

The development of an incident analysis tool for the medical field

Citation for published version (APA):

Vuuren, van, W., Shea, C. E., & Schaaf, van der, T. W. (1997). *The development of an incident analysis tool for the medical field*. (EUT - BDK report. Dept. of Industrial Engineering and Management Science; Vol. 85). Technische Universiteit Eindhoven.

Document status and date:

Published: 01/01/1997

Document Version:

Publisher's PDF, also known as Version of Record (includes final page, issue and volume numbers)

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

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Report

L T Y O F T E C H N O L O G Y M A N A G E M E N T

The development of an
incident analysis tool for the
medical field

by

W. van Vuuren, C.E. Shea & T.W. van der Schaaf

Report EUT/BDK/85
ISBN 90-386-0405-7
ISSN 0929-8479
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**Keywords: RISK-ANALYSIS / MEDICAL INCIDENTS / RISK
MANAGEMENT**

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Vuuren, W. van

The development of an incident analysis tool for the medical field / by W. van Vuuren, C.E. Shea and T.W. van der Schaaf. - Eindhoven : Technische Universiteit Eindhoven, 1997. - (Report EUT/BDK, Eindhoven University of Technology, Department of Industrial Engineering and Management Science, ISSN 0929-8479; 85). -

ISBN 90-386-0405-7

NUGI 683

Subject headings: Risk Analysis / Medical Incidents / Risk Management

Contents

1. Introduction	1
2. PRISMA	2
3. Moving into the Medical domain: the MECCA project.....	5
3.1 Why?	5
3.2 First Steps	6
3.3 Differences between industry and the medical domain.....	6
4. ECM Medical Version.....	8
4.1 The model.....	8
4.2 Differences	10
4.2.1 Structural changes	10
4.2.2 Changes to facilitate use.....	12
5. Discussion	15
5.1 Face validity	15
5.2 Testing of the Model	16
5.3 Further developments	16
References	18

1. Introduction

Risk management in the medical domain and medical accidents in particular are receiving growing interest from researchers in industrial engineering and management science, psychology, and human factors. Historically there has been little systematic attempt to explore and assess safety for both staff and patients in a medical domain, particularly within a hospital setting (Vincent, Ennis & Audley, 1993). Though an interesting variety of quality assessment and audit methods have gained in popularity, the scope of most systems excludes safety. Conversely, many methods exist to analyse safety and risk in industrial settings, particularly in high risk industries such as chemical processing, nuclear power, transportation and most notably in aviation.

Researchers are beginning to investigate error in medicine and to evaluate its impact on patient care and safety. Studies in anaesthesia (e.g. Runciman *et al.*, 1993; Campling *et al.*, 1995; van Vuuren, 1996a), Accident & Emergency departments (e.g. Shea, 1996; van Vuuren, 1996a), the intensive care unit (e.g. Beckmann *et al.*, 1996; Wagenaar *et al.*, 1993), and those focusing on the contribution of human error in medicine (e.g. Moray 1994; Helmreich & Schaefer, 1994; Cook & Woods, 1994) represent some of the projects at the beginning of a wave of growing interest and concern for safety in medicine. However this steadily increasing interest has not yet led to a flexible, powerful and practical tool to monitor, analyse and improve systems' safety performance.

In this paper we first briefly describe PRISMA, an incident approach originally developed in the chemical process industry. Following this, the experiences of the first PRISMA applications in the medical field are outlined, leading to some important differences between the medical field and industry for the development of the medical version of PRISMA. Finally, the medical version of PRISMA is described in detail. Some first validation results are reported, and further developments are outlined.

2. PRISMA

PRISMA (Prevention and Recovery Information System for Monitoring and Analysis) is a tool capable of being used continuously and systematically to monitor, analyse and interpret incidents and process deviations (van der Schaaf, 1996). Originally developed to manage human error in the chemical process industry, it is now being applied in the steel industry, energy production and in hospitals. The initial focus on safety consequences has been extended to provide an integral approach that is able to manage all adverse consequences (safety, quality, environment and reliability), based on the assumption that a common set of causal factors is responsible for these various issues.

The main goal is to build a quantitative database of incidents and process deviations, from which conclusions may be drawn to suggest optimal counter measures. These counter measures can assist not only in the prevention of errors and faults, but also to promote recovery factors and to ensure timely corrective action. PRISMA uses both actual but rare accidents and the abundantly available near misses to accomplish this.

The PRISMA approach consists of the following main components, which will be discussed briefly:

1. The Causal Tree incident description method.
2. The Eindhoven Classification Model (ECM) of System Failure.
3. The Classification/Action Matrix.

Causal trees (van Vuuren & van der Schaaf, 1995), derived from fault trees, are very useful to present critical activities and decisions which occur during the development of an incident. These activities and decisions are presented in chronological order, and show how different

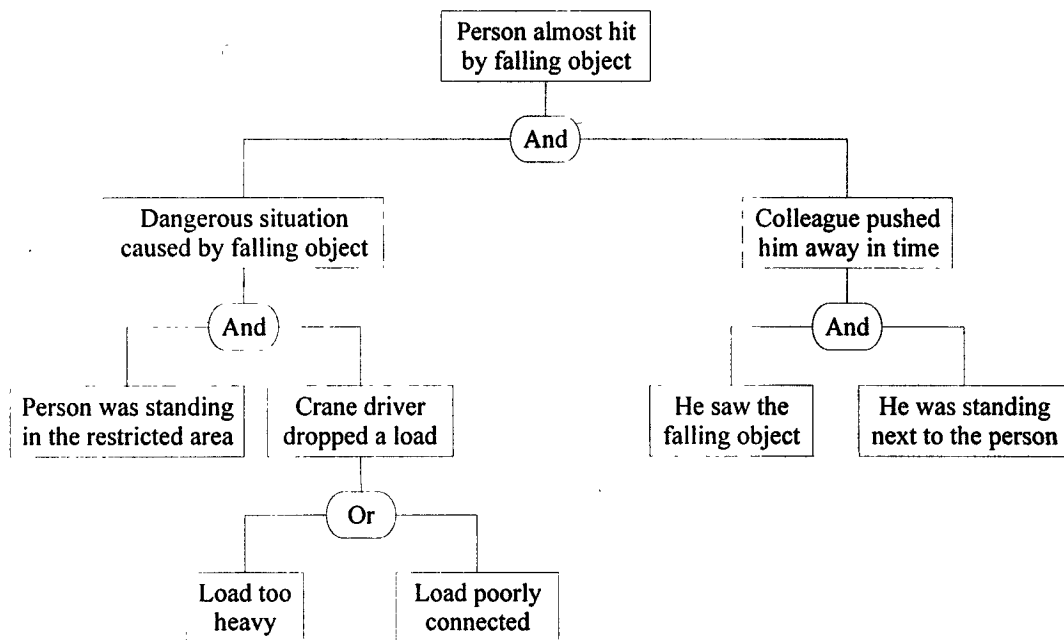


Figure 1: Example of a causal tree describing a near miss.

activities and decisions are logically related to each other (figure 1). It becomes clear when using causal trees, that an incident is the result of a combination of many technical, organisational and human causes. The ‘root causes’, which are found at the bottom of the causal tree, are the main product of the first phase of PRISMA, and constitute the inputs to the second phase: classification of failure root causes.

To classify technical, organisational and human root causes, a model is needed. The Eindhoven Classification Model (figure 2) was originally developed to classify root causes of safety related incidents in the chemical process industry. The ECM focuses on three types of causes separately and in a pre-defined order. First technical problems are considered, by looking at the design of the equipment used, construction problems, or unexplainable material defects.

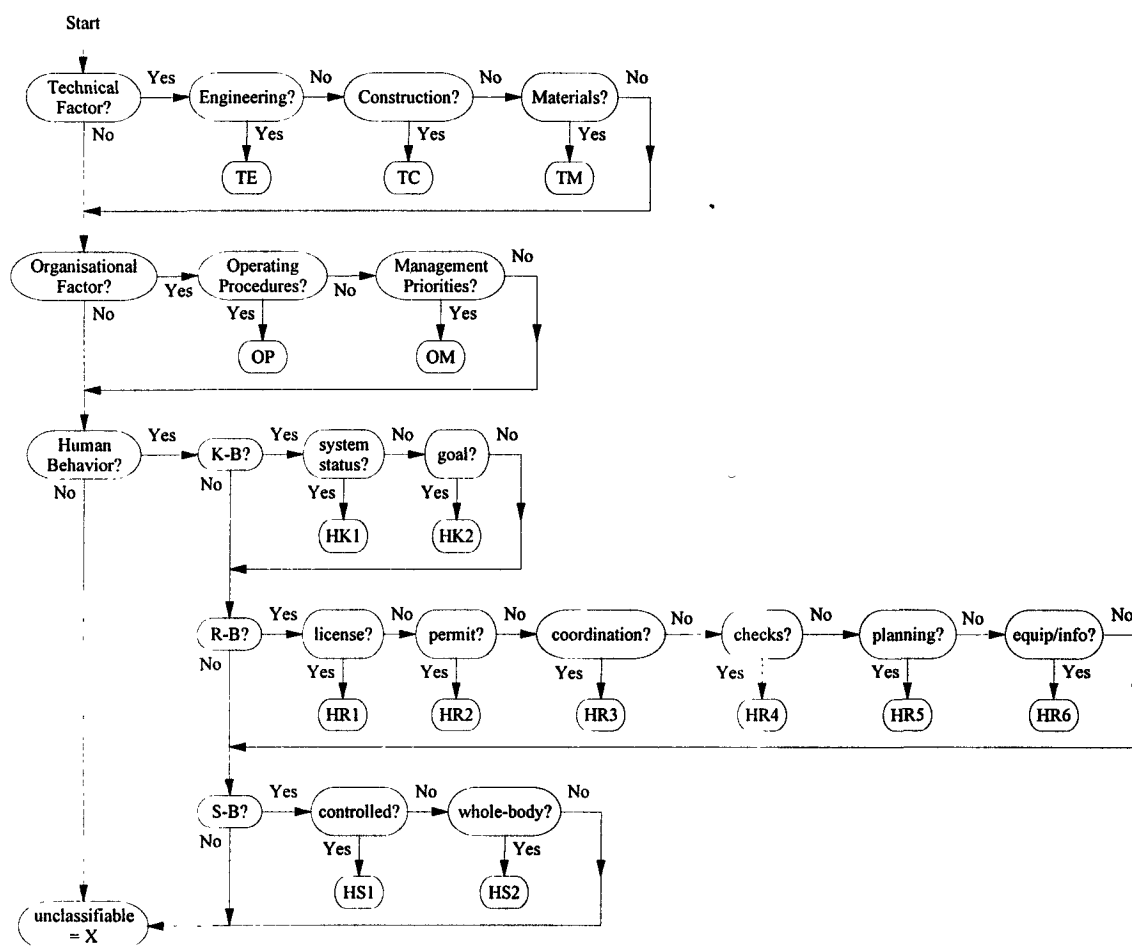


Figure 2: The Eindhoven Classification Model (van der Schaaf, 1992).

The second step focuses on contributing factors at an organisational level, such as the quality of procedures, or the priorities of management. Only after looking at possible technical and organisational problems are human causes considered. This order is chosen to counteract the sometimes strong bias within companies to start and stop analysis at the level of the operator as the end-user, and leave the technical and organisational context of any mishap unquestioned.

The human section of the model is based on the SRK-model by Rasmussen (1976). Rasmussen has developed a basic model of human error based on three levels of behaviour: skill-, rule-, and knowledge-based behaviour (S-B, R-B, K-B). This SRK-model has been operationalised to describe operator errors in process control tasks by combining it with characteristic task elements, which as a whole, cover the entire spectrum of operator sub-tasks. The last category ('unclassifiable') is reserved for those contributing factors which can not be categorised in one of the above mentioned categories.

In order to develop an actual tool for risk management it does not suffice to stop at the analysis stage of failure classification. These classification results must be translated into proposals for effective preventive and corrective actions. To fulfil this purpose a Classification/Action matrix was developed, incorporating the theoretical foundations of the ECM.

In the matrix (figure 3) the most preferred action in terms of expected effectiveness for each classification category is indicated by 'X'. The last column's 'no!'s refer to particularly ineffective management actions, which are none the less often encountered in practice.

	Equipment	Procedures	Information & communication	Training	Motivation
TE	X				
TC	X				
(TM)					
OP		X			
(OM)					
HK1			X		no!
HK2			X		no!
HR1				X	
HR2				X	
HR3				X	
HR4				X	
HR5				X	
HR6				X	
HS1	X				no!
HS2	X				no!

Figure 3: The Classification/Action Matrix.

3. Moving into the Medical domain: MECCA

3.1 Why?

The MECCA (Medical Errors and Complications Causal Analysis) project has evolved from the successful implementation of PRISMA in industrial settings. This success suggested that the system might have wider applications in non-industrial settings. The medical field appears to be an equally complex, dynamic and high-risk domain. Interest from within the medical domain in quality improvement and by extension, risk management, is growing. Various health care professions are increasingly aware of and receptive to innovations from beyond the medical field regarding safety and system improvement. The conference on 'Examining Errors in Health Care: Developing a Prevention, Education and Research Agenda', held in Rancho Mirage, California on October the 14th, 1996 can be seen as the breakthrough in the US in this field. At the Eindhoven University of Technology, the Safety Management Group started the MECCA project (van der Schaaf & Shea, 1996) to investigate the application of PRISMA in the medical field. The aim of MECCA is to study the feasibility of applying 'lessons learned in industry' to the medical domain.

The absence of a systematic approach to safety in this high-risk domain is surprising from a legal standpoint. Differences exist in rates of litigation internationally, for example in the US it has been estimated that 1 in 4 doctors will be sued for malpractice each year (Charles *et al.*, 1984), while in the UK 2.5 % of the Medical Protection Society's 11,000 members has a claim or complaint lodged against them annually (Vincent, Ennis & Audley, 1993). Internationally, little formal legislation exists regarding the implementation and use of safety oriented systems. In the UK Clinical Audit is now a statutory regulation in all clinical disciplines while Quality Assurance and Total Quality Management systems are popular in North America. Neither of these explicitly covers safety management. In the Netherlands, accidents and near accidents are reported to a special committee in each hospital, but the process is not mandatory anymore, and proper analysis and feedback, both to managers and to the originators of these reports, are rare and less than productive.

The majority of incidents are dealt with through existing complaint and compensation channels. At the same time patients (and their lawyers) are becoming better informed and actively participating in their own health management. They are demanding better information systems, including improved systems for complaints and compensation. An active approach to safety and risk management demonstrates an institution's commitment to patient and staff safety. It is surprising that such a system is not more actively encouraged by management, and by the malpractice insurance companies, in the increasingly competitive and budget minded health care market.

The implementation of risk management systems is also ethically consistent with the aims of health care organisations. All attempts to enhance patient care should be pursued on moral grounds alone. The implementation of a safety system will also raise staff and patient awareness and concern for safety. This is the manner in which one expects health care organisations to conduct themselves given the nature of their business.

3.2 First Steps

The MECCA project has focused primarily on individual hospital departments. The radiology, and surgical departments of a major teaching hospital in the Netherlands and two Accident and Emergency departments (A&E) and an anaesthesia department in the UK were the first sites investigated. Following a period of familiarisation, data was gathered through observations and voluntary incident reporting. Incident analysis was performed and feedback was immediately given to the individual who reported an incident regarding its analysis and interpretation. A final report was written for each department at the conclusion of the research. This included a summary of specific recommendations for a department based on analysis of their database of incident root causes.

Currently MECCA is being applied in two new medical fields. In the US MECCA has been adopted as the incident analysis method for a national project in transfusion medicine, supervised by the FDA. A similar project has been started for a local blood bank in the Netherlands. Recently, a new project has begun to implement MECCA in the Intensive Care Unit of a large teaching hospital in the Netherlands.

3.3 Differences between industry and the medical domain

Based on our experiences so far, several important differences between the medical and industrial domains have been noted. The most remarkable difference exists at an organisational level. The organisational structure and management of a hospital differs from that routinely found in industrial settings. The aim of the hospital is to unite a variety of independent specialist departments under one roof for expediency. Departments are financially and organisationally independent of each other while coexisting in a dependent relationship within the hospital. Their interdependence and reliance is necessitated by the demands of their work; they could not function independently.

The research suggested that a contrast exists between the general skill and education level of staff in heavy industry and those in health care. There appears to be a high level of professionalism, self-regulation and group membership and identification throughout the health care system. This extends from nurses and doctors to paramedics and medical administrators. Individual self-reliance and decision-making are common in the medical field, while the use of pre-established protocols in task performance occurs predominantly during learning phases. The application of protocols is ultimately determined by each individual and is related to their personal experiences.

In the industrial settings studied self-regulation appears to be considerably lower, given the ever present written procedures, and strict hierarchical structures in decision making. Routine tasks are performed according to the rules and procedures outlined. The research suggested that less independent decision-making is required and is frequently discouraged in industrial settings. Questionable or unusual situations are instead referred to a higher level decision-maker for rectification.

An interesting, unique, and unpredictable factor in the medical field is patients. Data clearly shows that patient related factors, often beyond the control of staff, significantly influence

system function and therefore the quality of care delivered. The diversity of these factors renders them difficult to assess and manage as a single group. Traditionally, patient-related factors were recognised merely as part of the job of working with people. They were viewed as the quirky and unpredictable side-effects of dealing with human beings. Consequently, the negative impact of patient related factors are simply managed, as and when they manifest themselves during a patient's treatment. While some patients may be incapable of communicating with staff hindering diagnosis and slowing treatment, others may have unavoidable physical attributes such as obesity which unpredictably and sometimes adversely influence treatment.

4. ECM Medical Version

4.1 The model

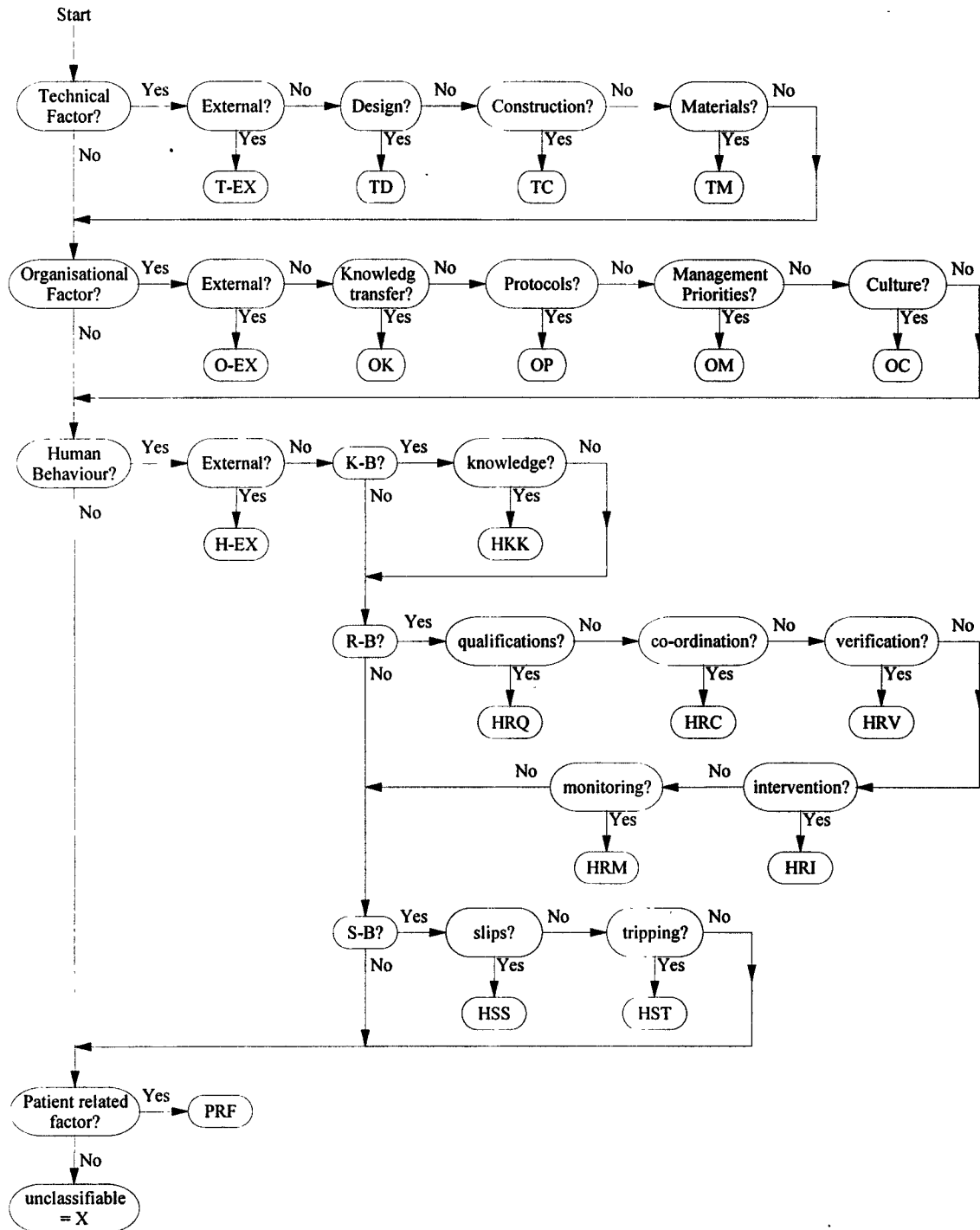


Figure 4: The Eindhoven Classification Model: Medical Version.

Changes to the original Eindhoven Classification Model are grounded in the MECCA projects performed in the anaesthetic and A&E departments. The anaesthesia project (van Vuuren,

1996a) resulted in 15 incidents and 79 root causes. The initial A&E project resulted in 25 incidents and 127 root causes (Shea, 1996) and a follow-up study assessed 19 incidents and 93 root causes (van Vuuren, 1996a). The modifications to the original model have been made to facilitate its implementation, acceptability, and use in the medical field. Before discussing the actual differences, the categories of the medical version of the Eindhoven Classification Model (figure 4) will be defined.

Technical

<i>External (T-EX)</i>	Refers to any technical failures beyond the control and responsibility of the investigating organisation.
<i>Design (TD)</i>	Failures due to poor design.
<i>Construction (TC)</i>	Correct design which was not followed accurately during construction phase.
<i>Materials (TM)</i>	Rest category for those material defects not classifiable under TD or TC.

Organisational

<i>External (O-EX)</i>	Any failures at an organisational level beyond the control and responsibility of the investigating organisation.
<i>Transfer of Knowledge (OK)</i>	Refers to failures resulting from inadequate measures taken to ensure that situational or domain specific knowledge or information is transferred to all new or inexperienced staff.
<i>Protocols (OP)</i>	Failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, poorly presented).
<i>Management priorities (OM)</i>	Refers to failures resulting from management decisions in which safety is relegated to an inferior position when faced with conflicting demands or objectives.
<i>Culture (OC)</i>	Refers to failures resulting from a collective approach and its attendant modes of behaviour to risks in the investigating organisation.

Human

<i>External (H-EX)</i>	Refers to human failures originating beyond the control and responsibility of the investigating organisation.
<i>Knowledge (HKK)</i>	Refers to the inability of an individual to apply their existing knowledge to manage novel situations.
<i>Qualifications (HRQ)</i>	Refers to the incorrect fit between an individual's qualifications, training or education and a task.
<i>Co-ordination (HRC)</i>	Refers to a lack of task co-ordination within the organisation or team.
<i>Verification (HRV)</i>	Concerns failures in the correct and complete assessment of a situation including relevant conditions of the patient and materials to be used <i>before</i> starting the intervention.
<i>Intervention (HRI)</i>	Applies to failures that result from faulty task planning and execution.
<i>Monitoring (HRM)</i>	Pertains to failures during monitoring of process or patient status during or post-intervention.

Slips (HSS) Refers to failures in the performance of fine motor skills.
Tripping (HST) Refers to failures in whole body movements.

Patient related

Patient related factor (PRF) Failures related to patient characteristics which are beyond the control of staff and influence treatment.

Unclassifiable

Unclassifiable (X) Rest category for failures that can not be classified in any other category.

4.2 Differences

The initial differences outlined in section 3.3 highlighted the need to modify the existing taxonomy. Fundamental structural and functional differences were identified between the initial domains of application and the medical field.

In PRISMA's first area of application in chemical processing plants, the model focused primarily on human error. This corresponded to the demands of the field at that time. Further research in different industrial settings emphasised the need to expand the two original organisational categories (van Vuuren & van der Schaaf, 1995). Van Vuuren's (1996b) research strongly suggested that the culture of an organisation (OC) and the ability of an organisation to transfer situational or domain specific knowledge among workers (OK) contributed to incidents and required recognition and further investigation. Besides structural changes to the model, a number of minor changes were required to facilitate the use of the model by those on the shopfloor in the medical domain. Both will be described in the remainder of this chapter.

4.2.1 Structural changes

The significance of making the distinction between internal and external factors originates from the typical organisational structure in the medical field as described in section 3.3. In a hospital setting, a variety of specialist departments are united under one roof for expediency. The departments are financially and organisationally independent of each other, while coexisting in a dependent relationship within the hospital. Because of this dependent relationship the (safety) performance of a department may be negatively influenced by the performance of another department. Since the different departments in a hospital are organisationally independent of each other, these external factors are beyond the direct control of the department that is being adversely influenced by them. It is the obligation of each department or service to manage its own internal affairs.

Not only are external factors beyond the control of the department, it is also very difficult to assess the real causes behind these external factors. It is of little use to hypothesise in great detail about the origins and accompanying corrective actions of root causes in other departments. For this reason, only the three main categories of technical, organisational and human have an external category, to be used when a root cause occurs outside the

investigating department in one of these three general areas. Sub-categories on an external level are left out of the model.

The research of Shea (1996) in two British Accident & Emergency departments, clearly showed the complex relationship between hospital departments, senior hospital management and external influences such as government policy changes. It was apparent that the functioning of individual departments was directly affected by external factors.

As described earlier in this section, PRISMA's first applications focused mainly on human error, leading to an overemphasis on human behaviour in the original Eindhoven Classification Model. This corresponded to the demands of the time and the belief that incidents can be best prevented by eliminating human error. Over the past few years attention has shifted to the contribution of the organisational setting in which the employees have to operate. Adding organisational categories to the new model can therefore be seen as a result of a theoretical development process. The actual changes to the model are supported by empirical incident data collected in both industrial and medical domains (van Vuuren & van der Schaaf, 1995; Shea, 1996; van Vuuren, 1996a & 1996b).

The first organisational category added, transfer of knowledge (OK), captures the failures that result from the inadequate transfer of formal or informal, domain specific knowledge and information. This is predominantly a problem for new staff (both regular staff, and nursing and medical students). It is difficult to manage effectively and is frequently only haphazardly addressed. The usual introductory tour and/or meeting is given after which one is expected to learn on the job. In the medical domain this is unacceptable and dangerous, combining unsupervised learning with unsupervised practice.

The culture of an organisation (OC), including the collective approach and its attendant modes of behaviour to safety and risk, appear to strongly influence incidents. Incidents in the medical and industrial domains revealed that an individual's behaviour was influenced by the prevailing culture of the group or department.

The penultimate category of the new model is called 'Patient Related Factors' (PRF). As discussed in section 3.3 this category is intended to capture the failures that arise due to uncontrollable and unpredictable patient factors. In the original classification model the category 'unclassifiable' (X) acts as a rest category. As a guideline, when approximately 5% of all root causes end up in this category, re-examining these unclassifiable causes should be considered. Some causes may simply be incorrectly classified while others may suggest that a new category requires consideration and possible development.

As is shown in Table 1, 10% of the root causes in Accident & Emergency studies appeared to be unclassifiable using the original model. Re-examination of these unclassifiable root causes in the medical data suggested that a new category was necessary. The majority of the unclassifiable root causes appeared to be patient related. The new category is intended to capture these root causes. The category unclassifiable (X), in its role as a rest category, continues to play its original, important function in the medical version of the model.

	<i>Technical</i>	<i>Organisational</i>	<i>Human</i>	<i>Unclassifiable</i>	<i>Total</i>
<i>Number of root causes</i>	4	73	64	15	156
<i>Percentage</i>	2%	47%	41%	10%	100%

Table 1: Distribution of combined results of A&E studies (Shea, 1996; van Vuuren, 1996a).

4.2.2 Changes to facilitate use

Next to these structural changes, several changes to the model have been made to facilitate implementation and use in the medical domain. Every domain has its own specific jargon and characteristic task elements. The original model was developed for industrial settings, which differ on these aspects from the medical domain. Changes are made to cope with these differences. These changes and some general remarks will be discussed in the remainder of this chapter.

The original technical category of 'engineering' is re-labelled as 'design' to improve its understanding and breadth of application in the medical field. The original term of engineering did not include medically specific problems such as the poor design of drugs (i.e. having serious side-effects). The new category still refers to failures resulting from the poor functional design of items and now may include not only equipment or hardware but also items such as medications, dressings, labels and forms. The technical categories of 'construction' and 'materials' remain unchanged.

At the organisational level the first category is now called 'protocols' (OP). In the original model this category was called 'procedures'. The term 'protocols' is preferred over procedures, because in the medical field the term protocol is regularly used and readily understood. In both industrial and medical settings numerous protocols are developed to be used in various situations. In many instances the well-intended protocol is left unused. In some circumstances this is due to the sheer volume of protocols; there are just too many, thus people ignore them completely. In other cases protocols may be inaccurate, poorly presented, ineffective or simply unworkable.

Management priorities (OM) remain an influential factor in incident evolution. In conflicting situations, safety is often given a lower priority than production schedules in industry. This practice was also identified in the medical field where it jeopardised patient care. In many instances senior management policies seriously threatened and undermined the successful functioning of the departments studied (Shea, 1996). Staff were expected to compensate and little could be done in the face of unrealistic budget constraints handed down by poorly informed management.

The original taxonomy incorporated Rasmussen's (1976) skill-rule-knowledge based classification schema for human (cognitive) behaviour. The differences in characteristic task elements found between the industrial setting and the medical domain supported revisions to the human factors section of the model to improve its implementation and comprehension. This involved minor alterations to existing categories and more appropriate terminology to facilitate the use of the model.

At the knowledge based level of the model the two original knowledge-based categories of 'status' and 'goals' are reduced to one, 'knowledge' (HKK). A distinction between the two original categories was difficult to make accurately and this rendered the second category called 'goal' difficult to use. The data suggests that a broader, higher-level category is more useful in the medical domain. The original two categories had similar countermeasures, thus their combination does not affect the recommended countermeasure for this category. Root causes that occur when an individual is unable to apply existing knowledge in a novel situation are now classified under HKK.

Similar alterations are made in the rule-based categories to improve the implementation of the model. The original six categories have been reduced to five. Two of the original categories, 'license' and 'permit' have been combined to improve the model's applicability. The possession of a 'license' in the sense of a diploma or general qualification, is assumed in the medical field. The need for a temporary 'permit' in order to perform a specific, infrequent or unusual task, simply does not occur in the medical domain, while it is very common in industry. This category was therefore found to be unnecessary. To improve its comprehension in the medical field the first category is now called 'qualifications' (HRQ). This more accurately represents the circumstances in the medical domain. This category captures the root causes related to individuals performing tasks for which they are not correctly or adequately qualified. This category thus incorporates the original two. In these instances the failure occurs strictly at the individual level when there is a failure on the part of the individual to acknowledge or compensate for their own lack of skill or knowledge when performing a task.

Before proceeding with the intervention, one must verify that everything required to successfully perform the task is prepared. This category is called 'verification' (HRV). In the original category called 'checks', this category only involved confirming that equipment and system status were as expected before a task was begun. The new category includes the correct and complete assessment of the patient and any necessary materials before beginning a task. Not only should necessary equipment be ready but patient status must be confirmed.

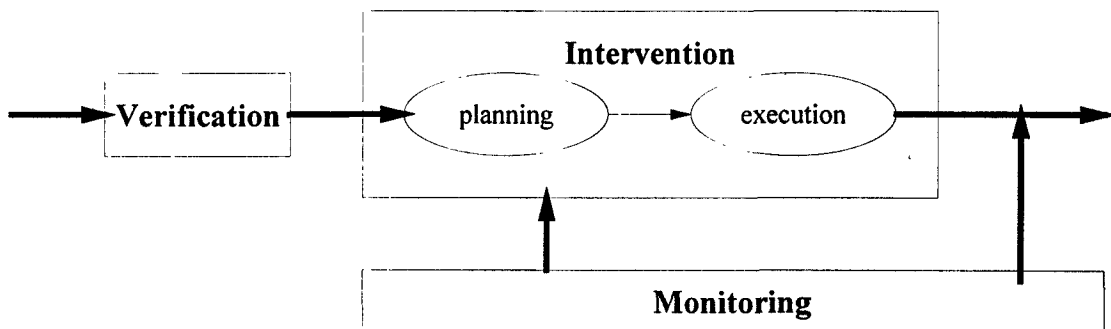


Figure 5: Relations between verification, intervention and monitoring.

Once the situation is assessed, the planned task must be correctly executed. At this point, errors may occur due to faulty planning or poor task execution. In the original model the 'planning' category includes errors that occurred during the planning stage of a task and those occurring during its execution. To clarify this category the term 'intervention' (HRI) has replaced 'planning' in the medical version, since both planning and correct execution are required for successful interventions.

A second category was created to identify the errors occurring during and after the intervention. It is common in patient treatment to monitor the progress of a patient following the execution of a particular task. Indeed, a variety of parallel tasks may be involved at various times during a patient's treatment. The individual must both monitor the state of the process as it progresses and perform the intervention at the same time. Failures occurring during this period are classified as 'monitoring' (HRM) errors if an individual fails to review patient and

system status during treatment. Monitoring therefore includes observing both the process and patient status during and after the intervention. In figure 5, the process of verification, intervention (which involves both planning and execution) and monitoring is visualised, to clarify again the difference between verification and monitoring. Verification is the checking that happens before the intervention. Monitoring is the checking that happens during and after the intervention.

The third and final level of the human behaviour part of the model deals with skill-based behaviour. The two categories remain unchanged except in name from the original version, to facilitate understanding and use. The first category is called 'slips' (HSS). This refers to failures in the performance of fine motor skills (like typing, or handling surgical instruments). The second category is called 'tripping' (HST) and refers to failures due to whole body movements. These are often referred to as 'slipping, tripping or falling' errors.

5. Discussion

5.1 Face validity

Given the differences identified between the original fields of application and the medical domain certain areas were of predictable significance. The difference in organisational structure between the medical domain and industry, the high level of professionalism in the medical field, and the importance of the patient as an influential factor, were all indications for possible changes to the model. As is shown in chapter 4 these issues were all supported by the data collected in the medical field, giving a good indication of the face validity of the data.

The singular organisation of hospitals which attempts to co-ordinate financially and professionally autonomous departments under one roof, suggested that problems would arise at the interface between these independent but related departments. The addition of the external category for technical, organisational and human factors is meant to identify failures that arise when one must cross a boundary into another department. This category should facilitate the accurate allocation of responsibility for problem resolution, both for the department performing the investigation and the department responsible for the problem. The investigating department should no longer feel compelled to account for and compensate for problems that it simply cannot solve alone. Certainly problems will continue to occur within the investigating department that are related to external factors, but the department will be able to rapidly and pragmatically identify their external source, improving their own efficiency and effectiveness in managing problems. Effectively managing the interface between the investigating departments will be an important step to make if one intends to improve a system's safety performance.

A second predictable 'interface problem' that is given a significant position in the new model is the interface between the department and the patient. Managing this interface is a distinctly medical issue which until recently appears to have been overlooked. The need for the development of the 'patient related factors' category was also implicit from the data. Clearly there were factors beyond the immediate control of staff that influenced patient care and related solely to the patient. It is time to realise that unless such factors are recognised and collated little can change.

The data indicated that some failures were related to the high level of individual knowledge found in the medical field. There appears to be an implicit expectation among staff of certain levels of competency and professionalism which are neither clarified nor offset should they be lacking in any specific way. The ability to identify and perhaps then acknowledge apparently inconsistent levels of knowledge should improve a department's ability to manage this issue. Related to this knowledge based problem is the issue of knowledge or information transfer within a department at an organisational level. Particularly when there is a frequent rotation of (mainly junior) doctors, attention should be paid to the efficient and effective training of new employees. When knowledge transfer (in particular situational or domain specific knowledge) is ineffective or inefficient the ability of individuals to function, and therefore also patient safety, is impaired.

5.2 Testing of the Model

To us the model appears to be comprehensive and robust coping with all of the root causes identified in both projects. To extend the validation process of the new medical version, a dozen individuals have been asked to classify the root causes of the same set of 12 incidents, using the medical version of the Eindhoven Classification Model¹. All individuals were given the causal trees of the 12 incidents, incident descriptions of the incidents, and a brief explanation of the PRISMA approach and the new classification model. Besides classifying the root causes, the respondents were asked to keep a diary of all difficulties and questions they ran into during the process of classifying the root causes.

The individuals differ from each other on two important aspects. The first aspect is experience with the original PRISMA approach (including the original Eindhoven Classification Model). About half can be considered experts in using this approach and model. The others are complete novices in the field. The second aspect is knowledge of the medical domain, for which a similar division is used. Both aspects are important to determine the level of insight (into the PRISMA approach, and/or the medical domain) required to understand and use the model effectively.

After classifying the root causes every respondent's classifications were compared with the researchers' opinion about how they should be classified. Differences between classifications, and the reported problems that occurred during the process of classifying, were used as input for an open discussion between the respondent and the researchers. These discussions have led to several modifications of the model, and the definitions of the classification categories. This has resulted in the model as is shown in figure 4 in chapter 4.

The discussions showed that the model and definitions could be modified to improve understanding and facilitate use. However, most differences in classifications were caused by a different interpretation of the root cause involved. The root causes in the causal trees were described in the briefest possible way. On one hand this is required if the respondent is not to be influenced by the description. However on the other hand, this often leaves the description of the root cause open to different interpretations. This occurred to both medical and non-medical respondents. After explaining the original intention of the root cause, (i.e. as part of the incident as a whole) most classification differences could be solved without further discussions.

5.3 Further developments

Current research by the Eindhoven Safety Management Group continues to investigate the role of organisational and recovery factors and their incorporation in the model.

The ECM: Medical version will be implemented and tested in other medical areas to extend its field of application. Also, a group of experts in the field of safety management, human error, and medical incidents will evaluate this medical version at the First International

¹ The details of this first validation are described in another internal EUT report (van der Schaaf, van Vuuren, & Shea 1997).

MECCA Workshop at the Eindhoven University of Technology in May, 1997. This again will provide input about possible modifications and improvements to the model.

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