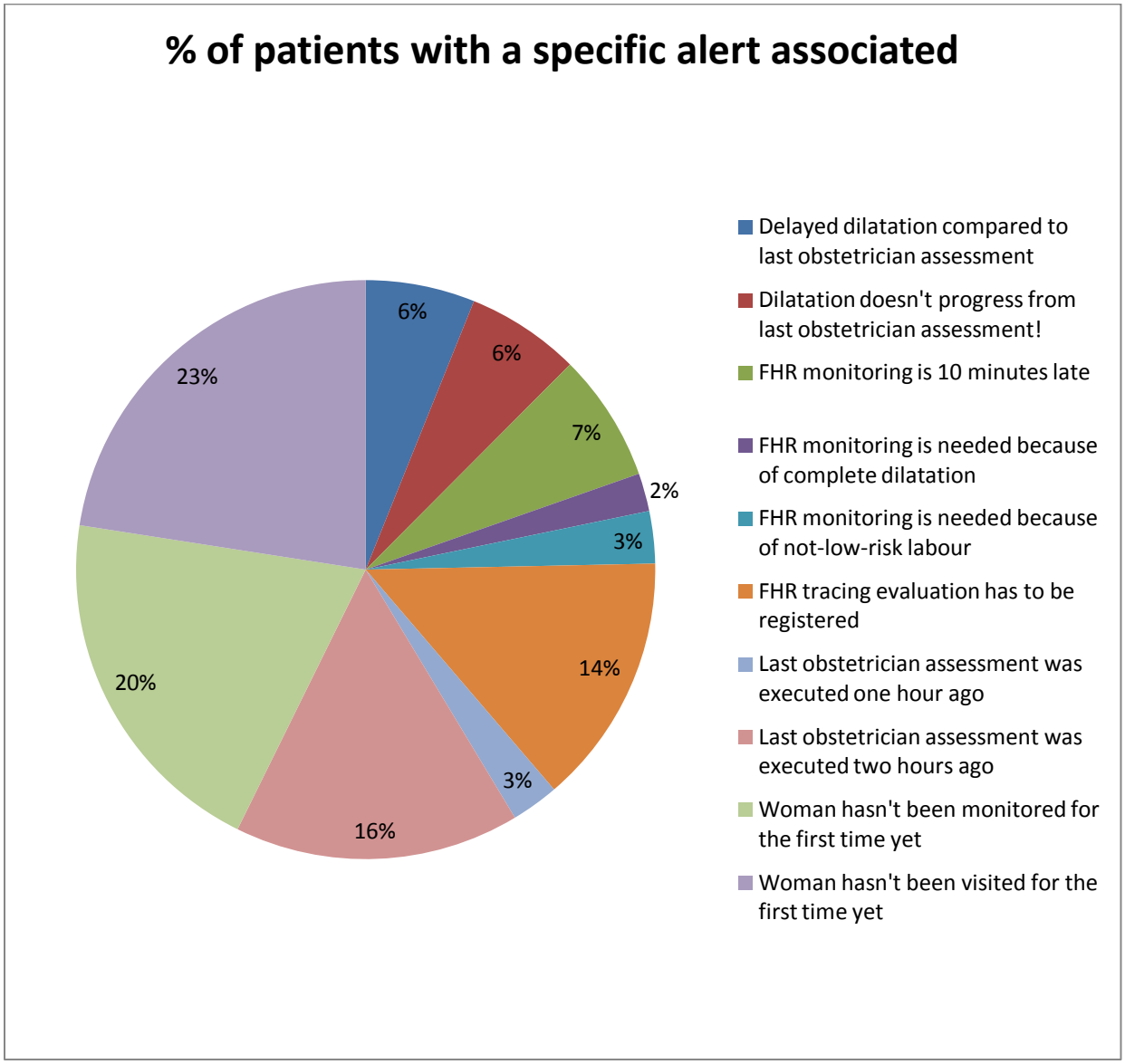

Figure 22: % of patients with a specific alert associated

Figure 22 show percentage of patients with a specific alert associated. Specific alerts provided by ReMINE are depicted showing their frequency of occurrence.Woman hasn't been visited for the first time yet alerts occupy the biggest pie with 23%. It means that the time from admission to first visit is most frequently exceeded. 2nd biggest pie is occupied by the woman

hasn't been monitored for the first time yet with %20 which can be related with the biggest pie. Remine encourage the organization to begin treatment in its ordinary time. The following bigger alerts are last obstetrician assessment was executed two hours ago and FHR tracing evaluation has to be registered with respectively %16 and %14.

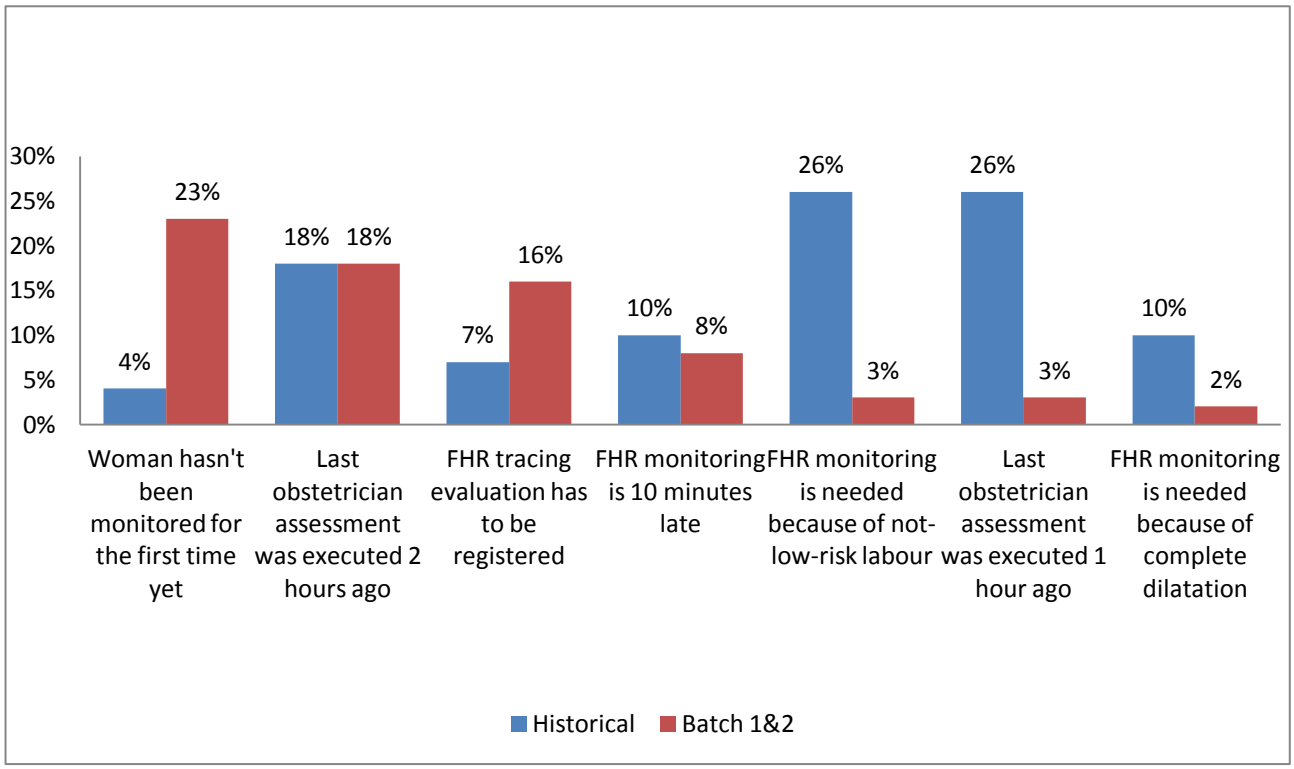

Figure 23: The differences between batch 1&2 and historical each alert types

In figure 23, the differences between batch 1&2 and historical periods are shown clearly for each alert types. The benefit of adopting ReMINE is clearly demonstrated by the reduced incidence of alerts associated to higher risk for patients (the last three in the figure)

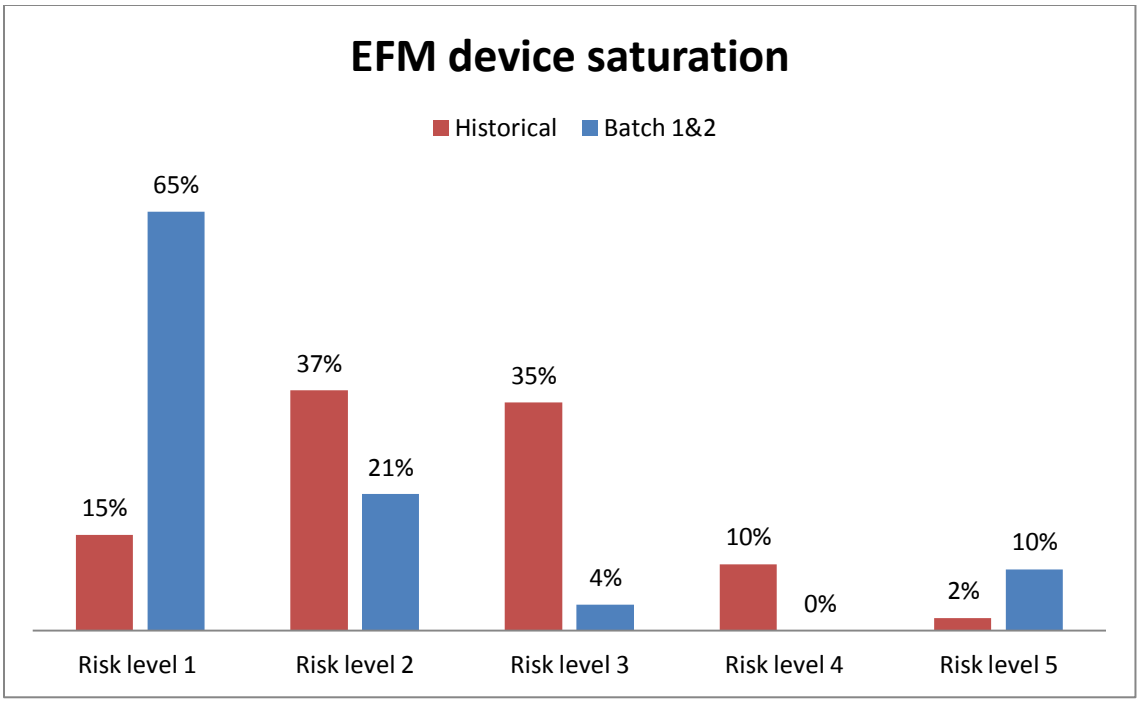

Figure 24: Average number of EFM device saturation alerts per context risk level

EFM device saturation has low risk level. The biggest amount of alerts are concentrated at risk level 1 and 2. There is medium risk level on historical period for EFM device saturation. These results clearly show that ReMINE is able to reduce delays and protocol misapplications to patients exposed to relatively higher risk

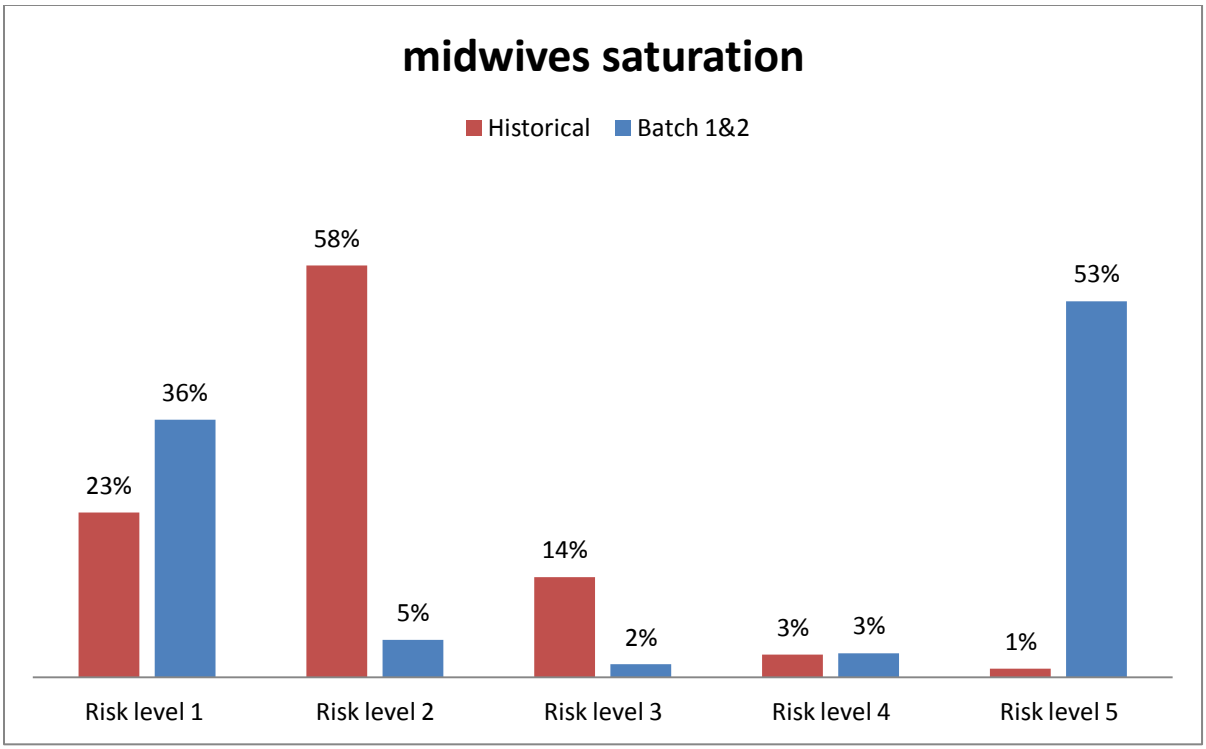

Figure 25: Average number of midwives saturation alerts per context risk level

Midwives saturation has low and high risk levels. The biggest amount of alerts are concentrated at risk level 1 and 5. This can be explained by irregularity of the number of midwives or condition of patients. There is medium risk level on historical period for midwives saturation.

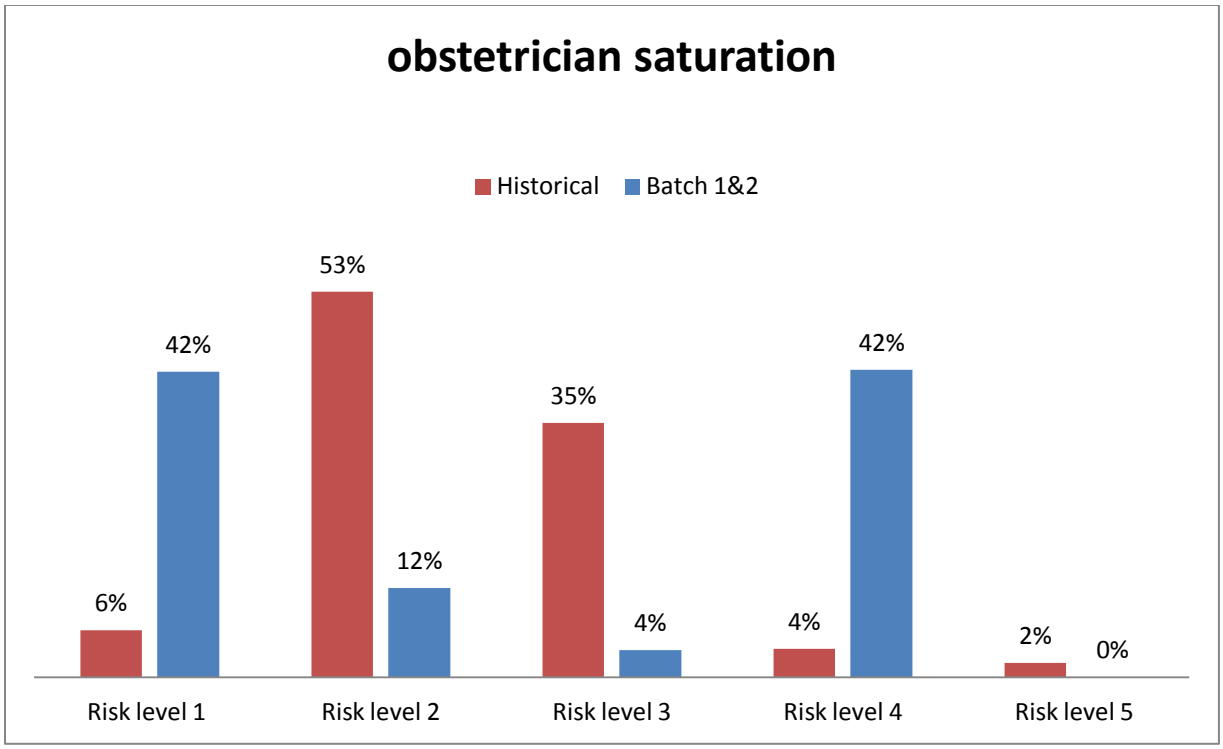

Figure 26: Average number of obstetrician saturation alerts per context risk level

Obstetrician saturation has low and high risk levels. The biggest amount of alerts are concentrated at risk level 1 and 4. This also can be explained by irregularity of the number of obstetrician or condition of patients. There is medium risk level on historical period for obstetrician saturation.

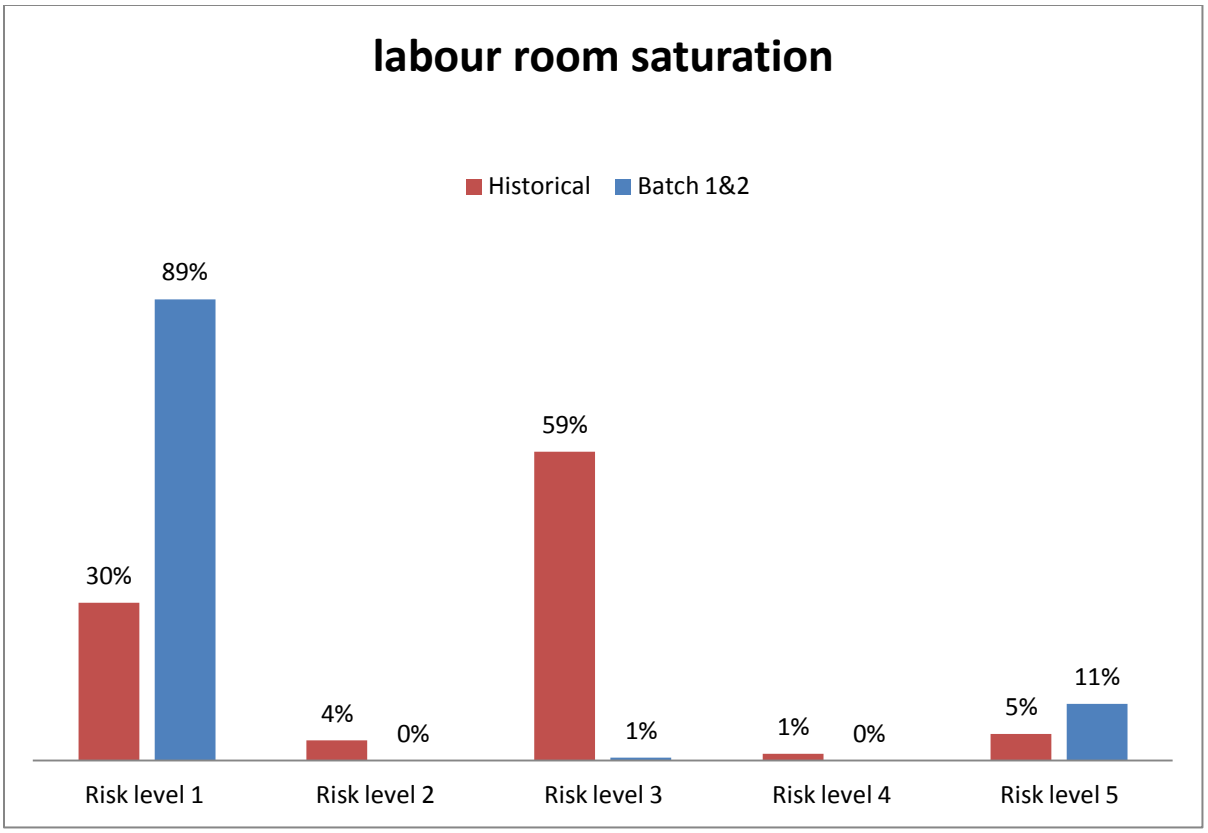

Figure 27: Average number of labour room saturation alerts per context risk level

Labour room saturation has low risk levels. The biggest amount of alerts are concentrated at risk level 1. Even though there are some alerts on risk level 5, this may not affect the overall situation. There is medium risk level on historical period for labour room saturation.

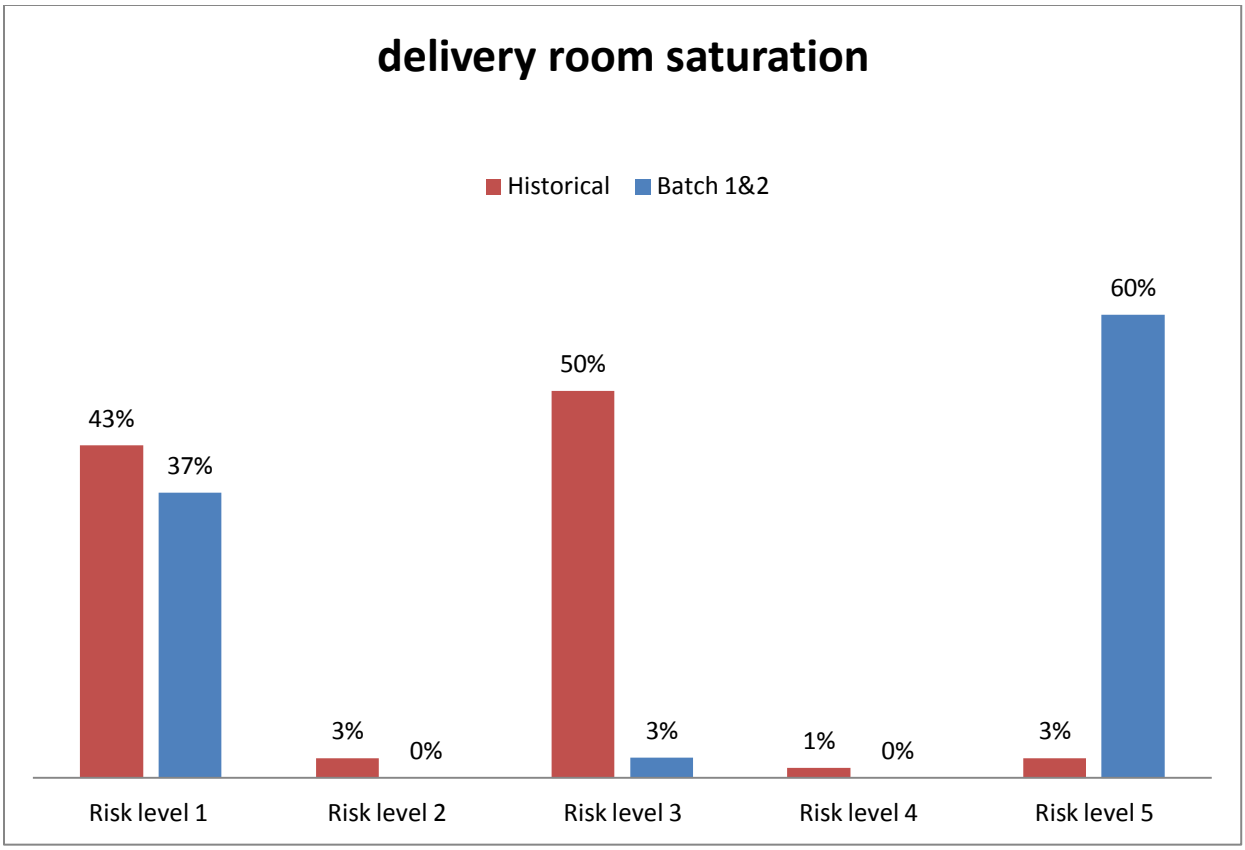

Figure 28: Average number of delivery room saturation per context risk level

Delivery room saturation has low and high risk levels. The biggest amount of alerts are concentrated at risk level 1 and 5. Delivery room saturation can be counted as critical because there are more alerts at risk level 5. There is medium risk level on historical period for delivery room saturation.

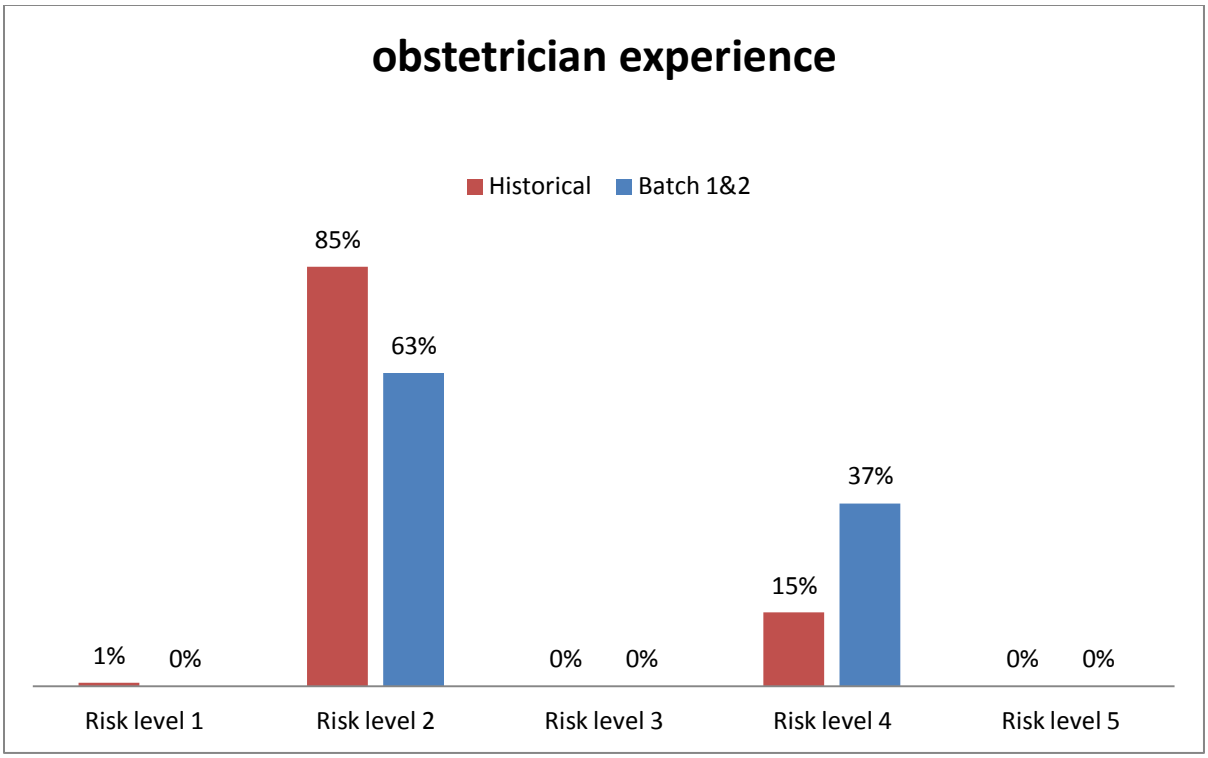

Figure 29: Average number of obstetrician experience alerts per context risk level

Obstetrician experience has medium risk level. The biggest amount of alerts are concentrated at risk level 2 and 4. Even though the obstetrician experiences are not high , it can be considered that they have more than average experience. There is medium risk level on historical period for obstetrician experience

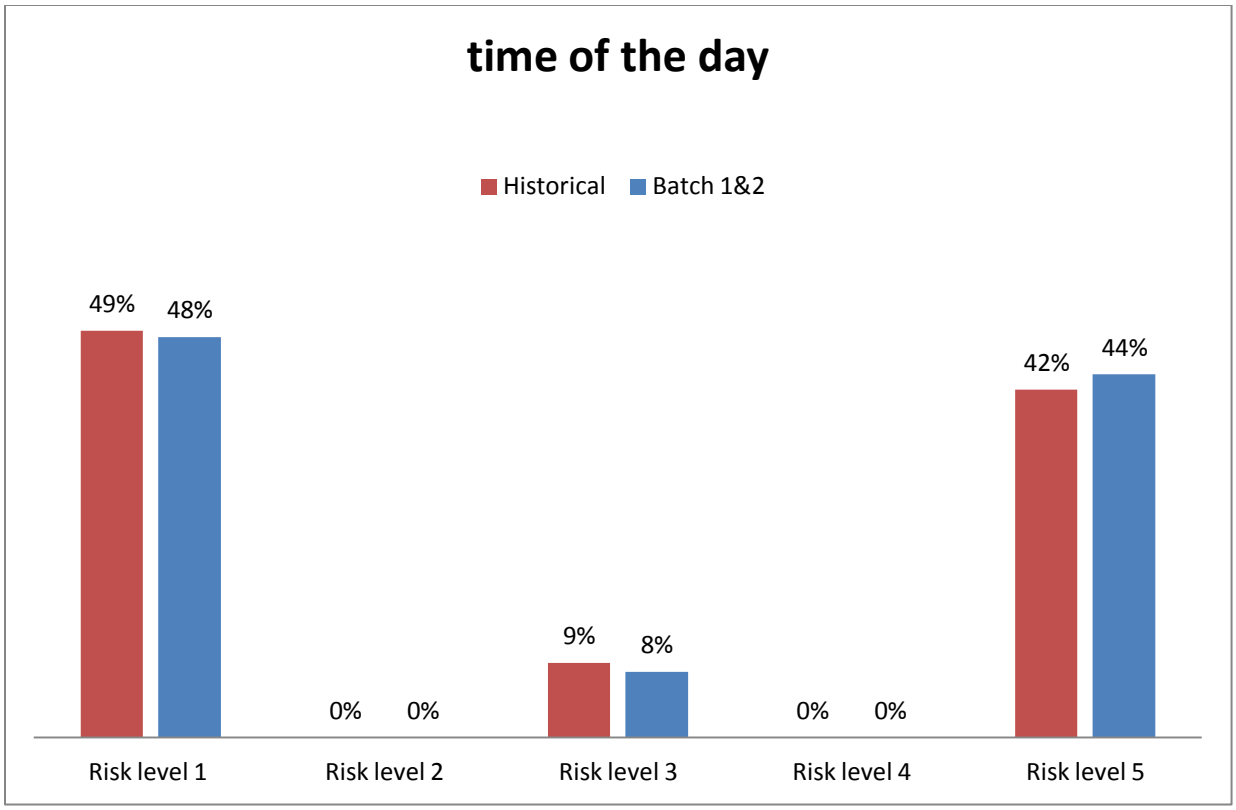

Figure 30: Average number of time of day alerts per context risk level

Time of the day has low and high risk levels. The biggest amount of alerts are concentrated at risk level 1 and 5. The irregularity of the time of the day affects midwives and obstetrician saturations directly. Same irregular risk level distribution has obtained on historical period.

Looking at the previous set of figures 24-30 concerning the distribution of alerts given different risk levels due to different critical resources, it is apparent that by using ReMINE healthcare professionals are provided with focused alerts and able to better allocate available resources according to patient needs and risk level (e.g. several alerts for midwives saturation on low risk patients and no alert for unavailability of experienced obstetricians for patients at risk level 5)

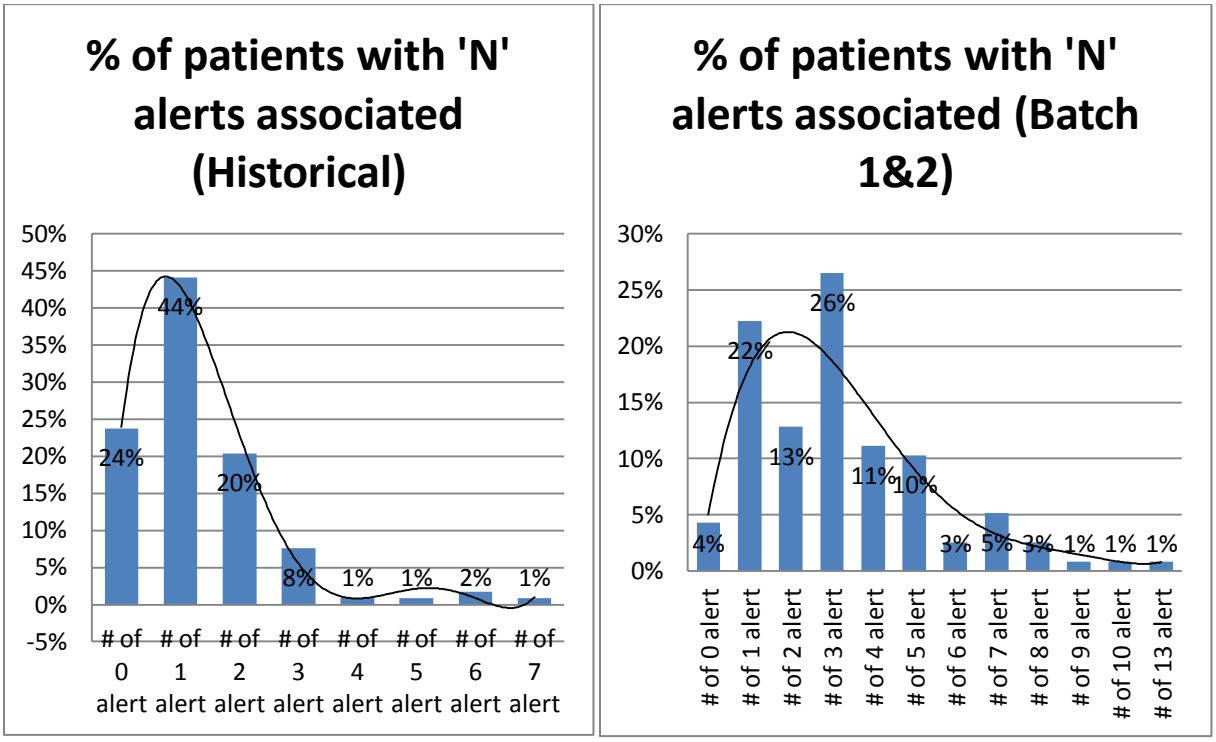

Figure 31-32: % of patients with 'N' alerts associated

Due to work load increase, number of alert distribution is around 3 alerts per patient for batch 1&2 periods while it is around 1 alert for historical period. Work load increase means that more patients are admitted to the labour service. The distribution of alert intensity can be seen in the figures 31-32 by means of parabolic curves.

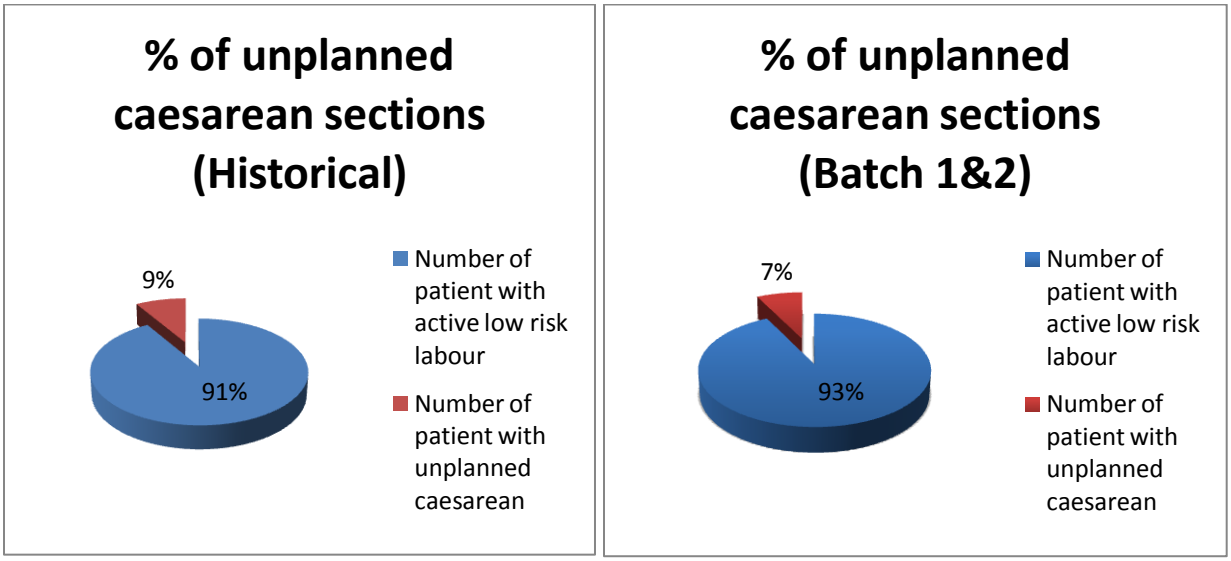

Figure 33-34: % of unplanned caesarean sections

Unplanned caesarean sections decrease on batch 1&2 periods. This reduction is not about patients who are in better situations. Unlikely, we have more patients who are in worse situation but the managing skills of the organization get better. Thus , the unplanned caesarean section percentage decrease positively.

When we examine patient density on historical period, batch1 period and batch 2 period, it can be seen that number of patients per day increase from historical to bath 1 period.

January 2010 – July 2010 124 patients

July 2010 – January 2011 159 patients

February 2011 – June 2011 150 patients

For our statement we have no numerical proofs from Sacco data. We got this state from our last meeting notes.

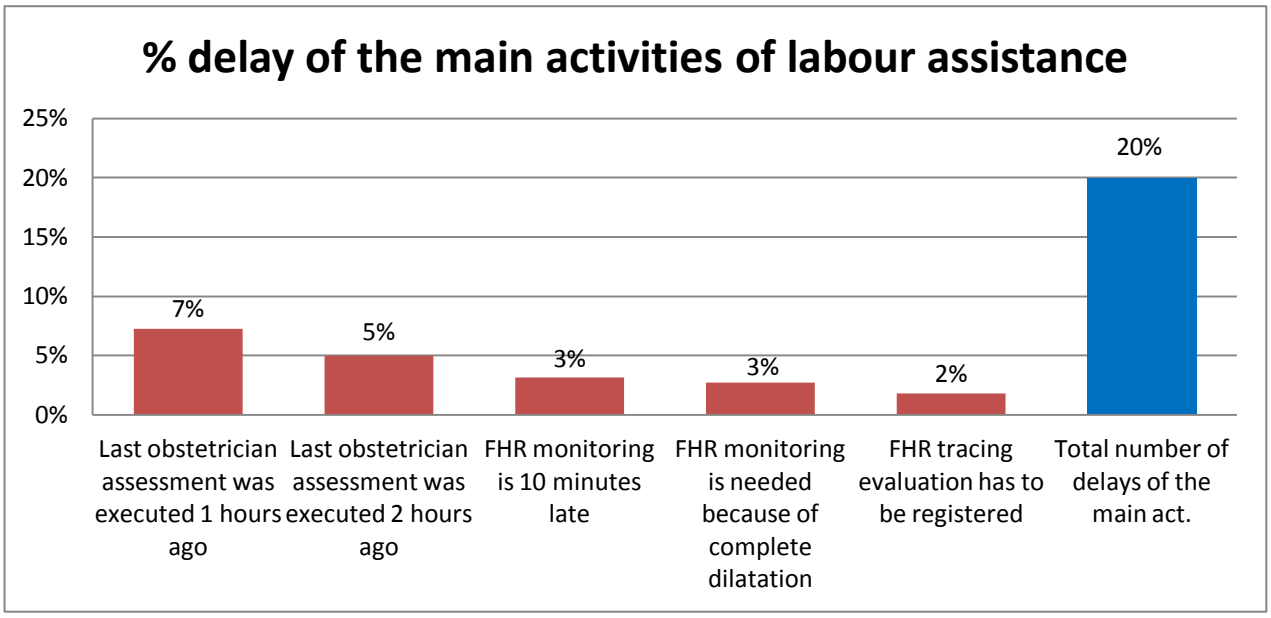

Figure 35: % delay of the main activities of labour assistance

Since there is no available data on historical period, the delay of the main activities of labour assistance situation is examined for only batch 1 and batch 2 data. Indicator 1 is about average delay of the main activities of labour assistance. As shown in the figure , the %20 percents of main activities has been delayed. The delay of main activities can affect the labour assistance in negative way. In pilot hospital, the most frequent delays occur in the obstetrician assessments which are about %12 of delays of main activities. Remine would improve quality of treatments with the warnings. at least by managing delays in a better way, i.e. reducing the most critical one and accepting the less critical. The rest of delays are about Fetal Health Record (FHR) monitoring and tracing which are respectively %6 and %2 of delays of main activities.

6. Conclusion

Health IT has already been shown to improve medication safety. Although the evidence is mixed for areas outside of medication safety, the fact that several studies have improved patient safety with implementation of health IT which has potential to drastically improve patient safety in other areas of care. As with any new technology, health IT carries benefits and risks of new and greater harms. To fully capitalize on the potential that health IT may have on patient safety, a more comprehensive understanding of how health IT impacts potential harms, workflow, and safety is needed.

Main aim of this study was the evaluation of E-Health solutions for patient safety by quantitative performance assessment of the ReMINE Platform. ReMINE was to be implemented to 2 different Italian pilots, namely Niguarda and Sacco Hospitals. ReMINE supports the management of stroke acute phase in the A&E at Niguarda and patient assistance during labour at Sacco. 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 be fully implemented to the pilots, however a data set from Niguarda and Sacco Hospitals were simulated with ReMINE and delay alerts of ReMINE and initial data of the hospitals 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 shows that there is not a reference duration for each task as they show high standard deviation for each patient.Nevertheless, 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 were 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.

At Sacco Hospital, total number of alerts generated by ReMINE is 377 and number of alerts generated per patient is approximately 4. It clearly shows that ReMINE has informed the relevant practitioner with 4 times in which the time limit is exceeded. Time is a key factor for labour assistance. For each patient, ReMINE would control the clinical pathway with the warnings. Obviously 3.22 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 supports avoiding delays when enough resources are available. Indeed, ReMINE does not affect the delivery time, but with the help of the alerts, the unnecessary time losses are prevented. With the total of 377 delay alerts and 3.22 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

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