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Zdravstvena informatika ï Varnostni postopki za identifikacijo pacientov in pripadajoļ ih (podatkovnih) objektov

Health informatics - Safety procedures for identification of patients and related objects

Medizinische Informatik - Sicherheitsvorschriften für die Identifikation von Patienten und dazugehörigen Objekten

Informatique de Santé - Procédures de sureté pour l'identification des patients et des objets associés

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Health informatics - Safety procedures for identification of patients and related objects

Informatique de Santé - Procédures de sûreté pour l'identification des patients et des objets associés

Sicherheitsvorschriften für die Identifikation von Patienten und dazugehörigen Objekten

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Foreword

This document (CEN/TR 15299:2006) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This document has been prepared by working group (WG) III - Safety, Security and Quality. The authors of this document were A. Sanna, M. Wilikens, A. Borio di Tigliole, G. Klein and P.A. Bonini.

This work addresses how the procedures for identification of Patient and Patient Related Objects can be carried out in the healthcare process with the active support of Information Technologies, in order to minimize the risk of errors with potential serious safety hazards.

The Patient Related Objects include:

— pure information objects (i.e. electronic/physical records as physiological data or prescriptions), and

— physical objects obtained from the Patients (i.e., blood samples or other biological materials) and intended to be used for a specific Patient (i.e., medications or prostheses).

The overall aim of this document is to provide a road map for the development of Patient safety related standards in the domain of health informatics that will actively support Patient safety in the healthcare process.

0 Executive summary

The increasing organizational complexity of the healthcare system is widely recognized as a factor of risk for the Patient in the healthcare process. Thus, Patient safety is becoming an emerging issue for the professional and social community. Healthcare professionals and Citizens are both calling for appropriate solutions, as it is evident when considering the high frequency and the contents of Patient Safety related articles in the scientific literature and in the mass media.

US President Clinton on December 7, 1999 "… took strong new steps to ensure Patient safety through the prevention of medical errors…" according to the results of a study released by the US Institute of Medicine estimating that "… more than half of the adverse medical events occurring each year are due to preventable medical errors, placing as many as 98 000 Americans at unnecessary risk. In addition to the severe health consequences these errors can cause, their cost in lost income, disability, and health care is as much as $29 billion annually."

President Clinton's initiatives include the creation of a task force to submit recommendations, the emission of a directive to federal agencies which administer health plans (serving over 85 million Americans) to implement error reduction techniques, the approval of a multi-million dollar investment in research and additional budget for error prevention initiatives in 2001.

It is important to highlight that the adverse medical events can be generated in the healthcare process either as a result of the overwhelming complexity of a specific clinical case and as a result of trivial errors in a well known procedure (e.g. the mix up of medications, biological samples and Patient records, the misinterpretation of objective data).

In this respect, the healthcare system performance in a given clinical case is but the result of the system as a whole, i.e. the result of interdependent performances of innumerable co-operating subsystems, most of them being, or depending from, the performances of human operators.

The system performance (a very complex issue indeed) includes the risk of failure due to the human component, i.e. the operator performance; in order to minimise the impact of human fallibility in the safety critical environment of the healthcare system, it is important to design processes that addresses the positive control of Patient safety critical data.

The procedures of identification of Patient and Patient Related Objects is the unique intervention point with the highest potential for minimising the risk of human errors and violations in the healthcare system and for deploying an appropriate infrastructure for maximising the performance of the interaction of the health informatics systems with the real world.

In order to obtain such a result, the present CEN/TR defines a framework for:

— the definition of safety critical objects in the healthcare process (MOS: Minimum Object Set) and the related safety critical data (MDS: Minimum Data Set) according to modelling methodologies as IDEF or UML,

— the definition of the rules of interaction among safety critical objects in the process, and

— the acquisition and processing of safety critical data by health informatics systems.

Finally, the present CEN/TR defines a possible roadmap for a stepwise approach for an effective standardisation activity in the area of Patient Safety, including the main health sub-processes that involve the hospitalised Patient as: Laboratory Medicine and Pathology, Bio-imaging, Drug Therapy Management, Blood Transfusion Management, Surgery Management. Such sub-processes can be considered, from a process modelling perspective, a case-mix that covers most of the process requirements of Patient safety for the hospitalised Patient and an appropriate starting point for the health processes that involve non-hospitalised Patients.

1 Adverse events in the health care system

1.1 Background

The healthcare sector is the largest single service sector, accounting for approximately 600 billion Euro in the European Union (approximately 9 % of the GDP): a remarkable and unique feature of this market is represented by the relevant social and political attention on the healthcare system, which is an obvious consequence of its mission to protect the health of millions of citizens.

The complexity of the healthcare system is rapidly growing, due to the concurrent increase in medical knowledge, biomedical technologies and age of population. This results in an exponentially increasing number of individuals undergoing a greater number of medical acts (either preventive or therapeutic) during their lifetime. In a typical case of hospitalization, the number of medical events, as well as the number of healthcare professionals taking care of a single Patient, is much higher today than it was in the past. In addition, because of financial constraints, hospital management is pressured to reduce the Patient stay. Thus, not only the number of medical events per Patient increases significantly, but they are also concentrated in a shorter time.

In such a tremendous increase of organisational complexity, the human operator performance in the healthcare system is becoming a key issue. In fact, the Patient life is at stake in the healthcare system: unexpected negative Patient outcomes can be generated not only as a result of erroneous application of complex clinical cognitive processes (e.g. diagnosis in a clinically complex case), but also as a result of a single, trivial error in a well known procedure (e.g. the mix up of biological samples).

In order to gain an insight on the role of human performances in the healthcare system, we will refer to the Medical Practice Study that has been carried out by the Harvard School of Public Health. This comprehensive study focuses on the concept of Adverse Event (AE) on the Patient, where an AE is to be intended as «… an injury that was caused by medical management (rather than underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both.». The investigators reviewed 30 121 randomly selected records from 51 randomly selected acute-care, non-psychiatric hospitals in New York State. Adverse events were found in 3,7 % of hospitalizations. Of these, 70,5 % of events led to disabilities of up to 6 months duration; 2,6 % caused permanent disability and 13,6 % led to death. Technical errors or flaws in an operation procedure, or test were the most frequent (44,4%). It has noteworthy been pointed out by the authors that, extrapolating these data to the population of the United States, this situation would be the equivalent of three jumbo jet crashes every two days. The use of a comparative risk approach, i.e. comparison with other systems having safety concerns in term of Customer/third parties risks as aviation, is a very delicate matter indeed, but it is necessary from a cultural point of view, not to consider healthcare as an absolute term of reference.

In comparing the healthcare and the aviation systems, the two basic differences are:

- pilot and crew share the same risks as Customer - Passengers, that it is not the case for doctors, nurses and Customer - Patients.
- Passengers are generally in normal health conditions, while Patients are not.

The first point, i.e. Operator and Customer risk sharing, is an element that forces systems toward a "synchronous" attention to the problem from either Customer and Operator perspective or, in other words, forces systems toward a more general safety problem individuation and solving.

As far as the particular health state of the Customer/Patient is concerned, it should be pointed out that such an element does not justify differences in system performance: in fact, increased severity of consequences should call for increasing system defences versus hazards.

Both in the Aviation and the Healthcare systems Customer safety represents a relevant interest. The following Table 1 compares the main differences between the two systems.

Table 1 — Aviation and Healthcare system differences with respect to Customer safety

	Aviation System	Healthcare System
Customer vs. operator	Pilot and crew share the safety risk with passengers	Caregiver does not share the safety risk with Patient
Safety vs. Market demand	Safety increases the business (non-safety decreases the business)	Safety does not increase business but it affects market competition
Customer health conditions during system performance	Passenger is in normal health conditions	Patient is in particular health conditions
Error reporting policy	Anonymous	Punitive
Near-miss accidents	Incrementing system safety database	Incrementing operator expertise
Accident outcomes	Evident	Wide range that varies from no effect to evident
Chance for camouflage of accident outcomes	Not realistic/minimal	Existing
Private interest in accident camouflage	Not realistic/minimal	High, both at the operator and enterprise level
Accident lawsuit impact vs. enterprise profitability	Relevant impact	Marginal impact
Role in Military Strategy	Offensive	Marginal/Defensive
Synergy with military driven investment and spin off in past 50 years	Relevant	Marginal
European market	Not available	600 billions Euro/year (9 % EU-Gross Domestic Product)
History	150 years	2000+ years
Human Bias	Fear of accident	Expectation of miracles

1.2 Healthcare professional's errors and Patient safety risk

Patient safety in the healthcare process is an emerging issue. The growing number of scientific as well as mass media information produced in the recent years is producing awareness of the problem both in the healthcare professional and in the man-of-the-street. Distinctive initiatives in this area have been launched by:

— The American Medical Association (AMA) in 1997. This initiative, the National Patient Safety Foundation (NPSF) has the mission of improving Patient safety in the delivery of health care. Distinct literature is available in the NPSF Web Bibliography, grouped in categories such as: "Administration, legal and policy", "Anesthesia", "Core", " Critical care, Intensive Care Units", "Diagnostic decision making", "Drug, medication", "Effects of error on doctors, patients, and their Relationships", "Ergonomics and cognitive factors", "General adverse events", "Human-machine interface", "Laboratory", "Pediatrics", "Radiology", "Reporting systems", "Surgery".

— The Italian Tribunale dei Diritti del Malato (Court for the Patients' Rights) together with the unions of hospital doctors (ANAAO ASSOMED) and of general practitioners (FIMMG) in 1999. This initiative, the Carta della Sicurezza nella Pratica Medica (Chart of Safety in Medical Practice) resulted in a guideline document that has been presented in Rome April 8, 2000.

In the following, some excerpts from scientific literature and mass media are given to illustrate the problem.

In a study by Gopher on errors in Intensive Care Unit (ICU), it was reported an average of 1,7 errors per day per Patient out of an average 178 "activities" per day; 29 % of these errors were reported as potentially responsible for serious or fatal injuries. The resulting 99 % proficiency level, i.e. 1% failure rate, is substantially higher than what is tolerated in industry, particularly in hazardous fields such as aviation and nuclear power. As W. E. Deming points out: "... even 99,9 % may not be enough. If we had to live with 99,9 %, we would have: 2 unsafe plane landings per day at O'Hare, 16 000 pieces of lost mail every hour, 32 000 bank cheques deducted from the wrong bank account every hour!".

In recent studies Adverse Drug Events (ADE), that are clinical events suffered by Patients as a result of inappropriate drug therapy management, have been identified as the single major cause (19 %) of error in hospital settings. Examples of inappropriateness includes both decision making errors (inappropriate drug prescriptions with relation to patient clinical state) as well as organizational errors (e.g. wrong drug - administration of drug different from the prescribed one, wrong dose - administration of a dose of drug different form the prescribed one, incorrect drug prescription – prescription of drug to a Patient which is known to be allergic to it).

Recent quantitative studies report 2,43 ADEs per 100 hospitalized Patients. Patients affected by ADEs almost double (1,88) death risk and prolonged hospital stays (average +1,91 days). In considering occurrence of ADEs in the management of drug therapy, a study indicated 49 % errors in the "Ordering stage", 26 % errors in the "Administration stage", 14 % errors in the "Dispensing stage" and 11 % in the "Transcription stage". In order to have an insight of the general trend of the problem, a 9 year study concerning medication prescribing errors in a teaching hospital is quoted in the following chart (Figure 1) refers to an hospital in the 631-674 beds range during the study timeframe.

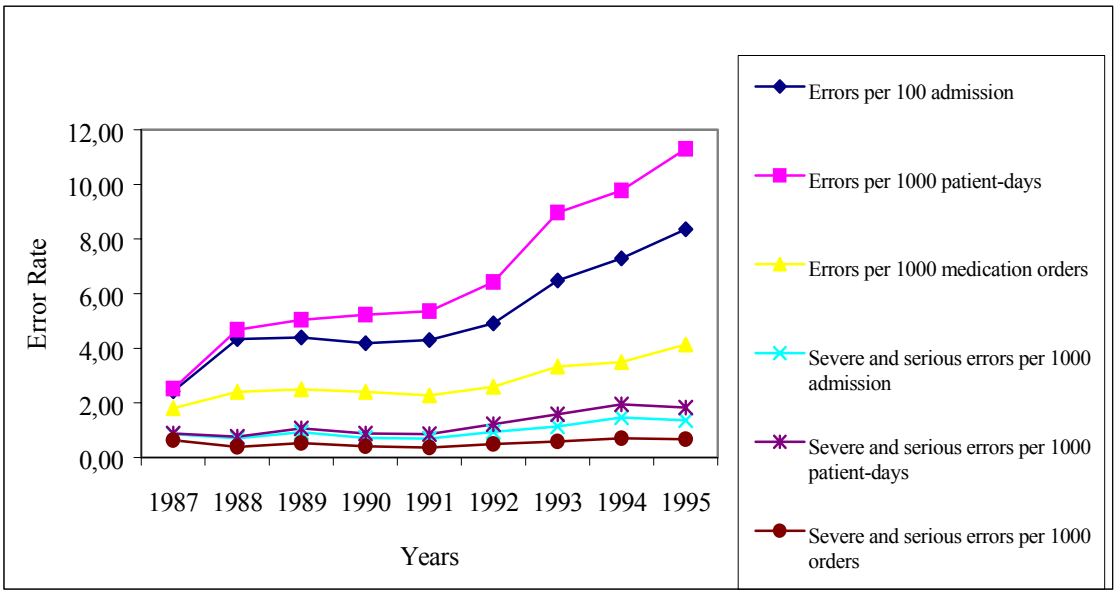

Figure 1 — Drug related errors in hospital

Patient and related biological sample misidentification is also a significant cause of serious or fatal injuries. As an example, it is noteworthy that in blood transfusions (one of the most safety critical healthcare processes), in spite of the rigorous blood administration policy, ABO incompatible transfusion results in a fatal transfusion error rate of 1/600 000 (ref. 2,2 million units of red cells are transfused each year in Great Britain) and the major sources of error are due to the Failure to identify patient (43 %) and Blood issued for another patient - error not detected at the bedside (15 %); in manually operating clinical laboratories reports 1 sample mix-up out of 200 is reported.

Another safety critical field of the healthcare system is nuclear medicine that involves the purposeful injection, ingestion or inhalation of material containing a small amount of radioactivity (i.e. a radio-pharmaceutical), mainly for diagnostic purposes. A commonly accepted misadministration rate is 1 per 10 000 administrations, resulting in an average nuclear medicine facility to experience less than one such event per year. It is important to notice that not all errors lead to misadministration. One reason is that nuclear medicine, like many other systems, is tolerant to some errors. For example, the specified standard of performance for dosage of some radio-pharmaceuticals is ± 50 % of the prescribed dose. An error leading to a smaller deviation from the prescribed dose would not be considered as a misadministration. The United States Nuclear Regulatory Commission (USNRC) built a database of information derived from Diagnostic Misadministration Reports submitted by licensees (850 reports occurring in 1989 and 1990): wrong radio pharmaceutical and wrong Patient administration accounted for more than 92 % of the reports. Extrapolating from data about the European nuclear medicine diagnostic activity (an average of 19 examinations per 1 000 Citizens, with peaks of 47 in Germany and 40 in Belgium) an estimated 500 cases of misadministration of radio-pharmaceuticals occur in Europe each year.

As general information, in the United States 1 % of hospitalized Patients are victims of healthcare system organizational avoidable errors.

Such information that is available in the scientific literature testify the interest of the scientific community for the matter. It is quite obvious though, that the man of the street has direct interest on the matter.

Hereinafter, excerpts from Italian and US news are listed, but similar news is common place in every country.

USA Today - January 22, 1997 - titles “Hospitals’ drug errors cost lives, drain resources” doubling a person’s risk of death in the hospital and costing an estimate $ 2 billion a year.

USA Today - August 3, 1998 - reports the dramatic story of two girls switched at birth in 1995: such a late discovery has been triggered by a traffic accident in which one was orphaned: such a case created a very complex human and legal dispute.

Corriere della Sera – March 28, 1999 – reports that in New Jersey a white couple gave birth to a black baby, after an assisted artificial insemination.

New York Times - June 3, 1999 - comments that the injuries due to the improper use of drugs can be considered as a “medical progress disease”. Except surgical risks, Patient drug administration is one of the most dangerous care event and “we aren’t investing the necessary resources to protect the Patient”.

Corriere della sera – February 20, 1999 – reports that a woman affected by diabetes died probably due to the administration of a glucose phleboclysis.

Il Giornale – April 16, 1999 – reports that an elderly man was forced to wrong care as a result of radiography mix up.

Corriere della sera – May 8, 1999 - reports that a woman fell into coma, probably due to a pharmacist who erroneously read a prescription that resulted in the wrong drug delivery.

Corriere della sera – July 18, 1999 – reports that a woman affected by leukemia died probably due to the administration of a wrong phleboclysis.

Corriere della sera – August 22, 1999 – reports that a young boy resulted pregnant as a result of lab tests mix up.

These few examples are just the tip of the iceberg, i.e. the events that are intercepted because of the exceptionality of the cases. Nonetheless, such examples clearly show how healthcare enterprises are facing the need for specific organizational and structural changes, satisfying the urge of systems able to minimize the incidence of human errors in the process. The political and social impact of healthcare can potentially play a strong role in requiring the introduction of healthcare systems and related standards that support improvements in safety and reliability in the healthcare processes.

A comprehensive study about error in medicine in the overall healthcare system carried out by the U.S. Institute of Medicine reports “… When extrapolated to the over 33,6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44 000 Americans die each year as a result of medical errors. The result of the New York study suggests the number may be as high as 98 000. Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43 458), breast cancer (42 297), or AIDS (16 516).

Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between $17 billion and $29 billion, of which health care costs represent over one-half.

In terms of lives lost, patient safety is an important issue just as worker safety. Every year, over 6 000 Americans die from workplace injuries. Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7 000 deaths annually.

The study recommends a comprehensive approach to improving patient safety aimed at a threshold improvement in quality over the next ten years.

Given the social and political relevance of such a study, December 7, 1999 the U.S. President Bill Clinton declared: “Ensuring patient safety is not about fixing blame. It’s about fixing problems in an increasingly complex system; about creating a culture of safety and an environment where medical errors are not tolerated.”

The White House communicate informs that: “Today, at the White House, President Clinton took strong new steps to ensure patient safety through the prevention of medical errors. The President held a meeting with

health providers and consumers; signed an executive memorandum directing a federal task force to submit recommendations on improving health care quality and patient safety initiatives. Under the President actions, the over 300 private health plans participating in the Federal Employee Health Benefits Program will be required to institute quality improvement and patient safety initiatives…".

2 Performances of the human operator in the healthcare system

2.1 General

Healthcare is (and will be in the future) a human-machine system, i.e. a technological organization, in which human, technical and organizational factors interact in order to deliver healthcare. In such a context, a Patient centered vision of healthcare delivery calls for the evaluation of human performance within the more general context of system performance. This chapter is based on James Reason's book: Managing the risk of Organizational Accident, 1998 Ashgate edition. For more details on the topic of this chapter and more in general on the topics of the organizational accident, the authors invite us to read this fundamental book.

2.2 The human activity space

Human performances and associated errors can be classified in many ways, but the most common is the classification of error related consequences for the system. A causal taxonomy helps in focusing on errors as consequences of underlying mental processes that are common to individuals acting in a system. To this purpose, we will refer to some basic concepts on human performances (Figure 2) according to cognitive science.

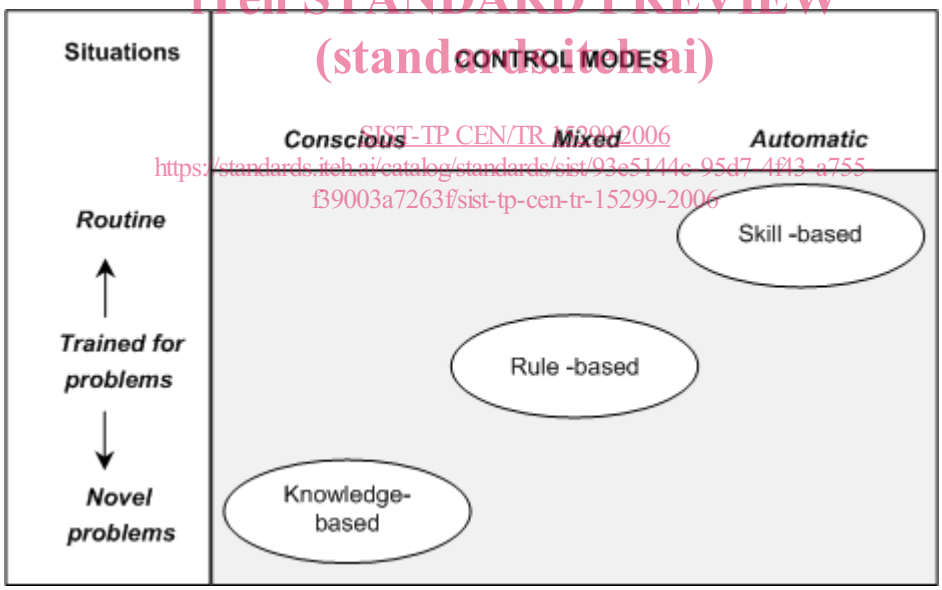

Figure 2 — Human activity space

The three main performance levels can be classified as:

— skill-based (SB);

— rule-based (RB);

— knowledge-based (KB).

A given human performance is the result of the combination of two factors: one depending on the individual (the individual control mode) and the other on the situation in which the individual is acting. These two dimensions define the so-called human activity space.

Human beings control their actions through various combinations of two control modes:

— conscious;

— automatic.

The conscious mode is limited in capacity, slow, sequential, error-prone, but potentially very smart. The automatic control mode is the opposite: largely unconscious and effortless, it is necessary to manage recurrence of everyday life. Naturally, human beings prefer to operate in the automatic mode whenever it is possible.

The nature of the situation in which an individual acts ranges from highly familiar everyday situations to entirely novel problems. In the middle range, situations require problem solving based on pre-training or documented procedures.

At the skill-based level, individuals carry on routine and highly practiced processes in largely automatic ways with occasional conscious checks on progress. The skill-based level includes the Patient and Patient related objects (medication, blood tube, medical report etc.) identification and tracking. The switch to the rule-based level happens when individuals need to apply memorized or written rules of the kind «if…then…do»: thus, they need conscious thinking to verify whether or not the solution is appropriate. The rule-based level includes for example known drug-drug interaction, drug-Patient allergy control, product lot/expiry data control, activity time scheduling and control etc. Generally, there is a resistance to come to the knowledge-based level and usually after repeatedly failing to find some pre-existing, effortless solution, individuals need time and concentration to come up with solutions. The knowledge-based level refers to all complex organizational and clinical knowledge applied to unpredictable states.

2.3 Human errors and violations

Human actions can be classified with respect to:

— • the goal intended to be achieved;

— • the behaviour with respect to procedures or rules to be followed;

— • the risk perception in the context of the action.

The intended goal discriminates between errors and successful actions: human error can be defined as the failure of planned actions to achieve their desired ends – without the intervention of some unforeseeable events (Figure 3). We are concerned with human errors: attentional slips of action, lapses of memory and rule-based mistakes, highlighted in Figure 3.