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**Risk Management in Hospitals:
Predicting versus Reporting Risks in a Surgical Department**

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1. Abstract

Medical errors are increasingly unacceptable in modern society; for ethical reasons, but lately also because of a rising trend in the number and amount of damages paid to ex-patients. As a result, a large training hospital and the Eindhoven Safety Management Group have started a joint project "Risk Management in Hospitals". In this project, the PRISMA safety management approach based (see PRISMA paper of Van der Schaaf) on a decade of work in the chemical process and steel industry was tested in the domain of medical treatment.

The project consists of five stages:

1. a prediction of the possible risks to patients.
2. an inventory of the real risks to patients.
3. the development and implementation of a voluntary incident reporting system.
4. the development of a set of minimum norms which a surgical department has to satisfy.
5. the development and implementation of a quality system based on the two methods of predicting and registering incident causes and the norms developed, not only on the Surgical Department (SD) but on every ward of the hospital.

In the first stage, the processes on the SD were described using a systems approach by In 't Veld. The predictions of the risks were made by using the Failure Mode and Effects Analysis (FMEA)-method.

In the second stage, an inventory of actual incidents and their causes was made by using Critical Incident Interviews as an input to the PRISMA incident analysis approach. A comparison was made between the results of the FMEA and the Critical Incident Interviews, thus comparing predicted vs. reported risks.

Now (June 1995) the project is halfway stages three and four. In stage three, a pilot has been started on the SD with an operational incident reporting system. In stage four, the set of minimum norms for every ward will be developed and tested: this will happen in the next few months.

In the future, the two methods will be used to predict and report also medical complications, accidents and near accidents with regard to negative physical consequences for nurses and doctors, events with negative effects on the environment, and events that cause higher costs for the hospital.

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Important concepts are defined in the appendix.

2 Introduction

2.1 Motivation for the project

This risk management project is a joint project of the Eindhoven Safety Management Group and the Catharina Hospital in Eindhoven, The Netherlands. The Catharina Hospital is a large teaching hospital with a clinical Surgical Department (SD) consisting of ten operating theatres (about 11,500 clinical operations a year) where a wide range of operations is performed.

The goal of risk management is to control the processes patients are going through on a SD in order to minimize the risks for patients and to obtain better care.

Additional goals for risk management are:

- the trend of rising insurance premiums and
- future quality legislation.

2.2 The research design of the project

The project consists of five stages:

Stage 1: A prediction of the possible risks to patients. This stage is divided into two parts:

In the first part, a model was made of the processes that take place in the SD. The processes were described by the system approach (In 't Veld [10]). In the second part, a prediction of the possible risks to patients was made. The predictions were made by using FMEA (Failure Mode and Effects Analysis) [1][3].

Stage 2: An inventory of the real risks to patients. This second stage is divided into three parts. They provide a basis for the next stage: a voluntary incident reporting system which is a permanent risk management tool. In the first part, twenty Critical Incident Interviews were taken of which seventeen were useful and were described in detail by qualitative Causal Tree Analysis (see PRISMA paper of Van der Schaaf). In the second part of this stage, a comparison was made between the results of the FMEA and the Critical Incident Interviews. Finally in the last part, conclusions and recommendations were made on the basis of:

- the results and use of the process model;
- the results and use of the FMEA;
- the results and use of the Critical Incident Interviews;
- the results and use of the Eindhoven Classification Model;
- the results of the comparison between the FMEA and the Critical Incident Interviews.

Stage 3: The development and implementation of a voluntary incident reporting system [9]. This stage consists of three parts. The first part is a participant design with the SD staff of an incident reporting system based on the theoretical concept of a Near Miss Management System [8]. To make a participant design possible, several training sessions were held for nurses and doctors. In the second part a reporting system is set up. This implies a two month period in which the reporting system is actually operational under supervision of a member of the Safety Management Group. The goal is a fully autonomous reporting system after these two months. The last part of this stage is an evaluation, to improve the reporting system on the SD and decide on other future incident reporting systems on other wards in the hospital.

Stage 4: The development of a set of minimum norms which a ward has to satisfy. A surgical department must satisfy these norms to achieve process control and a maximum of safety for patients. This set describes what must be discussed, agreed and recorded between nurses and doctors at important policy making moments. It also forces the participants to decide and record not only who is authorized for certain tasks but also who is responsible.

Stage 5: The development and implementation of a quality system based on the two methods of predicting and registering incident causes and the norms developed, not only on the SD but on every

ward of the hospital.

3 Stage one: Predicting possible risks to patients

3.1 The process model of the Surgical Department

Three possible methods of describing the processes undergone by patients were examined:

- "SADT" (Structured Analysis and Design Techniques) [5];
- "Data Flow Diagramming" [2][3];
- "steady state" systems (system approach described by In 't Veld [10]).

The processes were finally described by the system approach [7]. The value of the "In 't Veld" method has been demonstrated in the construction of a process model for the SD. Strong points of the "In 't Veld" method are:

- processes are modelled in natural sequence (according to the time aspect in a flow);
- the possibility of using different aggregation levels;
- the use of measurement and control loops with norms.

This model must meet the following requirements:

- it must give insight into the processes that take place in the department;
- it must contain all aspects that are necessary and relevant for process control. These aspects are:
 - patient;
 - personnel:
 - medical;
 - nursing;
 - paramedical;
 - equipment;
 - instruments;
 - information;
 - interfaces (with other departments);
 - materials:
 - use;
 - consumption.
- it must be able to be used as an input to an assessment method for possible risks (FMEA, HazOp (: see section 3.2));
- it must give insight to all users so it can be used as a communication means between members of the project and others.

The process model of the Surgical Department consists of four main parts:

- 1 preparation of the patient;
- 2 anaesthesia;
- 3 operating on the patient and maintaining the anaesthesia;
- 4 recovery.

Each part is described by using the system approach of In 't Veld (see figure 1).

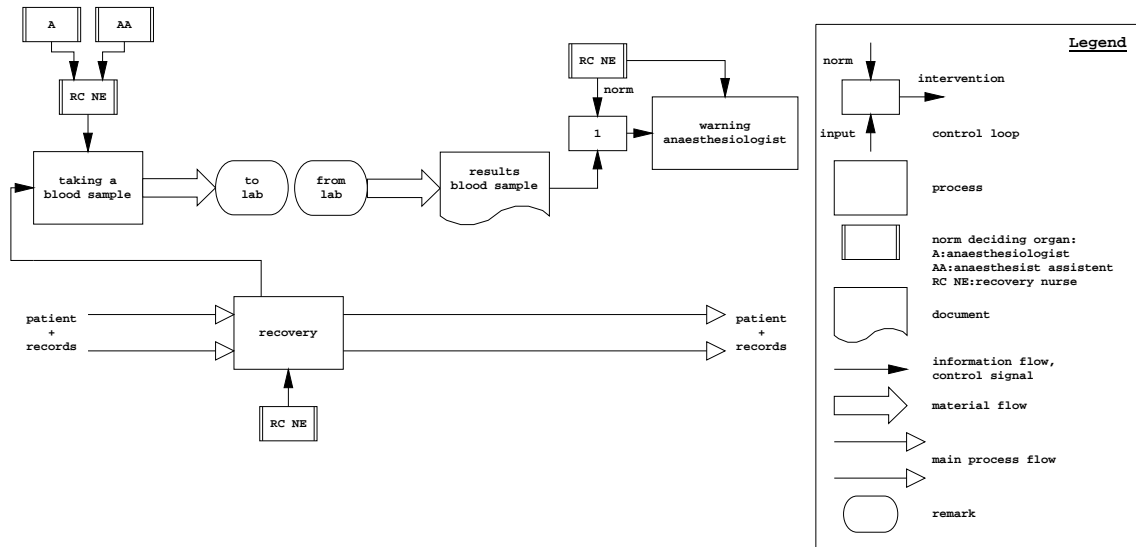


Figure 1 An example of the system approach of In 't Veld: a part from the process model of the SD (taken from the main part "recovery")

3.2 The assessment method for possible risks: the Failure Mode and Effects Analysis (FMEA)

Two possible methods for predicting the risks for patients were examined:

- FMEA [1][3];
- HazOp (Hazard and Operability) [2][3].

The predictions were finally made by using FMEA because of previous experience with the FMEA technique, and the absence of an experienced HazOp leader [7]. The main goal of the FMEA is to predict the nature and frequency of possible risks for patients on a SD.

FMEA is a technique which can be used on a system that can be separated into individual components. These components can be hardware blocks or functional blocks. The person who does the assessment should have a clear understanding of the functions of every component with all inputs and outputs. The failure modes of every component can be examined in a systematic way to establish the effects and causes of the failure modes. This information will be registered on a special form which contains the following columns:

- the failure mode(s) of every component;
- the effects of a certain failure mode;
- the seriousness of these effects;
- the causes of a failure mode;
- the frequency of occurrence of a certain cause;
- the extent to which a certain cause can be corrected.

The original FMEA concept works with one group which consists of members of all the relevant functions. Because of the extent of the group, however two groups were formed. The first group consisted of SD staff members holding functions belonging to the first, second and fourth part of the process model; they did the FMEA for the parts "preparation" and "recovery". The second group held functions belonging to the second and third part of the process model; they did the FMEA for the parts "anaesthesia" and "operating".

Every group did four two-hour sessions:

- the first session was held for the two groups together and consisted of a briefing about what would happen, when and how;

- the second session generated the failure modes, the possible effects and the seriousness of these effects;
- the third session generated the causes of the failure modes, the frequency of occurrence of these causes and the extent to which a certain cause can be corrected.
- the fourth session was used to generate counter measures for the causes with the highest RPN (Risk Priority Number = seriousness \times frequency \times extent of correction).

The results contain more than 800 causes. These causes were used as input to PRISMA, and classified according to the Eindhoven Classification Model so they can be compared with the results of the Critical Incident Interviews. The classification of the causes was done by three persons. They tried to reach consensus about the classification of a cause. The results were calculated in two forms:

- with a weight-factor for the estimated frequency (see figure 2). This weight-factor compensates the frequency of occurrence for a certain cause;
- without this weight-factor (see figure 3).

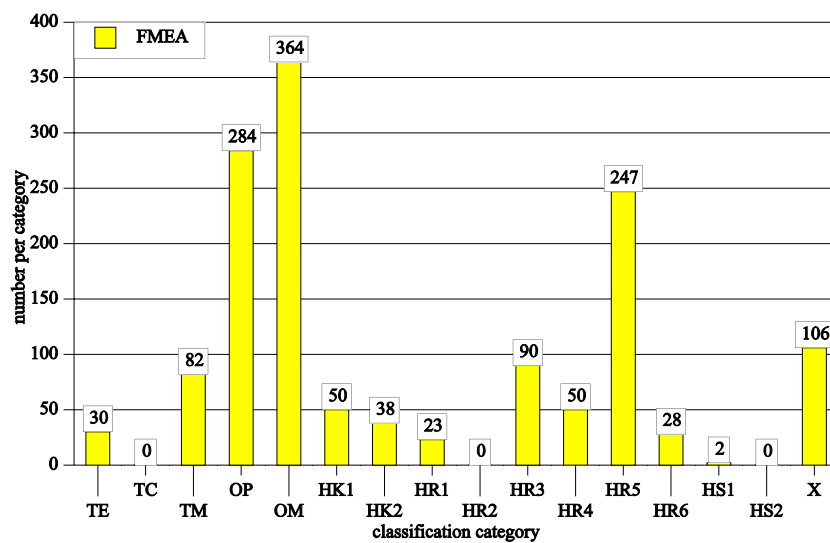


Figure 2 PRISMA profile of classified causes per classification category for both FMEA groups, combined with weight-factors: n=1394 (n=number of classified root causes)

As an important by-product, participating in the FMEA has raised the enthusiasm of the workers in the SD for the risk management project.

4 Stage two: Making an inventory of the real risks for patients

4.1 Critical Incident Interviews

Twenty Critical Incident Interviews (Flanagan [4]) were used to assess the real risks. This technique was used to collect confidential data about incidents, the Interview itself is also confidential.

The Interviews were intended to elicit information about accidents and near accidents which:

- happened recently;
- were closely experienced by the interviewee.

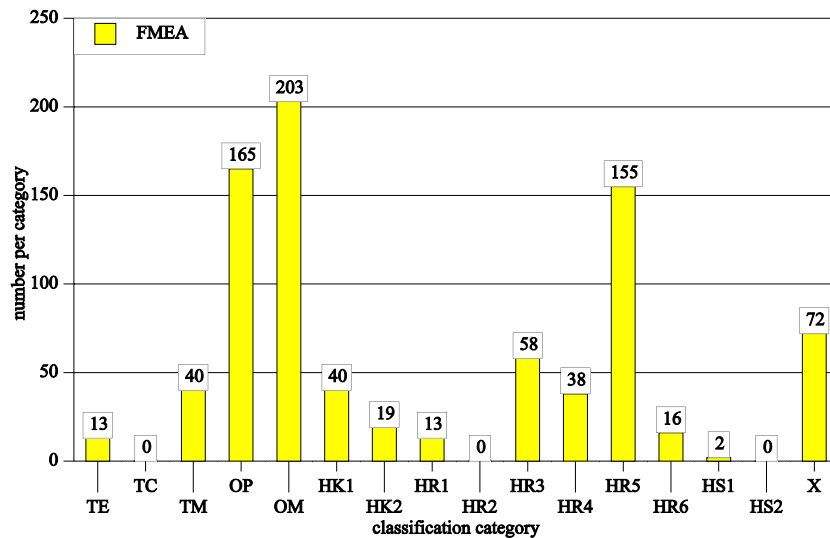


Figure 3 PRISMA profile of classified causes per classification category for both FMEA groups, combined without weight-factors: n=834

The main goal of the Interviews was to make an assessment of the nature and frequency of the risks for patients on the SD. In this way:

- a file was created which is used to get a provisional insight in the nature and frequency of the root causes of incidents on the SD;
- the value of the Eindhoven Classification Model for classifying the root causes of system failure on the SD was checked;
- a reference data base was created whereby:
 - the validity of the predictive FMEA method can be determined;
 - the quality (that is a check on reporting bias) of the future voluntary incident reports can be determined;
- an example could be given to the workers on the department to show them where a voluntary incident reporting system could lead to.

The Critical Incident Interviews were held in two sessions to check the consistency of the results. The first session yielded eleven usable Interviews and the second session six. At least one Interview was held for every kind of function in the SD.

The participants of the FMEA-sessions and the Critical Incident Interviews consisted of two separate groups, except only one person which took part of both the FMEA-sessions and a Critical Incident Interview because this was impossible to avoid.

The 17 usable Critical Incident Interviews were used as input to PRISMA:

1. A Causal Tree Analysis was made from all the Interviews and they were reviewed by the interviewer and the person who was interviewed. When events and/or relations were wrong or forgotten, the Causal Tree was altered.
2. The results of the Critical Incident Interviews yielded 95 root causes (see figure 4: n_{cii} =number of Critical Incident Interviews). The classification of these root causes was done by the same three persons who classified the causes found by the FMEA. The classification was done in the same way as for the FMEA: the classification team members tried to reach consensus about the classification of a root cause.

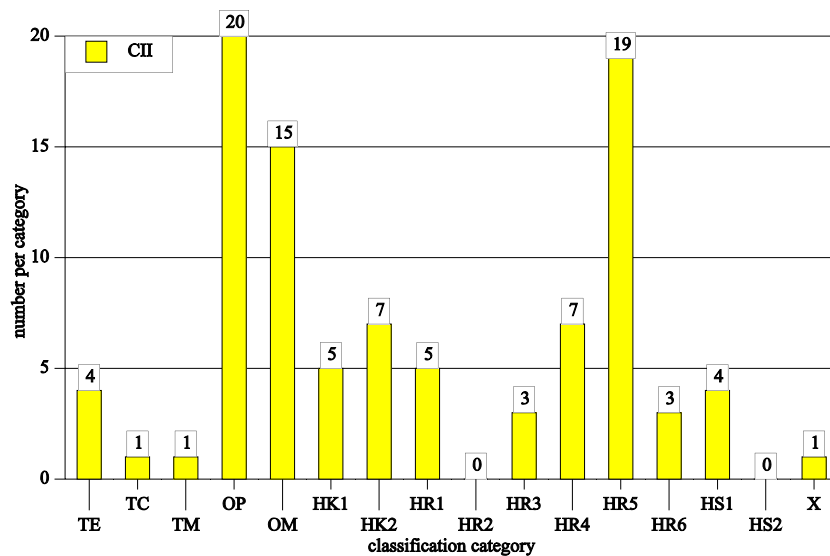


Figure 4 PRISMA profile of classified CII root causes per classification category: $n_{cii}=17$ and $n=95$

The most important results of the Critical Incident Interviews:

- the major part of the incidents is not reported to the FONA commission (FONA: Faults, Accidents and Near Accidents) and therefore unknown to the hospital's management;
- every incident has one or more recovery factors. More than $\frac{1}{3}$ of these factors did not lead to successful and complete recovery. The main reason for this is that medical doctors are not listening to recovery oriented remarks of nursing staff;
- a list of systematic failures was made during the Critical Incident Interviews so measures can be taken to eliminate these systematic failures;
- PRISMA is applicable to medical incidents in a SD [6].

Further research on how to integrate and standardise the legally required FONA reports and the voluntary incident reporting system is recommended.

4.2 Comparison between the PRISMA profiles of FMEA and Critical Incident Interviews

Four comparisons were made:

1. between the results of the complete FMEA with weight-factors and the results of all Critical Incident Interviews;
2. between the results of the complete FMEA without weight-factors and the results of all Critical Incident Interviews;
3. between the results of the "anaesthesia" and "operating" sessions of the FMEA without weight-factors and the "anaesthesia" and "operating" results of the Critical Incident Interviews;
4. between the results of the "anaesthesia" and "operating" sessions of the FMEA with weight-factors and the "anaesthesia" and "operating" results of the Critical Incident Interviews.

Comparison 3 and 4 were made for two reasons: first to see if it was possible to make a comparison between the results of the two methods on sub department level (that is the sections "anaesthesia" and "operating") and second, because there were enough Critical Incident Interviews ($n_{cii}= 13$) available to make such a comparison possible.

The result of the statistical comparisons is that Spearman's rank correlation coefficients are almost 5% significant (comparison 1 and 2), 5% significant (comparison 3) or even 2,5% significant (comparison 4).

As can be seen in figures 2, 3 and 4, the three classification categories with the most causes are the

same for both methods: the organisational factors "operating procedures" (ECM: OP) and "management priorities" (ECM: OM), and the human behaviour factor "planning" (ECM: HR 5).

This stage has demonstrated the potential of a voluntary incident reporting system.

5 Stage 3: The voluntary incident reporting system

The first part is the designing of an incident reporting system based on the theoretical concept of a Near Miss Management System (see also the PRISMA paper) whereby a participant approach is used. Because of this approach, the preferences of the SD can, if possible, be included in the system. In this way the acceptance and success of the system are enlarged. A commission has been appointed which designs the incident reporting system and controls the system when it is operational (this commission is further called the incident reporting commission). It consists of four nurses (which together cover all four main parts of the processes on the SD) and an anaesthesiologist and surgeon as representation of the doctors on the SD. The incident reporting commission was trained in several sessions how to analyse incidents using the PRISMA tools. In this way, they were able to participate in the design of the incident reporting system.

The second part is the setup of an operational reporting system. During the first two months, incidents will be handled by the incident reporting commission under supervision of a member of the Safety Management Group, not only to help the commission but also to alter the design of the reporting system when this is necessary after the evaluation. This evaluation after the first two months is not only to improve the reporting system on the SD but also to get a better starting position for future incident reporting systems on other wards in the hospital. The second and the last part of this stage are still in progress.

6 Stage 4: The development of a set of internal certification norms

The question behind the development of a set of minimum norms is whether it is possible to design a structure and norms which must be satisfied to assure process control for the medical and nursing processes on the ward.

A theoretical framework for a clinical treatment and nursing flow is given in figure 5 [11]. Every policy making moment has a medical and nursing component. A policy making moment must lead to an activity plan. This activity plan consists of a list of activities for doctors and nurses. The relevant doctors and nurses agree and record for every action who is authorized and who is responsible.

This stage of the research is also still in progress but it seems feasible to design a structure like the one in figure 5, as well as establish "quick-scan" norms to achieve a list of uncontrolled processes which can be altered to enlarge the reliability.

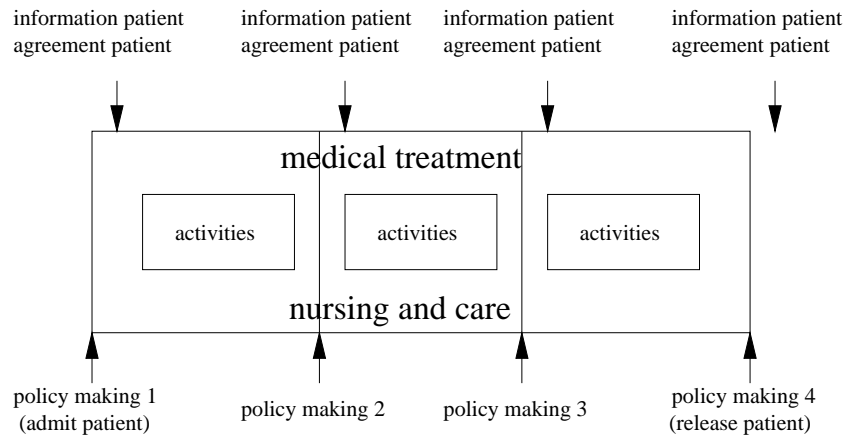


Figure 5 Clinical treatment and nursing flow [11]

7 Stage 5: The development and implementation of a quality system

It is possible to create a quality system with the two risk management instruments (FMEA and incident reporting system) and the quick scan list of norms. The quality system will not be only developed and implemented on the SD but on every ward of the hospital.

Eventually, the process deviation consequences on which the quality system will focus, shall be broadened to include not only unwanted physical consequences for a patiënt but also incidents with regard to negative physical consequences for nurses and doctors, events with negative effects on the environment, and events that cause higher costs for the hospital.

8 Literature

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Appendix: Definitions of important concepts

The following definitions are used:

- Risk
The possible events leading to process deviations which can have unwanted physical effects for the patient.
 - Risk management
Striving after process control in a systematic way to minimize the risks for patients.
 - Process deviation
Every deviation from normal in the process which can have unwanted physical effects for the patient; this consists of:
 - all accidents;
 - all near accidents;
 - all complications.
 - Incident
This consists of:
 - all near accidents;
 - all accidents.
 - Complication
A process deviation with temporary or permanent negative physical consequences for the patient of which the cause is unknown.
- Because complications need another management system (based on modelling: causes unknown (also see Van der Schaaf [8])) than incidents (based on monitoring), they are not included in this project.
- Accident
A process deviation that is not a complication and that leads to temporary or permanent negative physical consequences for the patient.
 - Near accident / near miss
A potential accident that
 - either by active (human) intervention
 - or by chance
 turns out well.

- Recovery
The active (human) intervention and/or the chance whereby a potential accident results in:
 - a near accident or
 - a much smaller accident (where the temporary and/or permanent effects were limited).
- Voluntary incident reporting system
A Near Miss Management System (Van der Schaaf [8]), based on monitoring. In such a system the root causes of near accidents and of actual accidents are:
 - classified,
 - registered and
 - analysedwith the purpose of learning from these incidents to prevent or limit the effects of future incidents.
- PRISMA (Prevention and Recovery Information System for Monitoring and Analysis)
Safety management and incident analysis tool-kit, consisting of:
 - Causal Tree Analysis to obtain the root causes of an incident;
 - the Eindhoven Classification Model to classify root causes in order to create structure in the enormous variety of root causes;
 - the Classification/Action Matrix which suggests effective countermeasures (see also PRISMA paper of Van der Schaaf).