DEVELOPMENT OF A CRITICAL INCIDENTS REPORTING SYSTEM IN MEDECINE

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Part I. INTRODUCTION

The project on Incident Reporting System in the health care system (PS/12/21) started at the end of 1999 until 2003 under the OSTC Phase II Scientific support program on workers' healthcare coordinated by the Belgium Ministry of Scientific Research. The final report of the research is available in French. The following document presents a synthesis of this report in the view to facilitate a large and rapid diffusion of the research among the international community.

I.1. Context of the Research

As an introduction to the project, it is useful to understand the issues considering before and during its development and therefore influential in its final format.

Today, more than ever, health care workers face unprecedented demands for production, safety, efficiency, and value. Recent trends to reduce the financial losses in the healthcare system have exacerbated pressures on workers, leading the major medical corporations to strike actions. In doing so health workers are displaying their frustration with the current health system's inability to provide adequate staff coverage and ensure their ability to practice safely in an increasingly dicey work environment. While such trends of optimization is undoubtedly motivated, it does highlight the point that despite statements to the contrary, these financial cuts have and will continue to negatively impact frontline care providers. Doctors are expected to take the rap when something goes wrong but everyone is able to wash his hands of a failure to provide a safe and quality work environment for the thousands of health workers. Nevertheless, there is a common perception that health workers are exposed to stress, having the life of the patient in their hands and having to operate under different critical conditions in scheduled and emergency situations (1-3). The implication of doctors' responsibility in accident investigation only increases these inherent stressful working conditions. Together, they can lead to impaired performance and health.

Anesthetists especially exposed

The statistical investigations carried out by insurance companies on the latter over the past few years show that anesthetists are sued more often than their fellow doctors practicing other specialties (4). This suspicion associated with the stressful work conditions ends up having an impact on the physical and mental health of the doctors, but the data on this is rare. Nonetheless, there are some studies available that can bear witness to this (5,6) Suicide among anesthetists (7), for example, has been used as an indicator of the high stress level in the specialty. In a recent study (8), we showed the high level of burnout in the French speaking anesthetist population (40.4%), with a highest score for doctors less than 30 years' old. The consumption of drugs and the abuse of alcohol frequently observed in doctors in training (9,10) have also been associated with extreme life conditions in the specialty, especially among young doctors. In our country and abroad, many institutional health-care providers work through the night and on week-ends and holidays. This is particularly true for medical residents who typically work extensively long hours, sometimes working more than 130 hours per week in shifts of 12 to 60 hours of duration. This pattern raises concerns about worker fatigue, the possibility for medical errors and their impact on the well-being at work.

To the extent that the doctors as well as the hospital staff have expressed their fears of having to face more and more trials and to deal with higher cost of malpractice insurance, we thought that it was important to try to better understand the factors at the origin of medical accidents. It is indeed indispensable that doctors be able to guarantee quality of care in order to reassure any doubts the patient may have and confirm that the resources allocated to medicine are used efficiently. This guarantee can only be made if the performance being questioned is analyzed. The systematic gathering of incidents is part of the indispensable tools for the improvement of the clinical working conditions and the safety of the patient.

As Blumenthal (11) has reminded us: "the manner in which doctors face up to their errors must and will change in the future, because the one they have adopted is inefficient" [translation by translator of "la façon dont les médecins font face à leurs erreurs doit et va changer dans l'avenir, car celle adoptée est inefficace."]. One of the challenges of this project is to modify the culture and the attitude towards medical errors. This must pass through the abandonment of the myth of medicine error-free medicine. Doctors will then feel more at ease with their "fallibility", and the patients more aware of their own vulnerability.

I.2. OBJECTIVES OF THE RESEARCH

The project aims at the development of a system of reporting and analysis of errors and failures in the medical environment in order to understand their origin, predict their occurrence and draw out corrective and preventive actions. The basis for this in the second program phase is that creating a supportive environment for continuous learning from experience within an organization calls for a strategy of improvement of working conditions, practices and well-being at work. Theoretical foundations for this can be found in the scientific literature on « risks in high-performance work systems » showing the role played by organizational factors (12-17). Many experts in human factors encourage a culture shift which acknowledges that providers don't fail alone. Organizations and systems have vulnerabilities, as do individuals, and the ingredients of many accidents are present long before a specific incident occurs. These latent features, combined with an inexperienced or fatigue caregiver may produce an equipment failure or a medical mishap. We think such mishap represent systems failure.

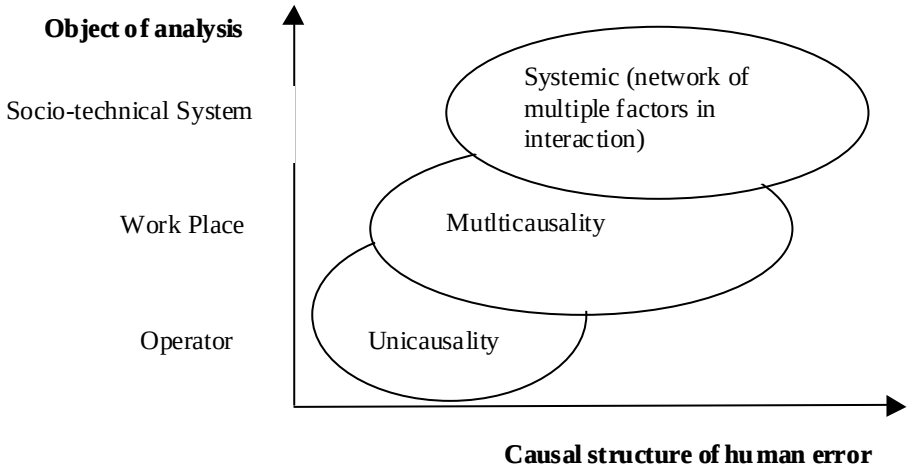
The taxonomy and the methodology for failure analysis developed in our project is in advance of other tools as it aims at illustrating the multi-causal aspect of the accident using the notion of "prototypical risk situation," characterized by some specific combinations of latent and active factors. Another major issue of the project is the application of the Incident Reporting System in practical working situations under the second phase program.

Our project is the first of its kind in Belgium and abroad in terms of its conceptual foundation (linking safety, quality and wellbeing at work). We were aware that such an information system could, if no precautions were taken, possibly compromises workers targeted by the declaration. That's why the working group which prepared and conducted the project included legal specialists, doctors and psychologists in order to resolve the ethical and legal problems of confidentiality and responsibility and to facilitate the change of culture within the working situation.

Part II Theoretical Framework

II.1. Evolution of thinking about causality of accident

Most high risk systems have been plagued by the problem of human error (12) and have designed some reporting forms to collect information about human performance. This measure is, in many countries, required by insurance companies. In general, the reporting form includes a detailed report of the incident, a classification of the nature of the incident and an appreciation of the contributory factors (Aviation Safety Reporting System (ASRS); AIMS 18). The method is often based on self-reporting and the potential for bias exists. A study carried out in an Australian hospital (19) using such a technique shows that in 80% of the reported cases, the accidents described are done so by nurses and are limited to problems which are relevant to them. Another bias comes from what psychologists call the « fundamental attribution error » that makes people focus more on the personal rather than the situational factors when seeing someone performing badly. Following these bias, the reports cannot be used as a statistical basis for estimating accident probability. The utility of this technique of reporting systems is in gathering sensitive information about the mechanisms of failure. In general, reported incidents are reviewed for common characteristics and classified into one of the three categories : human error, equipment failure and other complications. Within each category, the type of error or failure is broken down into subcategories reflecting the underlying causal processes of failure. Errors, for instance, can have different forms, different psychological origins, occur in different parts of the system. The choice of the subcategories reflects the definition that the designer has of an error. Hollnagel (13) has reviewed the different taxonomies of human errors that have been developed over the last twenty years. Schematically, we can differentiate three forms of taxonomy : the « slots », the « diagrams » and the « scenarios ». Each reflects a different model of causality of human errors which, in turn, will have practical implications on the remedial actions that result from analyses of the reporting techniques. The three forms of taxonomies appeared successively and today coexist. Figure 1 shows the evolution of the conception of causality together with the elements of the definition taken into account in the technique.



Evolution of thinking about causality of accident

II.2. Taxonomies

1.The "slots"

The traditional form of taxonomy used in reporting systems classifies human error into categories, giving error the status of technical failure and evaluating the probability of its appearance. The categories are usually predetermined according to some theoretical base. Human error is defined as a behavioural deviation from a prescribed course of action. This approach to human error has been widely used in nuclear power plant industries. Underlying cognitive processes are ignored as well as the context and environment in which errors occur. Classes can also be formed iteratively during the review of the reports. This is often the case when the collection of reports pursues a pragmatic goal such as the assessment of new technology. In general, classes here will be constructed on the basis of extensive field observations. In the assessment of a new drug delivery system in anesthesia for instance, the following categories have been developed through observation of anesthetists' interactions with the system: wrong syringe placement, mode confusion, error of encoding,.

In recent years, psychologists, influenced by the development of cognitive science, looked farther in an attempt to discover more generic error types. The concept of hierarchical structure of action was first used by Rasmussen (20) to analyze errors in the field. Reason (12) developed a taxonomy that differentiates between skill-based (SB), rule-based (RB) and knowledge-based (KB) errors :

- At the skill-based level, when we carry out routine, highly practiced tasks in an automatic way, slip*s* and lapses occur when the actions fail to go as planned but the plan is adequate. An example may be when a practitioner forgets to turn on the ventilator after he is interrupted by a telephone call. Slips refer to more observable actions. Lapses are more internal events.

- At the rule-based level, when we apply learned rules of the kind if - then, mistakes can occur when wrong decisions are made in the assignment of plans (misapplication of good rules, application of bad rules or failure to apply good rules). The action may conform to the plan but the plan is performed in a wrong situation. For example, practitioner can misdiagnose a disease but apply the good associated treatment. Typical rule-based errors occur when some information are ignored or processed incorrectly and pre-existing solution that have been successful before are applied.

- At the knowledge-rule level, when we resort to slow and effortful thinking after the failure of the pre-existing solutions, mistakes can occur when there is a lack of knowledge about the facts linked to the tasks and the tools to carry out these tasks. Errors often occur because the information processing capacity is limited. Examples of errors described by Dörner (1987) are the treatment of dynamic phenomena as static, the perception of different entities as more similar than they actually are.

There are other error taxonomies that have been influential. Rasmussen (20) differentiates errors according to their dependence on the mental operations implied in the task. The following categories exist: (a) detection of a demand, (b) observation, search for information; (c) identification of a system state; (d) development of a goal and strategic decisions, including

prognosis of future events; (e) generation of plans, decision to select a particular plan; (f) procedure; (g) execution and monitoring the plan. Errors can occur at each step. But there can be more than one error step in the same failure process. For example, practitioners can fail to detect information and then misdiagnose the problem.
The use of « slot » taxonomies to classify data from reporting systems provides a global indication about the occurrence of human errors. It has been largely used by the media to claim that 80-90 per cent of accidents involve human error and by the engineers to replace human beings by automation. The approach has had some impact on the way human error is perceived:

- *the context* : In the current slot taxonomy, error is classified into predetermined categories without information about the context in which it occurred. Several researchers proposed to cross-different dimensions; they classify human performance with reference to task elements (time, locus of occurrence), in order to identify patterns or task elements that have more potential for errors. However, errors are still classified according to their mode: what was wrong, not why. As Rasmussen (op.cit.) pointed out, in order to have an explicative value, the attributes adopted to define the task elements must be precise enough to define the characteristics of the internal mode of regulation of human behaviour as well. This cannot be practically realized in « adhoc » reporting systems. There is a need for a careful analysis of human behaviour activity in context with the help of observations and interviews to define the attributes of performance elements for which a reporting system can be devised.

- *mutually exclusive categories* : This is far from being met in the slot taxonomies presented. As mentioned earlier, different error steps can coexist in the same event. In addition, the three level of performance are not mutually exclusive. For instance, injection of drugs by practitioner is carried out at the SB level. The choice of the drug taking into account the patient state occurs at the RB or KB level. In these conditions, classifying an error according to the level of performance can be difficult. In addition, the result of such taxonomy based on psychological theory can be hard for the people concerned to use.

- *error determination* : Few taxonomies clearly specify the rules by which they determine the attribution of an error. There are several categories of standard that can be used. An error can be labelled as such by reference to a pre-defined model of task performance. This is limited to task for which a detailed knowledge about problem situations and how to solve them is available. Another standard is the comparison with standard operating procedures. For instance, in medicine, it is not possible to predict all the varieties of the problem situation but there exist some standards of care that provide some guides for activity in some conditions. A third approach is called the neutral observer criteria by De Keyser and Woods (21). It was developed regarding the dynamics and uncertainty of modern work situations. It is an empirical approach that compares practitioner behaviour during the incident to the behaviour of similar practitioners at various points in the same evolving situation.

For these reasons, slot taxonomies in reporting systems could be inadapted. The error process is too complex to be classified into one single independent category. Moreover, *human error is not a distinct category of human performance*. Attribution of error, as we said before, is more the result of a social judgement rather than an objective analysis.

2. The "Diagram"

An alternative for classifying errors is to use diagrams to describe the sequence of failures. The method consists of reconstituting graphically, in branching form, a series of causal combinations, starting from an event and searching (as far upstream as possible) its causes. First, researchers used the method to quantify human factors, by calculating the probabilities of occurrence of branches, causes and events. They adopted a technical approach to error. Progressively, their goal became preventive and diagrams were used mainly to emphasize the multi causal aspect of accidents. In France, the causal tree diagram, created in the 1970s by the Institute National Français de Recherche Scientifique (22) refers to the Failure Tree method formalized by Bell Telephone and adopted by the aerospace industry (23). It is a clinically oriented method based on two main phases: the construction of the tree and its qualitative evaluation. The tree is constructed by seeking out those events which, singly or in combination could lead to occurrence of the index event (previously defined). The process is then repeated in order to define each of the basic events. The time axis of the tree moves from left to right approaching the index event. The resulting event is considered to be the consequence of the preceding events. The examination of accident analyses often reveals sequences of actions aimed at recovering unusual situations. These are called these " vicariant actions." If successful, they should allow the elimination of the problem. But when they fail, they create a new, unexpected condition that will, in turn, have to be remedied.

As slot taxonomies, diagram techniques have some bias which in turn have an impact on the way people perceive error :

- *frame definition*: No well-established rules define how far the retrospective search for causes should proceed. The time of the retrospective analysis depends on the specific events of each accident and on the sources of information available (for instance, two years for Three Mile Island and nine years for Challenger). The technique can be easily used by the people concerned. For instance, in a textile factory, operators were trained to the diagram technique in order to improve accident analyses. First, they constructed very rich trees illustrating the latent factors which lead to human errors. Then, the retrospective search shortened and the analysis of the causes stopped when responsibilities were distributed. This illustrates the relation between a technique and its use in context. It shows the importance of linking research and remedial actions in order to maintain the use of a technique in the long term.

- *singularity*: One criticism often directed at the diagram technique is that a causal tree based on a clinical method only provides a singular set of facts and circumstances. In spite of this limit, a well-conducted clinical analysis remains a precious source of information. As opposed to a simple repertoire of circumstances and events leading to the production of an accident, the tree allows not only the representation, in a schematic manner, of the causal chains that exist between events, but it also reveals where and how the means of improving reliability can be applied. By applying this technique in a systematic manner to a wide variety of cases, we can locate typical configurations of accidental sequences, which will allow safety diagnoses without waiting for errors or accidents to arise.

- *knowledge of the system* : Constructing diagrams requires profound knowledge of the work situation and of the relevant models of human decision making. Close cooperation between several professional disciplines is necessary.

3. The “Scenarios”

In recent years, several investigators have looked farther into the idea of the multi-causality of accidents and question the extent to which interaction of factors are important influences on accidents compared to events or histories (24,25). In other words, does thinking about accident characteristics tell us about why accident and human errors occur at work. For example, in order to understand the significance of someone's behaviour at work, knowing about the associated factors is certainly important, but what may be much more relevant is the "history" of the person and his context, how the event came over time. This approach is also emphasized within dynamic work environments such as anesthesia where every particular situation configuration demands a different adjustment and tuning from the anesthetist. Human behaviour cannot be termed error by referring to some procedure as usually it does in rule-dominated domains such as a power plant. All the behaviours and ways of interacting should be considered with the task requirements and resources available at that time. Inspired by ecological theories (26), some researchers have probed the use of scenarios to describe accidents. The unit of analysis is then semantic. The idea is to provide a description of the environment that was directly relevant to the conducting of the behaviour. The scenarios capture the relationship between the environment and the activity and how this unfolds over time. From this perspective, it is the constant processes of interaction between the person and the environment that is important, rather than particular characteristics of the person or the environment at any particular time. It is clear that a person's behaviour or decision making can be explained by each event that precede it, much more significant is the whole episode and history of the person's involvement with the organization and the task. The major challenge is to distil the reported histories into a smaller number of scenarios containing the critical issues concerning accident analyses. Cook, et al. (25) have used the technique to collect a corpus of cases in anesthesia illustrating some generic cognitive difficulties. Researchers also looked for recurrence occurrence and used data from field observations and round discussions to filter out the relevant scenarios. One immediate implication of this taxonomy approach is that the initial assessment using formal categories and showing human error as the major cause of accidents should perhaps be supplemented by techniques that can assess behaviour in context. A further implication is that understanding the relationship between actors’ behaviour and task requirements gives us vital information about how and when to intervene to improve the man-machine-task system. Our work is inscribed in this theoretical current of studies.

PART III. METHODOLOGY

We develop an appropriate methodology to make best use of the other domains' experiences on reporting systems and construct a tool well adapted to the health care sector through:

- State of the art of the literature

- Building a common conceptual ground

- Developing the Incident Reporting System, taken into account the impacts of the event for the medical team

- Application of the Incident Reporting System in natural working situations

- Extension the approach to the whole hospital

- Project of Software Concept

PART IV. Results

IV.1. State of the art of the literature

There are different reporting systems in the world, in United-States and in Australia. These are some examples:

Names	Authors
General reporting system	Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (27)
Monitoring system for drug and equipment problems	Food & Drug Administration (FDA)
National Confidential Enquiry into per operative deaths	Campling et al. (28)
Edindburgh ICU Reporting System	Busse and Johnson (29)
Critical Incident Reporting System (CIRS)	Staender (internet)
Australian Incident Monitoring Study Generic Occurrence Classification (AIMS)	Runciman (18)
Medical Errors and Complications Causal Analysis (MECCA)	van Vuuren & Shea (30)

From our state of the art, we outlined them under four dimensions: their purposes, their interface, their limits and their recommendations.

1. Purposes

a) Prevention

The goal is to prevent accident and incidents on the base of the collect and analyze of the data. The taxonomy and the methodology to analyze data are important. Most of the approaches are empirical: the JACO has proposed for the collected accident the root cause analysis

b) Learning and training

The goal is to select interesting case from a learning point of view and share the information through seminar, publication, morbidity/mortality meetings.

c) Monitoring the reliability of the system

The reporting system aims to monitor the reliability of the system, looking to identify risk patterns that are of interest to a speciality as a whole from pooled data. Comparisons are difficult because the number of report can vary over time.

d) Management malpractice risk

Collection of data can help to prepare the defences in case of litigation (31)

2. Interfaces

There are different techniques to collect data. In the study by Cooper (32) incidents were recalled during a structured interview. In most study, reporters have been encouraged to fill in a report form as soon as possible after the incident. Thanks to the computerization of the hospitals, Sanborn et al. (33) used automatic recording of monitoring variables to study critical variations.

3. Limits

There are four major limits: lack of implication and motivation to report incidents, lack of visible and timely feedback, suspicion that reports will find their way into administrators and difficulties with data analysis and data definitions used.

4. Recommendations

Several studies made some recommendations in order to favour best use of the technique (Insitute of medicine, 2000, (34, 35). Secker-Walker et Taylor-Adams (37) identified them as follows :

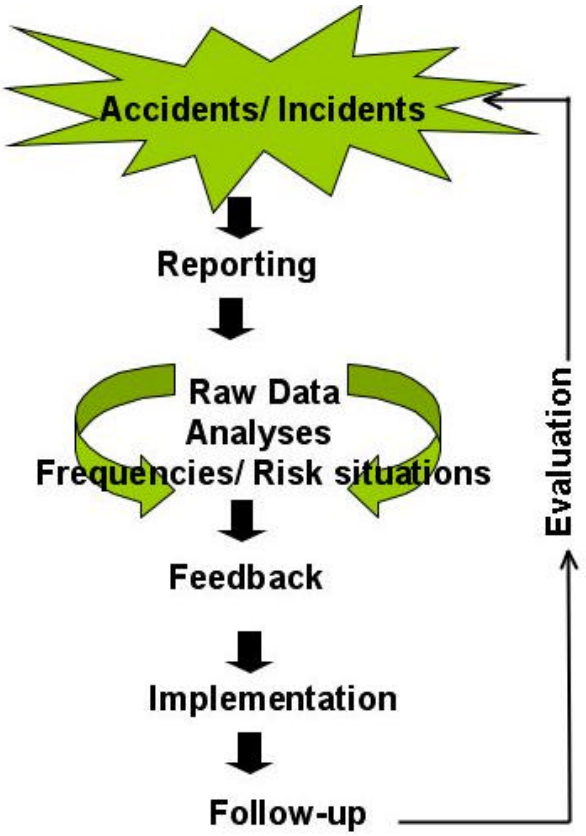
- Training the professionals
- Implication of the actors
- Identification of the risk and events to report
- Easy incident form
- Motivation for reporting
- A guarantee of confidentiality, protection of the data from litigation
- Timely, systematic and relevant feedback and reporting
- Evaluation of the system

IV.2. Building a common conceptual framework within the working group

This was one of the first activities of the project. As stated in the objectives, we believe that in order to be successful, it was mandatory to integrate conceptual knowledge from different domains (legal, medical, and psychological). For example, we found at least three different meanings to the term error within the working group: one psychological, one medical and one legal. Ambiguity can thus arise about what the system aims to collect as information. Thus, the group's first form of activity was (a) to develop consensus definition of error, incident, accident and critical event, (b) to identify which methods, models and techniques will be used and explain the reasons, and (c) to discuss about the conditions of confidentiality. All of the partners have been contacted by their open-mindedness and this speeded up the process of understanding each other.

IV.3. Developing the Incident Reporting System

This activity was the core of the project. The methodology proposes a series of functional steps that must be fulfilled in order to turn any reporting system: development of the reporting interface, data collection, data analysis, recommendations, implementation and evaluation. The organization of theses steps is shown in the following figure.



1. Incidents

The project aims at capturing the essence of problem situations encountered by workers, which are clearly more than a collection of only negative events, failures or errors.
An incident is defined as any event or circumstances that happens which could have or did harm someone or which could result in a complaint. The definition proposed has the advantage of favouring the collection of any type of problem situation, including those that ordinarily come up at work but which do not bring on harmful consequences because they have been treated in time ("near misses").

2. Capturing event / Event Description form

A wide variety of reporting systems and relevant theoretical information has been consulted in order to achieve the reporting form (18,37-39). The structure of the reporting form does provide some idea to the way the investigator thinks about events. The goal of the reporting sheet is on recording the information that is relevant to the incident as a whole and therefore will capture the reasons of the incident when the form is being completed at all. The instrument sheet (see appendix 2) holds fields required for the identification of the event and other fields necessary for the administration of the form. It has two components: part A for a free general description (narrative part) of the incident, part B for the system-wide description of the incident.

Narrative description: this section aims to collect a chronological and logical chaining of the events. The objective is to describe the history. Only factual information should be reported not interpretation. Key events will be coded by the analyst in the database. The objective is to facilitate analyses and identify risk that might lead to other incidents.
System-wide Event description: this section was designed to elicit the salient features of an incident, place in the context. The classification of the incident begins with the failure itself in terms of the domain. The idea is based on the concept of classifying each incident into one or more natural categories, with each incident being linked to its contributing factors, preventive factors and factors minimizing outcome. Those factors can be broken down into four large sub-classes: equipment factors, individual factors, team factors and organizational factors.

Example from the sheet

> Contributing factors linked to the equipment (failure, conception error…), to the individual (distraction, fatigue, confusion, stress…), to the team (communication, coordination, conflicting goal,), to the organization (information management, staffing, supervision, production pressure, time pressure,)

Event detection: This section is designed to capture information relating to how and who detected an event. This part is linked to the Event description sheet.

Examples from the sheet:

- Who:
- How (cues): instrumentation, communication, cognitive process, etc.
- When

One section describes the evolution and the consequences of the incident. The subject is commonly a patient in clinical domain but could be a piece of equipment in which a problem

was detected in isolation. Consequences are also often used to describe the incident by the worker (i.e. cardiac arrest, hypoxia.). Short term and long term consequences are listed and can also be used to evaluate the severity of the incident and guide the prioritization of the recommendation actions.

Another concept integrated in the form developed was the search for information concerning how the worker has lived the event and its impacts on health. At this stage, we have proposed that it be possible to document the link between safety, quality and well-being at work order to guide social or medical support.

Example from the sheet:

- What did you feel just after the incident: feeling of fear, angry, culpability
- Loss of sleep
- Loss of pleasure
- Other health problems

3. Database and Analysis

Even if there is now a consensus among experts to define accident as a system failure, data illustrating the multi-causal aspect of an accident are still rare. In most studies, the related-accident variables are considered in isolation. There are, in fact, few techniques and formalisms that can be used to describe the relationships between these variables. An important approach that was considered in the project was that of analyzing data in new ways, including cluster analyses so that systemic pattern or profile of risk situations may be sought. For this reason, it was necessary to have a database with sufficient data. The multi-departmental property adopted in the working group allow us to implement the reporting form simultaneously in two different hospitals, saving time to collect the necessary cases.

Aside the quantitative analysis, following a current of theoretical works on human factors (24-26,40), we have been questioning the extent to which a set of factors extracted from analyses of accidents have valuable significance for the users compared to events or histories. Experts have recommended the use of scenarios to describe accidents. The unit of analysis is then semantic. The idea is to provide a description of the environment that was directly relevant to the conducting of the behaviour. The major challenge is to distil the reported histories into a smaller number of scenarios containing the critical issues concerning risk at work. The cluster analysis proposed by looking for patterns of conditions will help us in this task, revealing “prototype risk situations” and generic recommendation measures.

4. Recommendations / Implementation

Traditionally, responses in health care have been set on rates of mortality and severe injuries. But, the current system proposed a broader approach because much of the cost of iatrogenic injury in the medical sector is created by high frequency, relatively low severity events. It is important to be able to search for these generic safety measures that may have wider application than the recommendations linked to severe specific events. However, recommendations can also be linked to the incident as a specific event. Each recommendation is assessed through the following aspects: cost/benefit, possible side effect, co-ordination with the others recommendations. The ability of the current system to collate and review effective protective barriers and preventive measures in the course of the event will be valuable for this task.

The recommendation can be constructed in a collaborative process by a group of persons based on the results of the data analyses (clusters of events, so systemic solutions proposed). The group produces a prioritized set of recommendations aimed at: limiting the like hood of an event, improving detection, mitigating the consequences, reducing the identified contributing factors, modify and improving the safety and culture at work. The list includes direct actions and indirect responses such as complementary investigation of the incident.
The direct recommendations can be very diverse; they may imply technological, ergonomic, organizational or training measures. They may be set at different levels: individual, departmental, systemic, national and international. Each measure is not exclusive. Rather, they should be integrated in a quality improvement approach.

It is obvious that reporting systems are based on the confidence established between the reporter and the analysis made of the reported data. Consequently, the responses and feedback play an important role in the long-term adherence of the actors to the system. The implementation of the recommendations must be well prepared (scheduling: starting time, duration, resources required...) and monitored.

5. Evaluation

Outcome need to be evaluated at two levels: Firstly, measurement of the effect size of a proposed intervention. Secondly, measurement of the impact of system wide implementation of multiple interventions. The first is straightforward where the intervention is applied as a single intervention. However as soon as the intervention become multi-modal or the point of intervention moves to a system or process, the capacity of traditional models to evaluate the effect is limited. System wide assessment of impact of a program of interventions is a more complex issue. A system change is often the result of a number of forces and agent acting in concert, and it is not possible to gauge the relative importance of each. New evaluation techniques are needed.

The system proposes to assess the outcomes not only in terms of change in rates and patterns of incidents (The lead-time to these changes is probably three to five years with the greatest benefits being seen in about ten years. For example, evidence of a substantial reduction in deaths attributable to anesthesia since the introduction of the new monitoring guidelines in the early 1990s was published only recently.), but also on economical, social, psychological and environmental criteria. These benefits may be at a number of levels:

At the Patient level
- Increased safety
- Minimize risk
- Improve satisfaction with the health care system

At the Practitioner/staff level
- Improve conditions of work
- Increased locus of control through the participation in incident monitoring in a safety culture
- Decreased stress and health problems
- Improve well-being at work
- Protection under quality assurance legislation

At the Management level

Feedback on the frequency and type of problem situations
Monitoring of local preventive measures
Comparison with organizational benchmarking

At the Health care system level
Improved systems
Reduced costs associated through the avoidance of potential litigation

At the Government level
Increased efficiencies
Decreased costs for the medical systems
Increased quality
Improves population health outcomes.

IV. 4. Guidelines

As we said before, some recommendations have been made in the Quality of Health Care US project as well as in the Australian report made by Runciman and his fellows (op.cit.). In our view, successful implementation involves establishment of the conceptual framework well ahead of time. Four frames must be considered: medical, technical, organizational and legal frames.

At the level of the medical frame, the collaboration and the involvement of the domain experts is indispensable to the collection and analysis of the data.
At the level of the technical frame, the techniques of analysis (classification and formalization schemes) together with their tools must be chosen according to the goal pursued. It is necessary to determine the form in which (computerized, verbal or written) the tools and the data would be accessible to the various users (the reporters and the analysts).

The technical frame must be sufficiently flexible in order to be able to be adapted to the various possible uses (safety improvement, learning or research).

At the organizational level, designers should make sure that the reporting system project is inscribed, from the beginning, within a culture of quality and patient safety improvement rather than a "blame culture" which aims to target individuals or hospital institutions. A large part of the effectiveness of the system depends on this. Several structural points must also be negotiated with the administration staff such as who will be responsible for the system, who will have access to the system and how that should be done, the degree to which information will be confidential or anonymous and what kind of feedback and dissemination of information will be given. Such questions should have an answer before the implementation of the system in order to favour its long-term usability within the system.

The last frame, the legal frame, is certainly as delicate as the organizational frame. At that level, the data gathered, along with the reporters and the managers of the systems must be protected. The protection can be developed along two axes: a legal axis and a pragmatic axis. On the legal axis, there is already a series of protections that are registered in the laws (e.g.: professional secrecy) and that can, possibly, be taken into account. However, we can also imagine that the legislature could grant some kind of privileged status to reporting systems that would protect them from legal investigations. On the pragmatic axis, it is possible to

ensure protection through several techniques: a confidential processing of information collected, a transmission of information in an anonymous way (see appendix 1), a de-identification of the reports once completed and security of the information system.

IV.5. Application of the Incident Reporting System in natural working situations

It is important to be aware that setting up such an information system consists of getting involved in long-term action that seeks to install a new culture.
Based on the experience gained from the earlier program and on the reflections developed above, we chose to privilege the medical specialty the most confronted to medical lawsuits and with whose we've been collaborating for several years: anesthesia.

1. Context of the experimentation

A pilot experiment is carried out in two anesthesia departments from two different teaching hospitals: CHU of Liege in collaboration with Dc Faymonville and Cliniques Universitaires de ST Luc (Brussels) in collaboration with Dc Aunac. This experiment has been progressively widened to other high-risk hospital sectors such as intensive care, emergency using the same specialized Reporting Form before being extended to other hospitals with a view to organizing a federal structure.

2. Procedure of data analysis

One of the goal of the system is to learn from data. This gives the analyst a great deal more options when it comes to selecting independent variables of interest but in the same time our systemic approach constraints statistical analysis because of the high number of variables included in the questionnaire. An exploratory analysis was conducted in order to identify links between causal factors or patterns (clusters) and identify prototypical risk situation (appendix 6).

3. Results

Since March 2002, 217 incidents have been reported, encoded and analyzed.

In order to respect confidentiality, we won't present in this report the detailed data concerning the events we collected in the two hospitals.

3.1. General characteristics

3.2. Gravity of the events

3.3. Contributing latent factors

3.4 Active Factors

3.5 . Defences

3.6. Problem Detection

3.7. Emotional and physical impacts for the implied person

3.8. Direct and Timely Feedback

Following the proposed approach, direct preventive and corrective feedback to specific events have been recommended and implemented in the hospitals on the base of the case-by case analysis made over the security meeting. For example:

Problem / Incident	Solution
Junior staff having to manage dynamic complex problems	Procedure of emergency call for help put into place to escape from fixation errors
Fatigue after night work	One day of recuperation introduced after night work
Problems encountered during intubations	Airway management skills program
Difficulties with respect to the communication and relation with surgeons	Simulator training program organized on communication and crisis management
Frustration feeling from the junior staff in respect to some time planning	Senior staff review of the time work organization
Staff suffering of health problems after having encountered an accident	Individual psychological support has been introduced to provide special support

IV.5. Extension the approach to the whole hospital

Additionally, the fact that our project and anesthetists had taken the necessary steps to establish an ongoing mechanism for critically examining practices, and that this had contributed to changes in the practices and work conditions was apparent to many outside the anesthesia discipline.
Our project received favourable commentary. This led to widespread expectations from other disciplines.
We start studies of incident monitoring in other medical specialties: Gynaecology, Geriatric and for the whole hospital, as well across two other hospital systems. According to the methodology, we developed the reporting forms following different steps: 1) observe the field, 2) identify the events to report, 3) create the form, 4) validate the reporting form, 5) implement the system, 6) evaluate the system. The three forms have been implemented and evaluated. They are presented in the appendix 3 et 4.

IV.6. Project of a Software Concept

In order to facilitate the use of the system in the hospitals (collection, coding and analyses), we developed a preliminary design for a software concept. The focus is to improve the usability over paper form. The nature of the form is problematic because of its size and

complexity. The design of the user interface is then important. An early prototype is now developed with the collaboration of designers.

Part V. Discussion and Dissemination of the results

V.1. Discussion

The project on Incident Reporting System in the Health Care System (PS/12/21) started at the end of 1999 until 2003 under the OSTC Phase II Scientific support program on workers' healthcare coordinated by the Ministry of Scientific Research.
The work and the results clearly demonstrated that given a suitable structure, the Incident Reporting System will be able to provide the data require to evaluate risks in complex professional environment with a view to improving the work conditions and well-being at work (following the general goal of the program).

The following are some of the critical issues:

- The OSTC Program has so far played the role of initiator and coordinator of the project. The prominent role played by central government means that Phase II Scientific support program on workers' healthcare enjoys a high political support. This can be used to reinforce the legitimacy and visibility of the project. The problem is that funding is highly dependent of political trends, and the duration of the program period is short (maximum three years for us), making long-term strategic planning difficult, as change of culture required.

- The program played a key role in creating and promoting multidisciplinary research activities and learning network. The workers (health care workers) have been closely involved in the project activities. This constitutes a solid basis for successful change at work. In addition, the involvement of legal specialists as partner of the work group reinforce the legitimacy of the project.

- It is obvious that there is still a lot of work to be done to raise awareness of the importance of the project among the public. The challenge for the next years is in fact how to shift the emphasis from the research level towards the level of a national and international interest and structure. This implied the implication of all the actors including managerial and political power instances.

This project is a multidisciplinary research project that is design to enhance the cross-fertilization of expertise between a numbers of different but complementary disciplines. The common aim is to support the quality, the safety and well-being at work.

V. 2. Dissemination

This project is a multidisciplinary research project that is design to enhance the cross-fertilization of expertise between a numbers of different but complementary disciplines.
During the development of the tool, the medical partners of the group project ask or discretion. This is usually a key point when dealing with human error, accident and culture changes.

1 Dissemination of the project in workplaces

Consequently, the dissemination starts with the application of the Incident Reporting System in two anesthesia departments from two different teaching hospitals: one at Liege and one at Brussels. This is logistically difficult and expensive in terms of time and resources required. This was organized directly by the partners of the working group and included:

- meetings to inform health workers on the reporting system, its goal and its culture,
- distributing reporting forms in the field,
- determining and implementing suitable recommendations with the help of the experts
- meetings held to discuss specific cases to provide social support and promote the change of culture planned as follows :

CHU Liege				**UCL Brussels**			
2000	**2001**	**2002**	**2003**	**2000**	**2001**	**2002**	**2003**
19.10	18.1	31.1	6.3	9.10	8.1	7.1	3.2
27.1	22.2	14.3	3.4.	6.11	5.2	18.2	10.3
9.3	15.3	4.3	19.6	20.11	5.3	15.4	24.4
8.6	26.4	23.5	11.12	4.12	23.4	3.6	
	7.6	17.10			7.5	14.10	
	18.10	19.12			16.6	18.11	
	6.12				26.6		
					29.10		
					26.11		

2. Dissemination through results and measures

A general idea of the impact of this process of dissemination can be obtained by looking the number of respondents. From now, we collected more than 200 Incident Reporting Forms, completed by workers mainly anesthetists and staff from the operating room.

The project is intended to promote changes at workplaces. It is premature to assess outcomes in terms of changes in rates or patterns of incidents. But, the project can be generally considered through its impacts on work conditions. Although statistical analyses of the database just started, direct preventive and corrective responses to specific events have been recommended and implemented in the hospitals. For example:

Another way of looking at the direct impacts of the project is the evaluation of the project given by the staff at the workplace. A small study has been made at the hospital of Liege where one section has been added to the form in order to identify what social support can be organize to improve the “after accident state”. All the respondents who have completed the section said that safety meetings organized to discuss cases have great value.

3. Dissemination by presentation at seminars, workshops and congress

The process of presenting the project has started for the public, for other hospitals and for other disciplines since 2000. Taking advantage of the multidisciplinary property of the work group, the project is promoted by sessions devoted to this topic in different sectors: scientific, medical and insurance / legal sectors.

Aside, the group project has organized in March 2000 a workshop with the team of the hospital of Geneva (Prof. F. Clergue) who has been working similarly in the domain and an international symposium on this topic in November 2002 at Brussels.

3.1. Scientific meeting and congress

- Towards the Identification of Prototypical Risk Situations in Anaesthesia as a Complex System. *Proceedings of Human Error and Clinical Systems Workshop*, University of Glasgow, AS Nyssen,15-17th April 1999
- ENOP Annual Symposium 2000, Paris (France), Prevention of human error, AS Nyssen, 23-25 mars 2000
- " Le risque de défaillance et son contrôle par les individus et les Organisations dans les activités à hauts risques ", CNRS, Gif-sur-Yvette (France), V De Keyser, 30-31 mars 2000
- 2nd Congress of Ergonomics on Ergonomics in Quality Management, Costa da Caparica (Portugal),. Keynote address sur : Normal Errors, V. De Keyser, 6-7 avril 2000
- 15th Annual Conference of the Society for Industial and Organizational Psychology, Hyatt Regency New Orleans, New Orleans, Louisiana (USA), " Human error prevention tools in the frame of the activity theory », V De Keyser, 14-16 avril 2000.
-Journée d'étude de la Société belge de Psychologie, Bruxelle, Mai 2000. L'erreur humaine et sa prévention. AS Nyssen
- Colloque Facteurs humains sur " L'homme comme ressource ", CETCOPRA, Paris (France), Activity and instruments. V. De Keyser, 6 juin 2000.
- Simulations et erreurs: recherche et formation : Club Evolution du travail face aux mutations technologiques, » Activité et outils des formateurs sur simulateurs », AS Nyssen,.Les clubs CRIN, AS Nyssen Paris, 10 octobre 2000
- A brief look in error, safety, and failure of complex system. European Cursus of laparoscopic surgery, AS Nyssen, Brussels, 24 November 2000.
- Journée scientifique : Des simulateurs pour se former en toute sécurité, HCBRA-Neder-Over-Heembeek, Brussels, 1 mars 2001. Place du simulateur dans la formation en anesthésie.
- La " mesure " des erreurs peut-elle servir d,outils de gestion des risques ? séminaire : " Le risque de défaillance et son contrôle par les individus et les organisations dans les activités à hauts risques ? Autour de la " mesure " du risque ", organisé par le CNRS (Centre National de la Recherche Scientifique) et le Ministère de la Recherche français, Gif-sur-Yvette (France), V. De Keyser, 12-13 mars 2001.
- Prevention of Human Errors in the Frame of the Activity Theory., Tenth European Congress on Work and Organizational Psychology. AS Nyssen & V De Keyser Praha 16-19 May 2001.
- Ethical Principles in Work and Organizational Psychology, S143, Tenth European Congress on Work and Organizational Psychology. AS Nyssen, I Hansez, V De Keyser, Praha 16-19/5 2001.
- Information Society Technology Conference, CEE, Dusseldörf,. Technology, safety and error : the need for multi-disciplinary research, AS Nyssen, 5/12 2001
- Prospective issues for Error Detection, Proceedings of the XXV International Congress of *Applied Psychology*, Singapore,7-12 July 2002.
- Invitation : Improving Medical Device Safety. *Clambake III Human Error Meeting*, University of Chicago Developing Center for Patient Safety and the Food and Drug Administration, september 19-22, 2002.

- Le simulateur comme outil de formation et de recherche, Proceedings of *ERGO-IA*, Biarritz, France, 283-389, AS Nyssen, 8-10/10 2002.
- Club Evolution du travail face aux mutations technologiques, » Activité et outils des formateurs sur simulateurs », AS Nyssen,.Les clubs CRIN, AS Nyssen Paris, 5 mars 2003
- Le risque de défaillance et son contrôle par les individus et les organisations dans les activités à hauts risques ? Autour de la " mesure " du risque ", organisé par le CNRS (Centre National de la Recherche Scientifique) et le Ministère de la Recherche français, Gif-sur-Yvette (France), AS Nyssen, 26-27mai 2003
- Naturalistic Decision Making Conference,Floride,USA,Invitation AS Nyssen*: Study of Human Error in complex systems, 15-18 May 2003*
- European Cursus on aviation ; Villa Ariane, « Human reliability and new technology », AS Nyssen16/7/03.
- Human Factors of decision making in Complex Systems, AS Nyssen : Prevention of Human error, AS Nyssen, 8-11 September 2003, Dunblane, Scotland.

3.2. Medical workshop and congress

- Pourquoi fait-on des erreurs ? Qu'est-ce qui nous incite à transgresser les règles?, XXXIII Réunion Internationale d'anesthésiologie et de réanimation, As Nyssen Paris, 17 mars 2001.
- Erreurs humaines, Prévention. Séminaires de spécialisation Reims, Lille, Anesthésie-réanimation, AS Nyssen & M. Lamy, 21 Juin 2001, Touquet
- "Les obligations médicales du licencié en science dentaire", I. Lutte, 6.10.01
- "De la responsabilité médicale exacerbée à l'indemnisation sans égard à la responsabilité", Bastogne, - I. Lutte, 19 octobre 2001
- " Responsabilité et prévention des accidents", CIMM, I. Lutte- 20.10. 2001
- "Responsabilité civile et pénale du médecin face à la justice et prévention.", AGEMO, - I. Lutte, 17.11. 2001
- "Les infections hospitalières, leur prévention, leur traitement et leurs conséquences médico-légales.", CHU Vesale Charleroi, I. Lutte, 20. 11. 2001
- "L'erreur et/ou la faute professionnelle : la mienne ...et celle des autres", CESI, - I. Lutte, 22.3. 2002 :
- "Quelques aspects de la responsabilité du biologiste clinique", FOCUS, I. Lutte, 19.4. 2002
- " Statut du foetus , aspects juridiques, impact du diagnostic antenatal., centre bioéthique, UCL, -I. Lutte, 30.4. 2002
- Journée Qualité : Risques, sécurité et médecine : Comment progresser dans les établissements de soins ? Genève , 7 6. 2002. Comment modifier l'environnement de travail du soignant pour améliorer la sécurité?
- Expertalia, 2 presentations : 1) infections nosocomiales, ; 2) la responsabilité médicale, 15.6. 2002, I. Lutte & Me Fagnart
- Drug errors, 1er symposium NURPHAR. I. Lutte, S Aunac, 25.5.2002
- Incident Reporting System, Cliniques St Pierre, Ottignies,Clniques St Pierre à Ottignie, I. Lutte, 18.09.2002
- Invitation I Lutte, Intensive care unit, UCL,17.10.2002
- Présentation du projet, S Aunac au Comité de qualité des Soins des Cliniques universiatires de St Luc, 22/1/03
- Développement d'un système de signalement d'incident/accident en Belgique, réseau Coviris, Assistance publique, Hôpitaux de Paris, AS Nyssen, 22/11/2003.

- 13th World Congress of Anaesthesiologists : Human Factors main cause of accidents and main factor for preventing accidents, AS Nyssen, Paris 18-22/04
- Euroanesthesia 2004,Developing a safety culture : Incident Reporting system, AS Nyssen & S. Aunac, Libonne 3-7 04

3.3. Insurance and legal seminars participation

- A cursus is organized on «mutlicausality of accident » and «responsability issues » in collaboration with Prof Fagnart and AS Nyssen at the CIFORM for expert insurance companies (Brussels)

4. Dissemination by publications

As indicated above, it had taken considerable time to establish a common database between the two teaching hospitals. We started the statistical analyses. However, the group project produce preliminary reports and articles providing information on the methodology and the project.

4.1. Reviewed Articles in international journals

- Nyssen AS, De Keyser V. Improving Training in Problem Solving Skills : Analysis of Anesthetist's Performance in Simulated Problem Situations. Le travail humain 1998, 61,4 : 387-40.
- Larbuisson R., Pendeville P., Nyssen AS., Janssens M., Mayné A. Use of Anaesthesia Simulator : initial impressions of its use in two Belgian University Centers. Acta Anaesthesiologica Belgica 1999, 50 : 287-93.
- Larbuisson R., Nyssen AS, Janssens M, Lamy M. Principes et intérêts du simulateur en anesthésie-réanimation, Le praticien en anesthésie réanimation 2001, (5) 4 : 225.
- Nyssen, AS, Larbuisson R, Janssens M, Pendeville P, Mayne A. Comparison of the Training Value of 2 types of Anesthesia Simulators : Computer Screen-Based and Mannequin-Based Simulators. Anesthesia & Analgesia 2002, 94 : 1560-1565.
- Nyssen AS, Hansez I, Baele P, De Keyser V, Lamy M. Occupational stress and burnout in anesthesia, , British Journal of Anesthesia 2003, 90 (3) 333-7.
- Nyssen AS, Aunac S, Faymonville ME, Lutte I. Reporting systems in health care: from a case-by-case experience to a general framework : an exemple in anesthesia (submitted to European Journal of Anaesthesia, Appendix 7).

4.2. Reviewed Book Chapters

- Nyssen, AS. Analysis of Human Errors in Anaesthesia : Our methdological approach: from general observations to targeted studies in laboratory. In C.Vincent & B.A. De Mol (Eds). Safety in Medicine, London : Pergamon, 49-63, 2000.
- De Keyser, V., & Nyssen, AS. The management of temporal Constraints in naturalistic decision making. The case of Anaesthesia**.** In E. Salas & G. Klein (Eds*)*. Linking Expertise and Naturalistic Decision Making,171-188, vol 4, 2001.
- Nyssen AS. & De Keyser, V. Prevention of Human Errors in the Frame of the Activity Theory, International Handbook of Work and Organizational Psychology, 10, Sage Publ,, 348-363,vol.1, 2001.

- De Keyser V, Nyssen AS. Activity and Instruments. In V. De Keyser & A. Leonova (Eds). Error Prevention & Well Being at Work In Western Europe and Russia, Kluwer, Ac. Publ.. Dordrecht, The Netherlands, 25-39, 2001.
- De Keyser V, Nyssen AS, Hansez I, Javaux D. Research and Context. In V. De Keyser & A. Leonova (Eds). Error Prevention & Well Being at Work In Western Europe and Russia, Kluwer, Ac. Publ.. Dordrecht, The Netherlands, 51-87, 2001.

4.3. Proceedings

- Training Simulators in Anesthesia : Towards a Hierarchy of Learning Situations. Proceedings of *Human Computer Interactions International 99*, Munich, Germany, 22-26 August, 1999. Vol. 1, 890-894.
- Evaluation des techniques de chirurgie minimale invasive par robot : une approche ergonomique systémique : premières constatations. Proceedings of the *ERGO-IHM*, 3 - 5 octobre 2000, Biarritz., France, 243-247.
- Pourquoi faisons-nous des erreurs ? Qu'est-ce qui nous incite à transgresser les règles ? Proceedings of the *Journées d'enseignement post-universitaire (J.E.P.U). Les risques de l'anesthésie*, Pitié-Salpetrière, 17-18 mars 2001 , CRI, vol. 1, 107-115.
- Prevention of human error in the frame of activity theory. Proceedings of the Tenth European Congress on *Work and Organizational Psychology*, Praha, 16-19 May 2001, 97-98.
- Prospective issues for Error Detection, Proceedings of the XXV International Congress of *Applied Psychology*, Singapore,7-12 July 2002.
- Improving Medical Device Safety. *Clambake III Human Error Meeting*, University of Chicago Developing Center for Patient Safety and the Food and Drug Administration, september 19-22, 2002.
- Le simulateur comme outil de formation et de recherche, Proceedings of *ERGO-IA*, 8-10 Octobre, 2002, Biarritz, France, 283-389.

4.4. Press Articles

- "Accidents : l'erreur de plus en plus humaine", Journal le matin, 8. 2000.
- L'ergonomie, Journal Trends tendance, October 2002

5. Dissemination by national and international collaborations

As a result of the dissemination process, other countries ask for collaborative work. In 2003, we start a collaboration with the AP-HP (assistance Publique-Hôpitaux de Paris, France), in the view to develop a generic reporting form.

The department of Work Psychology is a member of the ADVISES Network funded by the EC (Analysis design and validation of interactive safet-critical and error tolerant systems Network) with 7 other laboratories :

- Consiglio Nazionale delle Richerche established in Italy, [CNUCE-CNR].
- Risø National Laboratory established in Denmark.
- Technical University of Delft established in the Netherlands.
- Université de Liège established in Belgium.
- University of Paderborn established in Germany.
- Université Toulouse 1 established in France.

- University of York establishes in the United Kingdom

In that frame, we participated and organized different cursus on the topic of reporting systems.

Collaboration to the Hospital of Geneva (P. Garnerin, Prof. Clergue) in the frame of the Quality Cursus organized for the managers of hospitals.

V.3. Co-operation practices

This project is founded on the belief that we must integrate expertise for successful change of culture. The project used a number of mechanisms to enhance and support the collaborative enterprise.

Collaboration through the organization of regular close workshop meetings: These workshop meetings are organized at regular interval in order to support the transfer of expertise and lay the foundation for a multi-disciplinary work. During these meetings, we also invited additional participants (for example, insurances) to present some different work and share ideas.

Collaboration through the development of the Incident Reporting System : The project aims to standardize the Incident Reporting form between the different hospitals ; this required a close collaborative work from the CHU of Liege and Brussels and the others partners, using frequently internet-based communication technologies to support exchanges of information.

Collaboration through the development and use of one coding tool : We develop and exploit the same coding system to facilitate the statistical analyses. The partners of the working group (Dc Aunac, Dc ME Faymonville and AS Nyssen) are responsible for this activity at the different workplaces.

Collaboration and Dissemination through conferences and the preparation of papers: During the project, we produced a series of papers to document the progress of our complementary work. We also organized in common an international symposium on the topic and prepare an article to present the project outside.

V.4. FUTURE PROSPECTS

When developing a reporting system and managing a large amount of information as is required by an Incident Reporting System, it is important to be able to save and review the information. Future strategies should include:

- The provision of more complex data in electronic form to help analyses
- Redevelopment of the coding system to simplify analysis
- Extension of the specialty-based incident monitoring system to other specialties and to a generic reporting form
- Developing software interface based on a integrated chart and adapted to the incident reporting system

- Involving users in enhancement to the system and in facilitating the dissemination and implementation of remedial strategies
- Tight control over the confidentiality (security of the database)
- Effective legal structure to protect the database and the worker from any lawsuit
- Triangulation with other sources of data
- Long term investment in the validation of methods
- International database, analysis and reporting system
- Development of multi-skilled partnerships to undertake in-depth analysis of priority areas when resources are available. This will require clinicians to work with data analysts and epidemiologists.

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RAPPORT D'INCIDENT ET ACCIDENT

Vous êtes invités à compléter le rapport ci-joint quand durant votre pratique clinique survient un incident ou un accident

OBJECTIF	Rapporter tout incident, quelle que soit son apparence insignifiante, qui aurait affecté ou aurait pu affecter la sécurité du patient. L'incident peut avoir un caractère évitable ou non évitable.
ANONYMAT	Les identités de la personne rapportant l'incident et du patient concerné n'apparaissent pas dans ce rapport. La seule personne connaissant ces informations est vous-même.
INSTRUCTIONS	Décrivez simplement ce qui s'est passé, selon vous.
COORDONNATRICES	Dr ML Faymonville, AS Nyssen, asnyssen@ulg.ac.be
DETAILS	Il n'est **pas** nécessaire d'être très précis concernant la date et le lieu de l'opération dans ce formulaire. S.V.P., complétez toutes les sections de façon à ce que les données puissent être utilisables.

ITEM 1 : DESCRIPTION DE L'INCIDENT

Décrivez l'incident avec vos propres mots. Incluez tous les éléments qui peuvent selon vous avoir contribué à provoquer l'incident ou à en minimiser les conséquences. Mentionnez toute mesure à prendre pouvant dans l'avenir éviter un tel incident.

Incident multiple (entourez la réponse) : Oui / Non

N.B. : s'il survient plus d' un incident du même type "incidents multiples", merci de remplir un rapport pour chacun d'entre eux.

Pensez-vous que cet incident était évitable ? OUI NON Ne sait pas

ITEM 2 : QUE S'EST-IL PASSE ?

INCIDENT LIE AU CIRCUIT

Mélange des gaz……..	DL
Déconnexion……...	DI
Fuite……	LE
Mauvaise connexion……..	MI
Surpression…….……	OV
Rebreathing……..	RE
Autre incident sur le circuit…….	
Spécifier :……	OT
Aucun……	NI

CIRCUIT IMPLIQUE

Absorbeur de CO_2 (chaux sodée)...	AB
Sortie commune des gaz…….	CG
Tube endotrachéal ou équivalent…	ET
Débitmètre……..	FL
Arrivée des gaz frais……...	GS
Humidificateur, Nez artificiel,Filtre	HU
Circuit d'oxygène externe……...	OX
Valve sur le circuit…….….	CV
Valve d'échappement……..	PV
Système antipollution…….	SC
Tube et connexion……..	TU
Vaporisateur……	VA
Respirateur……..	VE
Tout autre circuit impliqué :	
Spécifier : ……...	OT
Aucun……..	NI

EQUIPEMENT IMPLIQUE

Ouvre-bouche et canule……..	AW
Compresse dans les voies aériennes	AP
Bistouri électrique et anse diathermique……	DI
Mauvais fonctionnement d'un équipement……..	EM
Appareil à perfusion……	IF
Aide à l'intubation……...	IA
Laryngoscope……	LS
Problème avec un équipement de surveillance……	MO
Tube nasogastrique…….	NG
Masque laryngé……..	ML
Aiguille et canule……	NC
Bandage et sparadrap……..	ST
Seringue……..	SY
Système d'aspiration……	SU
Table, brancard, support patient….	TA
Autre équipement :……	
Spécifier : ……..	OT
Aucun……..	NI

INCIDENT PHARMACOLOGIQUE

Phénomène allergique…….	AL
Contamination…….	CT
Drogue inadaptée……	IP
Interaction……..	IN
Surdosage……	OV
Effet secondaire……..	SE
Mauvaise drogue…….	WD
Sous-dosage……	UN
Autre incident lié aux médicaments	
Spécifier : ……..	OT
Aucun…….	NI

INCIDENT SUR LES VOIES AERIENNES

Intubation difficile……..	DI
Intubation bronchique……	EB
Extubation……..	EX
Intubation impossible……	FI
Absence de ventilation……	NV
Obstruction (incl. Vomissement ou spasme)……...	OB
Intubation oesophagienne……	OI
Traumatisme……	TR
Autre incident sur les voies aériennes : ……..	
Spécifier : ……..	OT
Aucun……..	NI

ITEM 3 : POURQUOI L'INCIDENT EST-IL SURVENU ?

FACTEURS CONTRIBUANT A LA SURVENUE DE L'INCIDENT		FACTEURS MINIMISANT L'INCIDENT		MESURES VISANT A PREVENIR L'INCIDENT	
EQUIPEMENT		**EQUIPEMENT**		**EQUIPEMENT**	
Manque d'équipement……	LF	Détection par un appareil de surveillance (Alarmes)……..	MD	Equipement supplémentaire……	AD
Manque d'appareil de surveillance..	LM	Spécifier quel appareil a détecté le problème en premier (un seulement)……..	ED	Appareil de surveillance supplémentaire……	AM
Problème d'app. de surveillance….	MP	Bonne aide au diagnostic……	AD	Procédure de contrôle de l'équipement……	EC
Problème de conception de l'équipement……	CE	Dispositif de sécurité adéquat…….	ES	Amélioration de la présentation de l'équipement……	ED
Impossibilité à contrôler l'équipement……	FC	Contrôle régulier de l'équipement..	RE	Procédures d'entretien de l'équipement……	EM
Environnement ou équipement non familier……	UN				
Problème avec un autre équipement Spécifier : ……..	OE				
Equipement inaccessible…….	EI				
Etiquetage de médicament…….	DL				
INDIVIDUEL		**INDIVIDUEL**		**INDIVIDUEL**	
Distraction……..	DL	Etat de santé du patient……..	HP	Formation supplémentaire……..	AT
Erreur de jugement/Prise de risques	EJ	Connaissance du patient……	IC	Systématique d'allègement de la fatigue……	FA
Erreur de diagnostic……	ED	Ré-évaluation périodique……	QA		
Erreur de confusion……..	EC	Conscience d'un danger imminent.	ID		
Faute technique…….	FT	Expérience ou formation préalable.	EX		
Erreur de procédure……	EP				
Erreur d'observation/ vérification...	EO				
Excès de confiance / routine……	ER				
Inattention……	IN				
Fatigue……..	FA				
Précipitation……	HA				
Pression pour aller de l'avant……..	PS				
Inexpérience :					
- formation inadéquate……	FI				
- connaissance inadéquate……	CI				
Evaluation préop insuffisante ou incorrecte……	PA				
Préparation préop du patient insuffisante ou incorrecte……	PP				
Etat clinique du patient……	SP				
Autre stress. Spécifier : ……	ST				
EQUIPE.		**EQUIPE**.		**EQUIPE**.	
Problème de communication……..	CP	Bonne communication……	EC	Amélioration de la communication.	IC
Problème de coordination……	CO	Changement de l'équipe …….	RA	Amélioration de l'assistance……..	EA
Assistance/ supervision inadéquate.	IA	Assistance expérimentée…….	SA		
Changement d'anesthésiste …….	CA				
Anesthésiste malade……	SA				
Participation de l'équipe chirurgicale……	SC				
ORGANISATION		**ORGANISATION**		**ORGANISATION**	
Problème de transmission des informations entre services……..	TI	Une bonne supervision……	SU	Amélioration de l'environnement…	IE
Problème de planification des activités……	PA	Procédures / algorithmes adéquats..	OP	Amélioration de la supervision…..	IS
Manque de support organisationnel		Disposition adéquate des ressources matérielles……..	OR	Personnel supplémentaire……..….	MM
Du Chirurgien ……	OC	Autre facteur		Activité d'assurance de qualité Spécifier (AIMS/M & M etc) ……	QA
De l'équipe……..	OE	Spécifier : ……...	OT	Développement de protocole spécifique……	SP
De l'hôpital…….	OH			Autre stratégie	
De la famille……	OF			Spécifier : ……..	OT
Liée à l'urgence du cas……	OU				
Autre facteur :					
Spécifier : ……..	OA				

ITEM 4 : ANESTHESIE ET PROCEDURE

CATEGORIE DE PROCEDURE
(il peut y en avoir plusieurs)

Cardiothoracique	CA
Cardioversion	CV
Chirurgie dentaire	DE
Procédure diagnostique incluant imagerie et biopsie	DI
Procédure thérapeutique	PT
Thérapeutique électroconvulsive	EC
Endoscopie	EN
ORL	ET
Chirurgie générale	GE
Gynécologie	GY
Hématologie	HE
Multidisciplinaire	MM
Maxillo-faciale	MF
Neurochirurgie	NS
Obstétrique	OB
Oncologie	ON
Ophtalmologie	OP
Orthopédie	OR
Chirurgie plastique et reconstructrice	PL
Radiothérapie	RA
Urologie	UR
Vasculaire	VA
Autre procédure. Spécifier :	OT
Aucune	NI

ADMISSION ELECTIVE
(entourez la bonne réponse)
Oui Non

TYPE D'ANESTHESIE
(un ou plusieurs)

Anesthésie générale	GE
Infiltration	IN
Anesthésie locorégionale ou bloc nerveux	RB
Sédation	SE
Aucune	NI

TYPE DE VENTILATION

Spontanée	SP
IPPV	IP
Aucune	NI

APPAREILS DE SURVEILLANCE EN UTILISATION AU MOMENT DE L'INCIDENT

Mesure de la pression dans les voies aériennes	AP
Mesure de la température des voies aériennes	AT
Alarme automatique de déconnexion	AD
Alarme manuelle de déconnexion	DA
Capnographe	CA
Débit cardiaque	CO
Pression veineuse centrale	CV
Doppler précordial	DO
Pression du ballon de tube endotrachéal	EP
ECG	EC
EEG	EE
Pression artérielle invasive	IA
Pression intracrânienne	IC
Spectromètre de masse	MA
Analyseur de N_2O	NO
Autre analyseur de gaz	GA
Oxymètre ou pulsoxymètre	OX
Analyseur d'oxygène	OA
Pléthysmographe	PL
Stimulateur nerveux périphérique	NS
Pression dans l'artère pulmonaire ou capillaire bloqué	PA
Tensiomètre :	
Automatique	AU
Manuel	SP
Spiromètre	SR
Stéthoscope Précordial ou œsophagien	ST
Température du patient	TP
Autre appareil de surveillance	
Spécifier :	OT
Aucun	NI

ITEM 5 : OU ET QUAND CELA EST-IL ARRIVE ?

Heure dans la journée

H	H	M	M	

Mois | | |

PHASE D'ALERTE
(une seulement)

Pré-induction	PI
Induction	IN
Maintenance	MA
Fin d'anesthésie	EM
Réveil	RE
Après la phase de réveil	PR

LIEU

Service des urgences	CA
Chirurgie ambulatoire	DA
Salle d'accouchement	DR
Salle de soins dentaires	DE
Unité de soins	GE
Radiologie	IM
Transport	TR
Salle de pré-narcose	IR
Soins intensifs	IC
Salle d'opération	OR
Autre dans l'hôpital Spécifier :	OI
Autre hors de l'hôpital Spécifier :	OO
Salle de réveil	RE

ITEM 6 : A QUI CELA EST-IL ARRIVE ?

GROUPE D'AGE DU PATIENT

Nouveau-né	
Moins de 1 an	
De 1 à 14 ans	NN
Supérieur à 14 ans	IN
Age en années	CH
	AD

CLASSIFICATION DES PATIENTS (ASA)

1 2 3 4 5

URGENCE : Oui / Non

ITEM 7 PERSONNES IMPLIQUEES

DEGRE D'IMPLICATION DU DECLARANT DANS L'INCIDENT		PERSONNES IMPLIQUEES LORS DE L'INCIDENT	
Impliqué……	IM	Anesthésiste……	PA
Assistant……	AS	Chirurgien……..	PC
Observateur……	OB	Infirmière……	PI
Degré de formation 1 2 3 4 5	DF	Technicien……..	PT
Anesthésiste reconnu 0-10 ans	AR	Entretien……	PE
10-20 ans		Accompagnant……	AC
> 20 ans			

ITEM 8 DETECTION DU PROBLEME

QUI ?	
Déclarant……..	QD
Autre personne	
Spécifier……...	QA
COMMENT ?	
Alarme…….	CA
Interpellation……	CI
Lors d'une vérification systématique…...	CV
Suspicion d'un problème	
- sur base d'un signe précurseur……	CS
- sur base de connaissance…….	CC
Par hasard……	CH
Autre,	
Spécifier……...	CD
QUAND ?	
Immédiatement……	IM
Après combien de temps ☐	
Jamais……..	JM

ITEM 9 EVOLUTION

DUREE DE L'INCIDENT	
Transitoire (< 5 min)……...	TR
Prolongé (> 5 min)……...	PR
EFFETS IMMEDIATS	
Arrêt cardiaque……	CA
Perturbation majeure……...	MA
Perturbation mineure……..	MI
Lésions corporelles…….	PI
Néant……...	NI
EFFETS A LONG TERME	
Eveil peranesthésie……	AW
Décès……...	DE
Morbidité majeure……..	MA
Morbidité mineure……..	MI
Hospitalisation prolongée……...	PS
Admission non programmée aux	
Soins Intensifs……	HD
Aucun……..	NI

ITEM 10 VECU

Après l'incident, quel sentiment avez-vous éprouvé ?	
Sentiment de rage contre :	
Equipements……..	SE
Soi-même……..	SM
Equipe……	SQ
Organisationnel……	SO
Sentiment de culpabilité : ……	SC
Questionnement……	QE
Après l'incident, avez-vous remarqué :	
Un manque de sommeil……	MS
Un manque d'appétit……	MA
Des difficultés de concentration……	DC
Un ressassement involontaire de l'incident……	RI
Une perte de plaisir……	PP
De la peur……	PE
Autre……	AU

ITEM 11 EVALUATION DU QUESTIONNAIRE

Les questions sont-elles suffisamment claires ?	
Oui ……	EC
Non……	EN
Ce questionnaire vous paraît-il fastidieux à remplir ?	
Oui……..	FC
Non……	FN
Combien de temps avez-vous mis pour le compléter.	
Ce questionnaire vous paraît-il bien structuré ?	
Oui……..	SC
Non……	SN

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