Human factors engineering in healthcare systems: The problem of human error and accident management

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Abstract

This paper discusses some crucial issues associated with the exploitation of data and information about health care for the improvement of patient safety. In particular, the issues of human factors and safety management are analysed in relation to exploitation of reports about non-conformity events and field observations. A methodology for integrating field observation and theoretical approaches for safety studies is described.

Two sample cases are discussed in detail: the first one makes reference to the use of data collected in the aviation domain and shows how these can be utilised to define hazard and risk; the second one concerns a typical ethnographic study in a large hospital structure for the identification of most relevant areas of intervention.

The results show that, if national authorities find a way to harmonise and formalise critical aspects, such as the severity of standard events, it is possible to estimate risk and define auditing needs, well before the occurrence of serious incidents, and to indicate practical ways forward for improving safety standards.

1. Introduction

Safety management is a typical proactive measure for safety assessment, which considers an organisation (a hospital, a plant, a company, etc.) as an integrated system, and combines standards, guidelines, procedures, auditing, safety policy, and quantitative risk assessment. The objective of safety management is to: anticipate and prevent accidents and incidents initiators; manage accidents that still occur; possibly recover normality; and limit or protect humans and environment from accident consequences, when prevention and recovery did not happen.

A safety management system (SMS) is an organised approach to managing safety, including the necessary organisational structures, accountabilities, policies and procedures [1].

The development and application of SMSs for accident prevention followed the occurrence of a number of very serious accidents occurred in the late 1970s in the domain of chemical, nuclear and process plants in Europe and US [2,3]. Nowadays, the implementation of safety management measures, based on SMS, is an essential means of compliance for ensuring that safety is adequately dealt with by organisations and industry in many domains, such as Nuclear Energy production [4], Railway Systems [5] and Civil Aviation [6,1]. Similarly, the implementation of SMS in the Medical environment is considered the way forward to manage incidents and accidents caused by errors and malfunctions [7]. These are indeed the cause of an increasing number of failures of medical systems, causing harms and damage to patients [8].

There are a number of essential aspects associated with the performance of valuable SMSs. These can be grouped into two
main categories: field related and environmental sources of information and data; and theoretical and procedural means. In reality, these two categories are not fully distinct and independent, as it is impossible to define and make valuable usage of data without appropriate modelling and reference paradigms. Vice versa, the lack of valuable field information and data invalidates the results of perfectly valid theories (also called sometimes “garbage-in—garbage-out principle”).

In a systemic perspective, the assessment of the overall safety of an organisation involves the assessment of integrated human and machine (technical) systems (HMS). Therefore, it is appropriate to speak about human error and accident management (HEAM) so as to cover that entire set of situations and interactions that may involve humans and machines. The need to include human factors (HF) considerations in the design and safety assessment processes of socio-technical systems is nowadays widely recognised by almost all stakeholders, from end-users to providers and regulators. The critical role assigned to HF is further enhanced by the common sense appreciation that it is impossible to conceive a plant that is totally “human-error free”. Indeed, human errors must be considered as an intrinsic component of any socio-technical system.

In this paper, a methodological framework is described that guides users in performing field studies, and data collection, and integrates and harmonises different theories for the exploration of such data for improving Safety and Quality Management in large organisations. Then, two crucial aspects of safety and quality management, namely evaluation of risk, and auditing processes, are discussed by which quality indicators can be identified and pinned down for accident prevention and amelioration of working contexts and performances. The importance of exploitation of data collected from reports about non-conformity events and from field observation is discussed in relation to two different domains, namely the aviation and the medical environments. Finally, the results of a safety and quality audit implemented in a hospital-ward of an Ear, Nose and Throat (ENT) department are shown, focusing on patients in need of accurate post-surgical medication treatment.

2. Description of HERMES methodology

2.1. Boundary conditions for safety methods

A methodology that aims at supporting designers and analysts in developing and evaluating safety measures, in complex and articulated systems, must consider two basic boundary conditions: it needs to be based on consolidated and reliable data, and requires the application of validated and generally accepted methods and techniques for handling the information contained in such data. In this way, it is possible to satisfy the needs and requirements of different stakeholders.

The accuracy and quality of data and methods identifies the effectiveness of the safety measures derived from the implementation of the overall safety management systems. The consideration for human factors contribution to the overall safety process represents a further degree of complexity, due to the fact that both data and methods related to human behaviour and performance are relatively less developed and consolidated than the equivalent approaches focused only on technical components. However, nowadays the design and safety evaluation of integrated HMS is no longer only the domains of designers and evaluators of hardware, but needs to be dealt with by teams of experts, including human factors specialists, such as ergonomists and psychologists, and engineers of hardware, software and communication. Consequently, the methodologies that aim at supporting the development of safety systems, have to consider the two above-mentioned conditions of availability of data and methods, bearing in mind that these refer to a very wide and complex variety of information and approaches that involve integrated variables, data sources, and theoretical constructs.

2.2. Areas of concern of safety management

In general, a Safety Management System entails three specific types of assessment: quantitative risk assessment (QRA), audit, and emergency management. For each of these areas well defined and consolidated methods exist, such as the technique based on Event Tree/Fault Tree approaches for risk assessment, or the threat and error management technique, etc. [1].

A further consideration is necessary for completing the process of appreciation and generation of measures for improving and safeguarding a specific system. This is related to the definition of appropriate and acceptable safety levels applicable to the specific system under scrutiny and its associated socio-technical environment, and to the different stages of the life of such system. Indeed, only by applying coherent specific methods at different stages of development and management of a system, it is possible to ensure effectiveness and preservation of adequate safety margins throughout the lifetime of the plant. Consequently, in all type of analyses, and for all areas of application, it is essential that adequate indicators be identified that allow the estimation or measurement of safety levels. As each system and organisation bear peculiarities and characteristics specific to their context and socio-technical environment, such indicators are unique for the system and organisation under scrutiny.

As an example, during a recurrent safety audit (RSA) process, a number of indicators of safety (IoS) are evaluated in order to assess that the system and organisation involved are operating within acceptable safety margins, i.e., the safety measures of the system conform with current norms and standards. Moreover, the RSA must ensure that current operational procedures and emergency management systems are consistent with the originally designed and implemented safety measures. As the organisation undergoes changes and modifications throughout its lifetime, it is necessary that the set of IoS are revised and adapted to the changes that occur and to the implementation of new safety standards and norms that are defined by the authorities.

2.3. Prospective and retrospective assessments

The discussion about the conditions necessary for ensuring the application of sound safety methods revolves around the correlation that exists between retrospective and prospec-
tive approaches. In fact, broadly speaking, the three main areas of concern of safety management may be associated respectively: audit to retrospective analysis, quantitative risk assessment to prospective assessment, and emergency management to a real time intermix of the two approaches. It is therefore essential to have a clear understanding of what are these different types of analysis and how they correlate.

Retrospective analyses are oriented to the identification of “data” associated with a specific occurrence and context (Fig. 1). They can be carried out by combining a number of methods and models that are extensively formalised and discussed in the literature, namely, root cause analysis, ethnographic studies, cognitive task analysis, data mining, and HF theories and models of human–machine interaction (HMI).

Prospective analyses aim at the “evaluation of consequences” of HMI scenarios, given a selected spectrum of HF theories and models of HMI, data and parameters, initiating events and boundary conditions, and creative thinking.

The basic difference between prospective and retrospective approaches lie in the fact that one (retrospective analysis) aims at understanding and extracting the lesson from past events and occurrences and the other one (prospective analysis) looks ahead and speculates, on a creative way, to assess safety levels of systems. A number of very important commonalties exist that have to be ascertained in order to ensure consistency and consolidation of the whole safety approach.

These commonalties consist of the human factors theories and human machine interaction models and of the data and parameters that must be shared amongst the two approaches. In fact, when the same reference models are considered for prospective and retrospective studies, then coherent methods and techniques are applied. In this way, data and parameters derived from retrospective studies of real events and evaluation of working environment can be fruitfully and coherently applied for prospective analyses. These common elements should be well identified, as they represent logical links between the two approaches.

In other words, to make prospective and retrospective analyses consistent with one another, it is essential that identical, or at least coherent, HF theories and HMI models should be utilised for both types of analysis. In this way, data and parameters derived from retrospective studies may be applied in prospective assessments without having to make inferences and judgement, which introduce further and unnecessary uncertainties on the evaluation of consequences.

The foundations of safety management consist in the clear understanding of these aspects and on the application of coherent methods.

2.4. Human Error Risk Management for Engineering Systems

The need to correlate prospective and retrospective studies in a logical analytical process that can support the consideration of HMI approaches in different areas of application has led to

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Fig. 1 – Safety measures as result of combination of prospective and retrospective analyses.
the development of a methodology that respects all requirements and basic conditions for their integration and mutual correlation [9]. This methodology is called Human Error Risk Management for Engineering Systems (HERMES).

HERMES is structured in a number of steps that may be applied in order to follow and preserve the basic requirements of congruence and consistency between retrospective and prospective studies, as well as to underpin the correspondence between recurrent HMI analyses and system safety and integrity, which change during the lifetime of a system (Fig. 2).

The correlated steps of HERMES can be discussed as follows:

- The models and theories that enable to describe the processes under assessment are part of the background knowledge and experience of the analysts and must be brought into play as initial condition.
- The performance of ethnographic studies is another necessary initial, sometime quite complex and time demanding activity. An ethnographic study enables to adapt the assessment to the specific system or environment for which the safety study is performed. The data collected during the ethnographic studies become integral part of the large database of information and data on which Data Mining is then applied.
- The investigation on accidents, past events, and reports about non-conformity situations is a very relevant process that leads to the identification of systemic failures, human behaviours, and/or organisational factors considered inappropriate for the circumstances under study. Root cause analysis (RCA) governs this process and enables to expand the vast repository of data for data mining.
- From the accident analysis it is possible to derive valuable information applicable to prospective studies. In particular, it is possible to derive causes, effects and reasons of errors; and to define parameters, indicators and markers of systemic failures and erroneous behaviours.
- These data and parameters are the basis for the evaluation, in a prospective analysis, of potential and hypothetical novel boundary and initial conditions for predictive risk assessment. In practice, using these data, parameters, boundary, and initial conditions in combination with the selected human behaviour model and error taxonomy, it is...
possible to apply risk methods to evaluate safety margins and outcomes of potential accidental scenarios.

- The same data, and in particular indicators and markers of systemic failures and erroneous behaviours, are fed to the auditing process in order to improve and update the list of indicators of safety on which the recurrent safety audits are based.
- The outcome of these prospective analyses can then be further utilised for generating possible accidental scenarios useful for training purposes, especially for crisis and emergency management.

The central step in this process is represented by the very rich and differentiated amount of data generated from all the above-mentioned process and available for development towards new information and predictive analysis.

Nowadays, the complexity and diversity of these data requires that different approaches are applied for screening the appropriate information for the needs of the user, filtering unnecessary data and ensuring that the noise generated on the output by such excessive amount of information does not affect the quality of the results. In many technological and socially complex domains and in particular in transport systems, notably aviation, and medical environments, especially large hospital structures, the problem of data screening and data mining is very important and has been recognised as central to the whole process of safety management, equal to the availability of valid analytical tools and theories of HMI[10,11]. For this reason, an important amount of literature exists on the techniques and methods for data collection and data mining of larger repository of information and data from different and varied sources[12–14].

In the following section, two examples are shown of possible application of HERMES to perform safety studies firstly by exploiting data collected from non-conformity reports and secondly by auditing working context from ethnographic analyses.

### 3. Exploitation of data about non-conformity events

#### 3.1. The culture of reporting for safety management

When performing safety assessment of a system there are two ways of analysing the risk associated to certain events. The first approach implies the preliminary evaluation, during design or assessment phases, of possible probabilities of unwanted consequences of various levels of severity. Obviously, the higher the severity of events, the lower must be the probability of their occurrence. Usually, safety authorities define acceptable levels of risk that have to assessed during design or assessment stages of a system in order to obtain certification and operation permission.

The second approach is associated with the normal operation of a system and with the occurrence of non-conformity events. These types of events are in many cases reported and data are collected and stored for evaluation and analysis.

Both types of approaches make reference to a safety matrix (Fig. 3) that defines usually four or five levels of severity, e.g., negligible, minor, major, hazardous and catastrophic, and four or five levels of frequency of occurrence, e.g., frequent, reasonably probable, remote, extremely remote, and extremely improbable. The risk, i.e., the combination of a certain severity with a frequency of occurrence, is considered either acceptable, or unacceptable, or further assessment and possible system changes are required according to rules and regulations defined by safety authorities.

During the design process, changes are introduced and revisions take place until the “calculated” risk does not fit within the required levels. During the lifetime of a system, occurrences and events build up the operating history of a plant. The analysis of the data and information collected about non-conformity events and various occurrences is of paramount importance in order to assess: (1) safe operability

![Fig. 3 – Example of Risk Matrix for the domain of civil aviation (adapted from [1]). The probability is expressed in “flight hour” (fl. hour).](image-url)
of a plant or system; (2) preservation of the level of risk within acceptable boundaries; and (3) trend of the overall safety performance towards potentially dangerous situations.

In this paper, particular attention is dedicated to the assessment of risk derived from the normal operation of a system. Two basic conditions are necessary: the availability of data about non-conformity events; and the definition, by the safety authorities, of the acceptable levels of risk and of the severity associated to a variety of standardised sets of events. In modern systems, even if the issue of safety is of great concern and is felt by the society at large, the achievement of these two conditions is extremely complex and difficult. This is a paradoxical situation, where on the one side everybody is concerned and convinced about the relevance of the safety issue, but it becomes more and more difficult to report on errors (either own ones or made by others), mishaps or failures. There are several reasons for this difficulty, which reside on liability issues, trust, and cultural concern. In particular, in the medical environment, even if human errors have shown to play an enormous role on the safety level, it is nowadays still very difficult to establish clear and defined rules both in terms of reporting, on the definition of standard non-conformity events and associated severity, and especially on liability issues.

In other domains, primarily chemical and petrochemical plants and transport aviation, the conditions for reporting non-conformity events and the norms for risk definition have been, to a certain extent, established. In this way, a process of cultural change within organisations is under development, by which, at management level, the liability issue is gradually being replaced by the focus on improving safety and quality of performance. In parallel, at front line level, the culture of reporting is also diffusing and becomes more popular, in combination with more trust and reliance on safety managers.

3.2. Requirements for collection of data about non-conformity events

The existence of norms, standards, and regulatory requirements for collection and analysis of data is the first condition that must be satisfied for starting the process of collection of reports on non-conformity events.

As it usually happens, the existence of requirements is coupled with operational measures for the implementation of the rules. In the case of reporting for safety assessment, the operational measures issued by safety authorities contain the definition of a list of crucial events that needs to be reported and a standardised severity level associated to each event.

The same implementation rules usually contain also the Risk Matrix that is applied for assessing the acceptability of the risk. An example of Risk Matrix for the domain of civil aviation is shown in Fig. 3.

In parallel to the normative requirements that give the regulatory aspect of the safety management, there exist a number of technical conditions that are essential. As clearly indicated in the HERMES methodology, the initial steps are the availability of adequate models and taxonomies for data collection and for describing the environments and their main actors (operators, maintenance personnel, nurses, doctors, etc.).

The most important requirement in this sense is the availability of a model, and associated taxonomy that enables to describe the system, the organisation and the environment under analysis. A very common and widely utilised model for representing working contexts and main actors is the SHELL model [15,16], originally developed for the aviation domain, but easily expanded to other domains such as health systems (Fig. 4). This model accounts for the basic components of a working domain and for their mutual interactions, namely:

- The human beings that work and operate in different working context and at different levels of the organisation: these are defined as Liveware (L) in the SHELL terminology.
- The parts, components instruments that are utilised by humans in order to carry out their duties: these are represented by the expression Hardware (H).
- The physical and social working contexts in which operations are carried out: these are identified as Environment (E). This vision of the Environment expands the concept of simple working context to embrace the social climate in which humans are called to operate. In particular, the expression Environment contains the interactions of human being with the management not directly involved in the actual performance of the job.
- The rules, standards norms and training that regulate the expected and normative behaviour of persons: these are called Software in SHELL terminology. In particular, this component aims at covering formal procedures that affect behaviour, especially when they are written and have to be followed in detail and, sometimes, they must be checked-out before closings jobs.

![Fig. 4 – SHELL architecture for medical environment.](image)
The interactions are represented in the SHELL model by means of the layout of the components (Fig. 4, left-end side). In particular, the model is focused on a human being (the L in the centre of the sketch of the model). This central element then utilise tools and parts (i.e., the L–H interaction) and interacts and co-operates with other human beings (i.e., the L–L interactions), while being affected by a certain social and physical climate (i.e., the L–E interaction), and by the existing procedures and training associated to the activity (i.e., the L–S interaction).

The SHELL paradigm applied to a medical organisation, such as an hospital, is depicted in Fig. 4 (right-end side), where the central figure is represented by a doctor, nurse or technician, and the other SHELL elements are clearly identified as the instruments utilised to carry out their activity (operating theatre, medicaments, examination machineries, etc.), the colleagues with whom one normally works with, the rules that govern the activity and know how derived from training, and finally by the overall hospital context, represented by the physical conditions and the influences derived from higher management issues.

In the domain of aviation, a very relevant effort has been dedicated to the development of a taxonomy based on the SHELL model and to adapt it to the specific domain. This taxonomy, called ADREP-2000 [17], has been adopted by the International Civil Aviation Organisation (ICAO) and is still undergoing continuous development and expansion. ADREP is nowadays utilised throughout the world and is commonly accepted and applied to classify systemic and human inappropriate behaviours and non-conformity events. By means of a data collection system based on ADREP-2000, each air transport operator, as well as each organisation of maintenance, air traffic control system, and airport operations is able to collect data and information about occurrences and non-conformity events and to confront their safety and risk levels vs. internationally accepted and approved standards. To carry out this process, in addition to collecting and storing data about non-conformity events, a set of tools are required, as discussed earlier, that enable the actual performance of safety analysis and assessment of risk.

In the medical environments very similar requirements exist that aim at developing the culture of reporting non-conformity events and classifying the data and performing appropriate analysis for error and incident prevention. Amongst several initiatives, it is important to mention the activity sponsored by the World Health Organisation for data collection and classification aimed at improving patient safety. In particular, the Conceptual Framework of an International Patient Safety Event Classification [18] represents an important step forward for the development of a commonly agreed taxonomy and classification methodology that enables the sharing and exchange of data on relatively common platforms.

3.3. Requirements for analysis of data about non-conformity events

In general, a non-conformity event is represented by an occurrence that has deviated from normal procedures and that has initiated a process that would have led to serious consequences, possibly an accident, if it was not controlled by some protections and barriers. In many domains, non-conformity events need to be reported in writing by the actors involved. Moreover, the list of non-conformity events to be reported is defined by the national safety authorities.

The goal of this safety requirement is to collect as much information as possible about the safety levels and the evolution of safety standards within an organisation, so as to enable auditing and early intervention when dangerous trends are discovered. To reach this most important and crucial goal of safety, it is not sufficient to collect data about non-conformity events, but it is absolutely necessary that sound analyses are recursively carried out, by means of consolidated and in-depth techniques. This is particularly true when focusing on human behaviour and on the so-called human error.

In the following, two possible exploitation of information contained in data bases about non-conformity events are discussed: the root cause analysis, for the identification of causes of non-conformity events; and the definition of the risk associated to an event or sequences of events that occurred and were reported.

These two approaches are not totally independent, as the definition of the risk that is derived to a system in relation to certain types of hazards can be evaluated only following a detailed root cause analysis. Consequently these two types of analysis are combined and framed in the HERMES methodology following the path that leads to design and safety management.

3.3.1. Root cause analysis

The identification of root causes of incidents is the major product of the analysis that can be performed on the reporting associated to an occurrence or a sequence of events. The search for the root causes requires the application of techniques and theories that are nowadays quite well developed and consolidated, both in the domain of systemic and human related failure.

In particular, with respect to human factors, the generally accepted methodological framework that is applied to different technological and social contexts, including medical environments, refers to the theoretical framework designed by Reason [19,20,21]. This approach aims at: (1) identifying errors and their manifestation; and (2) contextualising them in a picture that involves the social, managerial and physical environment in which they develop. In particular, the socio-temporal dimension of errors, with the well known distinction between active and latent errors, is defined which enables the analyst to distinguish between causal paths associated to the sequence of events under scrutiny (active failures) and other contributing factors occurred in a “distant” frame, either in terms of temporal dimension or at social and managerial level (latent failures).

An example of a technique that implements the conceptual framework designed by Reason and specifically adapted to combine systemic and human failures for root analysis [22] has been called Integrated Systemic Approach for Accident Causation (ISAAC) [9,6].

In the search for root causes of an event, the ISAAC method is applied in a retrospective way and requires the performance of a number of steps, namely (Fig. 5):
Fig. 5 – Integrated Systemic Approach for Accident Causation (ISAAC); procedure for root cause analysis (adapted from [9]).

1. Each Event is associated with possible failures derived from either, or both, human factors and/or systemic factors pathways.

2. In the case of Human Factors Pathway:
   - An active error is identified. This is the manifestation of the inappropriate action, which is usually classified as an "error". The analyst should assess whether certain personal factors and/or contextual factors can be recognised that fostered the specific error at the time of occurrence. These factors are a first set of root causes of the event, or primary root causes.
   - In addition to this first step of investigation, the possible contribution of latent errors must be investigated that played a specific and unique effect on the active error. These can be further detailed in two levels of latencies:
     - A sort of direct latent factors that may affect the specific active error. Examples of these types of latent errors are "Inadequate training", "Unclear Emergency Operating Procedures", etc.
     - A more subtle and complex type of latent factors, associated to higher organisational level (Organisational Processes), that play a much wider impact on other failures including those at systemic level. Examples of these types of latent errors are "Misleading policies", "Inadequate cost benefit indications", "Flawed selections of contractors", etc.

3. In the case of System Factors Pathway, a similar procedure is followed, where
• A **System Failure** is identified. This represents the actual malfunctioning of a component or a subsystem. It is firstly necessary to assess whether or not casual and/or contextual factors occurred that affected the specific system failure. These play the role of primary root causes of systemic failures and correspond to the personal and contextual factors associated to the human factors pathway.

• In addition, to these factors and primary root causes, the contribution of **Latent Failures** is investigated, and, as in the previous case, these are divided in:
  - Direct latent factors that may affect the specific malfunction or failure. Examples of these types of latent errors are "improper re-setting after maintenance of a protection system", "Erroneous design specifications for a safety device", etc.
  - Higher level latent errors, made at organisational level, which affect the whole system under scrutiny both for human and systemic aspects.

### 3.3.2. Risk assessment
An essential step of exploitation of the data collected through reporting about accidents, incidents, and, especially, non-conformity events, and of the associated analysis, is the identification of the modified levels of safety, as a consequence of such events, and of the new scenarios and safety requirements that may require the attention of the safety manager.

In other terms, a very important feedback from the data collection and analysis is the possibility to utilise the information and new incoming data in terms of risk. The approach proposed in the following section contains a combination of classical risk assessment approaches, as well as some innovative contributions that may require further validation and consensus by the safety authorities.

In particular, the first step in the process of assessing the risk derived to the system from a certain event, following the reporting of an incident, requires that the reported occurrence as a whole is firstly analysed in terms of sequence of events. This implies that a clear definition of what is meant by event is adopted and that the events highlighted in the report, and composing the incident, are structured in a sequence of time and logical interconnection. In practice, the events that compose an occurrence are firstly identified and then a time line analysis is performed.

An innovative way to analyse the events that compose an incident is to define an event simply as "a fact or an action that leads to a change of state of the system" and then to distinguish events in two categories, namely negative and positive events. A Negative Event is represented by malfunction or failure that causes the system to perform in irregular ways, different from the design, and that leads to uncontrollable, but containable consequences. A Positive Event is an event strictly correlated to a negative event, which represents a reducing fact or a barrier that stops the incidental chain, limiting the consequences of the overall occurrence.

The analysis of the overall occurrence or incident is then subdivided into the evaluation of the risk associated to each negative event that composes the event time line, and of the overall severity of the accident, mitigated by the effects of the positive events. This concept implies firstly that it is not possible to associate a measure of risk to an incident as a whole, but what may be evaluated and assessed are: (1) the individual levels of risk associated to each event composing the incident; and (2) an overall level of severity associated to the incident as a whole.

A second important aspect of this process is the importance of the concept of severity of an event, which is recognised as a crucial contributor to the assessment of the risk and safety level. Consequently, it is necessary that safety authorities define and establish commonly accepted criteria for associating severity to standardised sets of events. This is a very complex problem, as discussed above. In certain domains, in particular aviation, the definition of severity levels associated to events has been performed by the ICAO [1] and by several other international organisations such as the International Air Transport Association (IATA) [23]. In this way, each event is associated to an intrinsic value of severity (or criticality), also called absolute severity that establishes how “dangerous” the event is, regardless of the context in which it occurs.

The overall severity of an event, its frequency of occurrence and the associated risk enable a safety analyst to eventually evaluate the overall state of an organisation and “position” it in the “Risk Matrix” (Fig. 3). The calculation of these quantities entails a detailed analytical and statistical analysis. The techniques and methods utilised are the object of a very relevant debate and assessment at international level and within the academic and regulatory institutions. A detailed discussion of these aspects is outside the scope of this paper and can be found elsewhere [24].

### 4. Ethnographic analysis for auditing working contexts
The HERMES methodology has been applied to perform a preliminary study for the evaluation of critical areas and safety indicators in the domain of hospitalisation. The objective of the study was to improve nursing environment and to identify possible indicators that would enable auditing and prevention of risky situations [25].

The audit was performed on the Otorhinolaryngology (ORL) Department of a hospital, treating about 800 patients per year, and a ward dealing with surgical interventions was chosen for specific scrutiny. The ORL ward was organised in three shifts over the 24 h. Each nursing team was made of a sister-in-charge, and seven nurses. There were 17 beds in the ward.

The team of analysts (HF-Team) performing the study was composed of risk assessment analysts and experts in the specific hospital environment, with a strong background in ergonomics.

The commitment of the staff and the interest of the management in this study represented an essential and very valuable contribution to the success of the work.

The HERMES methodology was applied in three phases. The first one concerned the performance of the field study with observation of the working context and interviewing of nurses by means of a typical ethnographic approach. A detailed work domain analysis was also carried out, so as to define tasks and jobs for the different actors involved in the process [26]. This required selecting a model of reference...
for describing human behaviour. In the second phase, the analysis of existing reports about non-conformity events was combined with the outcomes of field studies for a detailed assessment of the working context and definition of safety indicators. Finally, in phase three, a number of recommendations about possible ameliorations of procedures and working habits were developed for increasing patient safety.

In the following, the field studies are presented in detail, whereas the evaluation of reports of non-conformity events is not reported for brevity, as this is the object of a separate study not yet completed. Some preliminary recommendations are discussed. The field studies consist in: (1) the evaluation of indicators of risk resulting from the assessment of the staff operating within the ward; and (2) the analysis of working context and quality of service from a user satisfaction perspective. In this case the “users” are the patients and the objective of the analysis was to assess, in parallel to the indicators derived from the evaluation of nurses’ activity, the quality of the nursing service from a patient perspective.

The two ethnographic studies make reference to the same task analysis, reference model and data collection approach and are discussed hereafter.

4.1. Task analysis and selection of reference model

In collaboration with the sister-in-charge of the ward of ENT, the plan and duties of the various personnel working in the ENT ward was revised. Table 1 shows a sample of tasks flowchart for day-shift and for all nursing staff acting in the ward, according to SHELL method. The complete table utilised for assessing safety, quality of performance and user appreciation of nursing was much more detailed and covered the whole set of activities carried out by the nursing staff [27].

The activity of ward was firstly studied from the nurses’ perspective, by a functional task analysis. Many tasks were subdivided according to the stages of a “normal” Ear, Nose and Throat (ENT) practice. Five stages of ENT activities were analysed, namely:

1. Assistance pre-operation.
2. Preparation of the patient on the day before the ENT operation.
3. Preparation of the patient on the day of the operation.
4. Assistance post-operation.
5. Special cases of oncology patients.

Each stage was further subdivided into specific tasks and for each task the functions to be carried out were identified. Particular attention was dedicated to the interaction of the nurse with the patient, in terms of assistance during the various phases of the permanence in the hospital.

The functions that were scrutinised in detail and described were as follows:

- Preparation of the prescriptions.
- Distribution.
- Dispensing of medicines to the patients.

From the task analysis and given the experience of the HF-Team it seemed appropriate to select the SHELL architecture [16] as the most representative paradigm for describing the interactions existing in the ward.

The various functions of nursing activity were represented in relation to the SHELL model, focusing in particular of the interaction nurses–doctors. An example of process of preparation of prescriptions and dispensing of medicines according to the SHELL framework is shown in Table 2. In the case described in Table 2, the central figure of the SHELL architecture (Fig. 4) is the “nurse”. The process of prescription implies the possible interaction with doctors and pharmacists, namely the doctor in charge of the patient, a consultant and the pharmacist, for the identification of equivalent drugs. Interactions occur in the doctors’ staff room. Prescriptions are recorded on a PC according to the hospital guidelines.

The process requires several steps, and possible loops may be started especially when the prescribed drug is not available and an equivalent one needs to be found.

4.2. Ethnographic study within the ward

In addition to the task analysis and selection of the SHELL model as reference paradigm, a typical ethnographic study was carried out.

In particular, the following steps were performed:

- A number of field observations, including recording of procedures and auto confrontation, were carried out.
- A number of unstructured interviews were performed.
- Finally, a questionnaire was distributed and data were collected with the aim of exploring the attitude and practices of nurses with respect to their system and working environment.

The objective of this process was to evaluate the areas of concern with respect to safety and the identification of possible indicators of human errors and safety management needs.

The population of nurses that were involved in the ethnographic study consisted of 35 persons in total, including three nurses in charge. The methods used to analyse the activities of the department have been both qualitative and quantitative. The qualitative analysis was based on field observation of the normal nursing activities and unstructured interviews. The quantitative approach concerned the evaluation of the feedback from the questionnaire distributed to the entire population of nurses in the ward.

The analysis of the interviews and ethnographic investigation helped in formalising a workflow of the activities of each shift, using SHELL as reference method. Other material that helped the analysis of the working processes were the procedures and protocols utilised in the nursing department for pre- and post-surgery, and the note book of the head nurse, which was made available to the investigation team.

4.2.1. Field observation

The qualitative analysis was based on audio and video recording of a simulated set of actions that a nurse performs during normal operations of collecting prescriptions and dispensing of medicines (Table 2). Only three nurses were involved in this
Table 1 – Sample of tasks flowchart for day-shift according to SHELL method.

<table>
<thead>
<tr>
<th>Task</th>
<th>I.P.</th>
<th>LP. WARD</th>
<th>IP MED</th>
<th>OTA MED</th>
<th>OTA OPT</th>
<th>OTA WARD</th>
<th>OTA COM</th>
<th>ST</th>
<th>H</th>
<th>E</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit patients with doctor</td>
<td>A-B-C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nursing case history, pen, notebook</td>
<td>Patient bed</td>
<td>Head-Nurse verbal training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>therapy, medical case history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care of the patient according to</td>
<td>A-B-C</td>
<td>A-B-C</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B-C</td>
<td>A-B</td>
<td>A-B</td>
<td></td>
<td>Bed pan – urinal bottle – gailpot</td>
<td>Patient bed</td>
<td>Guidelines Hospital – Professional training</td>
</tr>
<tr>
<td>their skills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reordering and control the patient bed</td>
<td>C</td>
<td></td>
<td>C</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B-C</td>
<td>A-B</td>
<td></td>
<td>Cart linen</td>
<td>Patient bed</td>
<td>Head-Nurse verbal training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient pain monitoring each 3 hours</td>
<td>A-B-C</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B-C</td>
<td>A-B</td>
<td>A-B</td>
<td></td>
<td>Pain card – VAS scale – Pen</td>
<td>Patient bed</td>
<td>Guidelines Hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control physiological parameters to the</td>
<td>A-B-C</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B-C</td>
<td>A-B</td>
<td>A-B</td>
<td></td>
<td>Parameters Card, Thermometer, Sf(1)mgomanometer, Phonendoscope</td>
<td>Patient bed</td>
<td>Guidelines Hospital – Professional training</td>
</tr>
<tr>
<td>patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific nutritional needs of the patient</td>
<td>A-B-C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Card plan post-surgery - infusional</td>
<td>Patient bed</td>
<td>ENT Protocol nutrition and clinical nutrition Machine manual</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>pumps – bottles nutritional - Special Menu - integrators - PEG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>room</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Uniform</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Settle constantly the ward.</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B</td>
<td>A-B-C</td>
<td>A-B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ward</td>
<td>Guidelines Hospital</td>
</tr>
</tbody>
</table>
process. However, this was deemed sufficient for the observers to become acquainted with the working habits and contexts of ward operations.

All sequences of the working process that goes from prescription of drugs by the doctor, selection, distribution and disposal of residues of the drug were simulated and video taped. The integrated analysis of the videos by the actors involved, i.e., the nurses themselves (auto-confrontation), contributed in structuring the work flow and task analysis.

4.2.2. Unstructured interviews
The unstructured interviews were conducted with two professional nurses of different gender, with the head nurse and with the secretariat of the ward. For a more consistent statistics a much higher number of nurses should have been interviewed. However, given the preliminary and exemplificative nature of the study, the number of persons involved was deemed sufficient.

The interviews were performed according to the method of “instructions to the double”[28] so as to simulate the normal working practices of preparation and distribution of the drug. The “instructions to the double” is a structured interview technique, but not directive, which is organised into four phases:

1. The first phase, aims at retrieving the vision that the worker has of the organisation, of the actual work, the hierarchy and working team.
2. The second phase aims at reviewing the activity of the individual operator, analysing in particular, the use of time, employment, moments of integration and co-operation, the use of space, the tools and procedures.
3. The third phase will reconstruct in detail the plan of professional behaviour. The operator has to instruct the interviewer to behave as if he/she was his/her deputy, imagining that no-one realises the exchange. This is not a reconstruction of what the stereotypical nurse would do, but should make a comprehensive and detailed description of what the specific actor does. Thus, it makes possible a reconstruction of professional competence specific of the particular operator and this generates a greater awareness of the work.
4. During the fourth stage, the interviewer returns to the interviewee the outcome of the interview and in so-doing a process of improved awareness of the activity and possible improvement, correction and clarification is started.

The reference model for the interviews was SHELL. The interviewee was placed at the centre of the SHELL structure (Fig. 4), and the questions were focused on each area of interaction, namely, relationship with patients and colleagues (LL), effects of the environment and management on behaviour (LE), interaction with instruments and material (LH), and application of procedures and training (LS). In addition to this, the personal attitudes and knowledge of the person were included in the analysis.

4.2.3. Questionnaire
The questionnaire was developed following the same reference SHELL model and consisted in 10 questions. The answers were structured according to a Likert scale approach for the answers, based 5 levels from “Strong agreement”, “Agreement”, “No opinion”, “Disagreement”, and “Strong Disagreement”. The questions were mixed in terms of agreement vs. disagreement and in relation to the argument, so as not to create habit in replying to questions.

The 10 questions are hereafter reported and the results of the collected data are shown in Fig. 6:

1. The regulations and instructions available in department are valuable to develop the knowledge necessary to perform the activities of preparation and delivery of drugs.
2. The working practices of activity are not fully matching the regulations and instructions.
3. The knowledge and information received during training to carry out the activities are insufficient and inadequate.
4. The tools for preparation and delivery of medications perform their functions in a reliable and effective way.
5. The support materials (manuals, procedures, lists, signs, etc.) do not adequately support the execution of the activity.
6. The physical environment (nurses rooms, lighting, available space, furniture, etc.) allows a comfortable execution of tasks.
7. The post-operating conditions of patients (age, body, attitude psychophysical, etc.) affect the execution of the activity.
8. The flow of information and operational changes is slow and inadequate and does not support the activity.
9. The distribution of work both at individual worker level and among workers is not appropriate for the optimal performance of jobs.
10. The distribution of work in three shifts and the number of staff is suitable to the activity.

4.2.4. Analysis of results

The main results of the analysis of data collected from the questionnaires are shown in Fig. 7, in terms of area of criticality according to the SHELL paradigm. The relevance of each area (in percentage) is obtained by averaging the results of the answers to the questions in the sense of criticality and relevance for patient safety. It is quite clearly noticeable that the area of most concern is associated to the performance of work in relation to environmental and social aspects (LE). This is followed by the relationships with colleagues and doctors (LL). Whereas no problems seem to exist in association neither to the training received and rules, nor to the tools and instruments available for carrying out the work.

The quantification of the interviews in terms of SHELL paradigm was not possible, as the open and discursive nature of the interviews could not be bounded by the mere association to one of the four SHELL interactions. The only type of analysis that was performed with respect to the answers to open questions was a further qualitative analysis. As supporting example of this issue, the summary of the interviews to a couple of open questions is shown in Table 3.

In particular, the first question (Q1) was aimed at exploring the opinion of nurses about the actual existence and quality of the regulations and standards applied in the ward, typically a “LS” type of interaction. However, in replying to the question, the interviewees expanded their views and consideration to the location and accessibility of manuals, typical of an “LE” type of problem, and to relationship and communication with colleagues and to mutual support in applying regulations, typical of an “LL” type of interaction.

Similarly, the second question reported in Table 3 focuses on “practices” at work. This is a very important issue, associated to the culture that exists within the hospital and ward, and is derived from unwritten rules, that governs the acceptable behaviour during the nursing practice. This is a typical “LE” type of activity. However, as already shown for question Q1, the discursive nature of the interview allowed the nurses

---

**Table 3 – Summary of answers to questions asked during the unstructured interviews.**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Knowledge and information necessary: availability in the ward of formal/written rules regulations and protocols</td>
<td>They are sought by nurses. Only a limited input is received from manuals. As the search is difficult, one is never sure of completeness. Information is contained in paper materials. The location of this material is not always easy for lack of space. Some document after several passages become unusable because it harms sheets. The exchange of information between nurses occurs during the shift change or within the shift. Communication is not always clear and careful. Personal aspects and attitudes of nurses can increase the communication problem and also basic nursing operations.</td>
</tr>
<tr>
<td>Q2</td>
<td>What do you think of the “practices” applied at work</td>
<td>Some working practices do not follow literally protocols or guidelines. This is due both to instructions (in some cases redundancy) is an immediate update of the material to be used as a result of a change in protocol (e.g., supply drugs almost never appropriate to the needs). The premises are small and uncomfortable. This entails a continuous adjustment and adaptation to the implementation of the guideline or to the ideal protocol. No attention on is paid to stocks of medicines and new formulations. In some cases there is no collaboration between nurses due personal reasons. This could lead to an isolation of the individual nurse.</td>
</tr>
</tbody>
</table>
Table 4 – Summary of answers to questionnaires distributed to patients.

<table>
<thead>
<tr>
<th>Group</th>
<th>Question objective</th>
<th>Acronym</th>
<th>Question value</th>
<th>Group value</th>
<th>Total average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reception</td>
<td>Patient opinion on welcome when entering the ward</td>
<td>Rec2</td>
<td>3.70</td>
<td>3.70</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Information received from doctors on patient health</td>
<td>MA1</td>
<td>3.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical attention</td>
<td>Availability to listen of doctors</td>
<td>MA2</td>
<td>3.68</td>
<td>3.67</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Courtesy of doctors</td>
<td>MA3</td>
<td>3.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resolution of patient health problems</td>
<td>MA4</td>
<td>3.64</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Information received from nurses</td>
<td>NA1</td>
<td>3.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attention dedicated by the nurses to patient needs</td>
<td>NA2</td>
<td>3.70</td>
<td>3.69</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Courtesy of nurses</td>
<td>NA3</td>
<td>3.74</td>
<td></td>
<td>3.49</td>
</tr>
<tr>
<td></td>
<td>Timeliness of response to a call with the alarm bell</td>
<td>NA4</td>
<td>3.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing attention</td>
<td>Comfort room</td>
<td>HP1</td>
<td>3.33</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change of linen</td>
<td>HP2</td>
<td>3.48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hotel performance</td>
<td>Cleaning of room</td>
<td>HP3</td>
<td>3.50</td>
<td></td>
<td>3.45</td>
</tr>
<tr>
<td></td>
<td>Cleaning of bathrooms</td>
<td>HP4</td>
<td>3.37</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cleaning of ward</td>
<td>HP5</td>
<td>3.56</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quality of food</td>
<td>RB1</td>
<td>2.93</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Room and board</td>
<td>Possibility of choice of food</td>
<td>RB2</td>
<td>3.08</td>
<td></td>
<td>3.19</td>
</tr>
<tr>
<td></td>
<td>Service of distribution of food</td>
<td>RB3</td>
<td>3.41</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comfort dining-room</td>
<td>RB4</td>
<td>3.37</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ward environment</td>
<td>Spaces dedicated to reading and recreation (television, games, etc.)</td>
<td>WE1</td>
<td>3.32</td>
<td></td>
<td>3.39</td>
</tr>
<tr>
<td></td>
<td>Care for the environment</td>
<td>WE2</td>
<td>3.42</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Privacy consideration</td>
<td>WE3</td>
<td>3.43</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

to expand their comments to subjects only marginally associated to practices, but relevant for the performance of tasks. As in the previous case, the issues of relationships with colleagues ("LL") and physical environmental conditions ("LE") were raised as major impairments to the performance of ideal activity.

4.2.5. Preliminary recommendations

The results of the analysis of field observation, unstructured interviews and questionnaire allowed the Human Factors Team involved in the study to develop a number of recommendations focused on the two areas of most concern.

In particular, it was proposed to:

a. find a new physical space for “preparation of prescription”, dedicated only to this function, as the inadequacy of space can be the source of many human errors;
b. improve the table relative to the patient data with clear indications about allergies and a clear procedure for dispensing certain drugs;
c. improve communications, especially during shift changes;
d. develop new legislation in terms of information about drugs, as this was identified as issue in terms of rules and standards.
e. completely revise the system for selection of “equivalent drugs” by using a software based tool already existing in other departments.

No prospective studies of consequences of possible human errors derived from these areas of concern have been carried out for this preliminary audit. This step in the application of the HERMES methodology would enable to assess the seriousness of certain factors with respect to human performance and the screening and prioritisation of types and modes of intervention accordingly.

4.3. Ethnographic study amongst patients

Nursing is a critical factor in determining the quality of care in hospitals and the nature of patient outcomes. Nursing personnel represents the largest proportion of patient care givers in a hospital. Nursing care in hospitals takes on added importance today because increase in acuity of patients requires intensive nursing care.

4.3.1. Data collection through questionnaire

On the basis of the nursing tasks (Table 1), a questionnaire was developed and distributed to the patients at the time of their discharge. The questionnaire, treated in an anonymous form, is oriented to a quality through the aspects “hotel” and “not-clinical” by the patient. The aim of the study was to achieve a response on the quality of facilities and performances of nursing personnel for the management of the trauma suffered by patient with hospitalization and surgery.

The questionnaire was developed following the reference SHELL model mentioned above and consisted in 20 questions divided in five thematic groups (Table 4):

1. Medical attention (MA), comprising four questions.
2. Nursing attention (NA), comprising four questions.
3. Hotel performance (HP), comprising five questions.
4. Room and board (RB), comprising four questions.
5. Ward environment (WE), comprising three questions.

An additional sixth thematic group, called “Reception” (Rec2), was added with a question focused on the first impact of the patient entering the ENT ward.

In total, 560 questionnaires were collected over a period of 1 year.

The answers were structured according to a Likert scale approach for the answers, based five levels ranging from “Excellent” to “Unsatisfactory”. The questionnaires were transcribed into a database at the end of each month, transforming the Likert scale in numerical values. No further statistical analysis of the data has to date been performed.

It has to be noted that external contractors carry out the activities related to the questions of groups HP, RB and WE. However, the contribution of nurses plays an important role in relations to the specific questions HP2, HP3, HP5, RB2, RB3, WE2, and WE3.

4.3.2. Preliminary analysis of results

The results of experimentation over 1 year of data collection are shown in Table 4 and Fig. 8. The values associated with the item “question value” are the average values calculated over the year. The outcome of questions relative to patient opinion (Rec2) is not included in the analysis of average values, as it was a single question asked to patients and it was only addressed to perform a preliminary qualitative assessment of patient opinion about the welcome received at first entry in the ward.

A marked tendency to relatively high scores and to fluctuation over different months is noticed for groups Rec2, NA and HP (Fig. 8), whereas group MA remains quite constant over the year at relatively high level. With reference to average values (Table 4), group NA presents the highest score (3.69), whereas groups WE (3.39) and RB (3.19) show the lower scores.

The trend of performance of NA has a clear tendency to rise in the period January–December; with a minimum value shown in March. Group MA remains quite stable, with no tendency to rise (average 3.67; min. 3.58 in February and max. 3.75 in June).

The outcome of activities carried out by external contractors (HP, RB, and WE) show lower values than those performed only by nurses. Within such these groups, the specific questions relative to activities which involve the nurses of ward, namely HP2, HP3, HP5, RB2, RB3, WE2 and WE3, present the highest partial scores.

In general terms, during the 1-year period of observation, all variables present a reduction in the month of March, which correspond to the highest number of admitted patients. On the other side, in August, in correspondence with the minimum number of admitted patients, these values increase and, in some cases, present peaks. A number of social and cultural aspects may be associated with these results. However, in order to achieve a critical statistical support for such considerations, a more consolidated set of observations is required covering several years of data collection and analysis. For this reason, no discussion is carried out in relation to social explanations for these results.

Based on the scores from the questionnaires, the sister-in-charge implemented a number changes in the management of the working plan of the nurses according with the aim to increase the score of each subgroup and in particular for groups directly related to nursing, i.e., nursing attention and hotel performance. To date, the main interventions have been made to the NA group but not the group MA. Further data collection is in progress and this will allow more consistent analysis of working contexts and further interventions.

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**Fig. 8 – Annual course of medium values for Thematic Groups.**
Summary Points
Current research state of the art:

- Safety Management Systems (SMS) for accident prevention followed the occurrence of a number of very serious accidents are part of safety legislation.
- Methods and techniques for implementing Safety Management Systems are well developed and known.
- Standardisation of SMS at international level in different domains is necessary and national safety authorities are collaborating at to reach such objective.

Contribution of this paper:

- Similarities and differences between aviation and medical domains are highlighted.
- Areas of concerns and, in particular, profiles and competences in need of consideration are identified.
- Results from field studies reveal the relevance of adaptive approaches and identify important differences between domains that may affect the harmonisation of standards.

5. Conclusions

This paper has debated the existence and availability of methods and techniques for carrying out safety management of large and complex organisations. In particular, the human factors contribution to incidents and non-conformity events was reviewed. The objective of assessing risk and identifying root causes of events, and, therefore, to pinpoint those factors that enable the early detection of dangers is no longer a question of methods and techniques. Indeed, these exist and have been shown to give reliable results, even when highly complex human factors aspects are involved.

The domain of civil aviation is typical of these types of interactions and leads the way in terms of implementation of norms and standards that require the application of adequate approaches for assessing regularly the level of safety of organisations. The effort implemented by national and international organisations and safety authorities to reach these objectives has been enormous and has led to the definition of reasonably accepted safety standards, at least in certain domains such as civil aviation. These are applied across countries, nations and cultures.

In the domain of medicine, this process has begun, but it is in its infancy and requires some more effort and iterations amongst national and international health authorities, political bodies and, last but not least, cultural changes at social levels. In practice, in the domain of health safety, this effort needs to be further sustained and promoted by all actors involved.

This paper has shown that methods and techniques are available and are becoming more and more efficient, enabling analysts to elaborate and extract valuable information from very complex and varied sources of data. The major effort now resides in the identification and harmonisation of standards and reference values to enable the performance of effective evaluations and comparison between similar health structures, and in the consolidation of the managerial support and appreciation for the work of reporting and analysis of those events, factors and aspects that eventually lead to a real amelioration of patient safety and well being.

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[8] British Medical Journal 320 (7237) (2000), special issue "Facing up to medical error".