Propositions
as a supplement to the thesis
‘Theory and practice of in-hospital patient risk management’
N.W.S. van der Hoeff
Delft, 10 November 2003

1. From a historical perspective, more attention has been paid to risk management by insurance companies than by the health care sector. (This thesis, chapter 1.)

2. Methods for listing and analysing risks enable us to get a complete picture of the incident and its causes so that prevention becomes possible. (This thesis, chapter 3–7.)

3. Risk management monitors the condition and performance of the quality system. (This thesis, chapters 3 and 8.)

4. It is impossible to determine the actual number of incidents in a hospital.

5. Focusing exclusively on errors and shortcomings is like drinking institutional coffee: one gets used to it. (Adapted from a statement by G. Op de Weegh.)

6. To err is human, to learn from one’s errors apparently is not.

7. How free is free trade if unofficial imports, bypassing official importers, are prohibited?

8. A computer virus is outright system pollution.

9. Being emancipated is not that easy for men or women.

10. A sceptic is not a doubter but someone who investigates. (Luc de Clapiers, Marquis de Vauvenargues, French philosopher, 1715–1747)

These propositions are considered defendable and as such have been approved by the supervisors,

Prof. dr. mr. dr. B.A.J.M. de Mol
Prof. dr. A.R. Hale
Stellingen
behorende bij het proefschrift
‘Theory and practice of in-hospital patient risk management’
N.W.S. van der Hooff
Delft, 10 november 2003

1. Historisch gezien is er meer aandacht voor risicomanagement vanuit de verzekeringssector dan vanuit de zorgsector. (Dit proefschrift, hoofdstuk 1.)

2. Methoden voor het inventariseren en analyseren van risico’s maken het mogelijk om een volledig beeld te krijgen van het incident en zijn oorzaken zodat preventie mogelijk wordt. (Dit proefschrift, hoofdstukken 3–7.)

3. Risicomanagement ‘mondert’ de toestand en effectiviteit van het kwaliteitssysteem. (Dit proefschrift, hoofdstukken 3 en 8.)

4. Het werkelijk aantal incidenten binnen een ziekenhuis is niet te bepalen.

5. Het uitsluitend signaleren van fouten en tekortschieten is als het drinken van instellingskoffie: het went. (Naar een stelling van G. Op de Weegh.)

6. Fouten maken is menselijk, leren van fouten blijkaar niet.

7. Hoe vrij is vrije handel als parallelimport niet is toegestaan?

8. Een computervirus is systeemvervuiling pur sang.

9. Het valt voor zowel mannen als vrouwen niet mee om geëmancipeerd te zijn.

10. Een scepticus is niet iemand die twijfelt, maar iemand die onderzoek. (Luc de Clapiers, marquis de Vauvenargues, Frans filosoof, 1715–1747)

Deze stellingen worden verdedigbaar geacht en zijn als zodanig goedgekeurd door de promotoren,

Prof. dr. mr. dr. B.A.J.M. de Mol
Prof. dr. A.R. Hale
NB!

CD Rom is bylage!
Theory and practice of in-hospital patient risk management
Proefschrift

ter verkrijging van de graad van doctor
aan de Technische Universiteit Delft,
op gezag van de Rector Magnificus prof. dr. ir. J.T. Fokkema,
voorzitter van het College voor Promoties,
in het openbaar te verdedigen op

maandag 10 november 2003
om 13:00 uur

doors

Nicolaas Wilhelmus Sebastiaan van der Hoef

technisch bedrijfskundig ingenieur
geboren te Culemborg.
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Prof. dr. A.R. Hale

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Dr. T.W. van der Schaaf, Technische Universiteit Eindhoven
Prof. dr. B.J.M. Ale, Technische Universiteit Delft, reservelid

Drs. G.J. Op de Weegh heeft als begeleider in belangrijke mate aan de totstandkoming van het proefschrift bijgedragen.

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All rights reserved. No part of this book may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying, recording or by any other information storage and retrieval system, without permission from the author.
This thesis is dedicated to Cheryl, Els, Gerard, Joyce and Riet, and
to Selena, Brendan and Sue-Ann: supercalifragilisticexpialidocious!

The road to wisdom?
Well, it's plain and simple to express:
Err
and err
and err again
but less
and less
and less.

Colophon

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Preface

This report is about the risk management research conducted at the Catharina Hospital in Eindhoven, the Netherlands; it has been written in such a way that it should be possible to replicate the research in other hospitals. Therefore, many data have been included to provide an insight into the modus operandi of the research, although a selection of data had to be made for obvious reasons, because otherwise this thesis would have become far too bulky. Any remarks, comments and questions will be welcome.

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<th>Description</th>
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<tr>
<td>APD</td>
<td>Automatic Peritoneal Dialysis</td>
</tr>
<tr>
<td>Arbo</td>
<td>‘ARBeidsOmstandigheden’, in English ‘working conditions’ or ‘occupational health and safety’</td>
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<tr>
<td>A &amp; E</td>
<td>Accident and Emergency</td>
</tr>
<tr>
<td>BW</td>
<td>‘Burgerlijk Wetboek’, in English ‘civil law’</td>
</tr>
<tr>
<td>CAPD</td>
<td>Continuous Ambulant Peritoneal Dialysis</td>
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<tr>
<td>CAVHD</td>
<td>Continuous Arterial Venous HaemoDialysis</td>
</tr>
<tr>
<td>CCU</td>
<td>Coronary Care Unit</td>
</tr>
<tr>
<td>CII</td>
<td>Critical Incident Interview</td>
</tr>
<tr>
<td>CIRMS</td>
<td>Complication and Incident Reporting and Management System</td>
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<tr>
<td>CSD</td>
<td>Central Sterilisation Department, in Dutch ‘CSA’ or ‘Centrale Sterilisatie Afdeling’ (see also <em>NedSter</em> which became the successor to the CSD)</td>
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<tr>
<td>CTA</td>
<td>Causal Tree Analysis</td>
</tr>
<tr>
<td>CVVH</td>
<td>Continuous Venous Venous Haemofiltration</td>
</tr>
<tr>
<td>DPA</td>
<td>Data Protection Act, in Dutch ‘WPR’ or ‘Wet op de PersoonsRegistratie’</td>
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<tr>
<td>E.N.T.</td>
<td>Ear, Nose and Throat</td>
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<td>ECM</td>
<td>Eindhoven Classification Model of system failure</td>
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<td>EPO</td>
<td>ErythroPOietin</td>
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<td>Eindhoven University of Technology</td>
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<td>fig.</td>
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<td>FMEA</td>
<td>Failure Mode and Effects Analysis</td>
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<tr>
<td>FONA</td>
<td>‘Fouten, Ongevallen en Near Accidents’, in English ‘errors, accidents and near accidents’</td>
</tr>
<tr>
<td>FTA</td>
<td>Fault Tree Analysis</td>
</tr>
<tr>
<td>FTE</td>
<td>Full-Time Equivalent</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<tr>
<td>HazOp</td>
<td>Hazard and Operability study</td>
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<tr>
<td>HFMEA</td>
<td>Health care Failure Mode and Effects Analysis</td>
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<tr>
<td>hr(s)</td>
<td>hour(s)</td>
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<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>IP</td>
<td>Identification Patient</td>
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xxiv  Abbreviations and acronyms

IRMS  Incident Reporting and Management System
ISO  International Organization for Standardization
MDO  'MultiDisciplinair Overleg', in English 'Multidisciplinary Consultation'
Medimath  automatic supply system of the Catharina Hospital named after the cabinet for the storage of certain materials
min.  minute(s)
MORT  Management Oversight and Risk Tree
MRSA  Multi Resistant Staphylococcus Aureus
Ms, six  see six Ms
MTCA  Medical Treatment Contracts Act, in Dutch 'WGBO' or 'Wet op de Geneeskundige BehandelingsOvereenkomst'
n  number
NedSter  company responsible for the sterilisation of instruments in the OR of the Catharina Hospital (see also CSD which was the predecessor of NedSter)
NEN  'NEDerlandse Norm', in English 'Dutch standard'
NIAZ  'Nederlands Instituut voor Accreditatie van Ziekenhuizen', in English 'Dutch Institute for the Accreditation of Hospitals'
NPR  'Nederlandse Praktijk Richtlijn', in English 'Dutch Practice Guideline'
nr  number
NZR  'Nationale Ziekenhuis Raad', in English 'National Hospital Council'
OR  function group Operating Room
p  power of a test
p.  page
PACE  'Proefproject ACcreditatIE ziekenhuizen', in English 'Pilot Project Accreditation Hospitals'
PD  Peritoneal Dialysis
pp.  pages
P & O  Human Resources Department
R.O.  Reversed Osmosis
RiMaZ  'RIlsicoMANagement in Ziekenhuizen', in English 'risk management in hospitals' (or 'RIlsicoManagement in Academische Ziekenhuizen', in English 'risk management in university medical centres' [80])
RPN  Risk Priority Number
S.D.  Standard Deviation
SADT  Structured Analysis and Design Technique
SINS  Systematic Incident Notification System
six Ms  Man, Machine, Method, Material, Measurement, Milieu
<table>
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Part I

Introduction and methods
General introduction

1.1 Introduction

This chapter provides a brief introduction to the research project, starting with the motives for undertaking it in section 1.2. A definition of risk management and reasons for implementing hospital risk management are discussed in section 1.3. In section 1.4, a brief overview is given of relevant hospital risk management issues mentioned in literature in general, keeping in mind especially the risk management framework which will be discussed in section 3.4. A summary description of the context of this research is given in section 1.5, viz. the health care situation in the Netherlands and at the Catharina Hospital. The chapter ends with an overview of the thesis, both with regard to its contents and to its research path, in section 1.6.

1.2 The motives for this research

The reduction of patient risks was the initial objective of this research. The research was initiated in the wake of the cancellation of a larger risk management project which had been designed to involve a number of hospitals, the so-called RiMaZ project, see also Koornneef [80]. The research took place in the Operating Room (OR) and Haemodialysis departments of the Catharina Hospital in Eindhoven, the Netherlands. These two departments were selected because they had originally been earmarked for participation in the RiMaZ project and wished to go ahead with the project in spite of its cancellation.

The aim of this thesis is to determine the structural causes of incidents and their potential as instructive lessons for preventing future incidents. Its main focus is on incidents and failure modes reported by doctors, nurses and paramedics, rather than on estimating patient injury or possible legal claims or complaints. For this purpose the use of voluntary incident reports was preferred because of the presence of contextual information (see section 1.4).

1 RiMaZ stands for ‘RIsicoMAngement in Ziekenhuizen’, in English ‘risk management in hospitals’ (or ‘RIsicoManagement in Academische Ziekenhuizen’, in English ‘risk management in university medical centres’ [80]).

2 The Harvard Medical Practice Study shows that ‘the vast majority of adverse events do not form the basis of a complaint or claim’ [103].
The reduction of patient risks can be broken down into roughly two parts: the assessment of risks and the organisational learning from the risks found. The main point of this thesis is the assessment of risks while the recent dissertation of Koornneef [80]—also by the Delft Safety Science Group—focuses more on the organised and organisational learning from assessed risks.

The reasons underlying this research are mentioned in the boxed text on the facing page. Because of the cancellation of the RiMaZ project, the Catharina Hospital decided to start its own risk management project with the help of the Eindhoven University of Technology (EUT) and the Delft University of Technology. It did so because of the hospital’s growing realisation that risk management was necessary in order to improve the safety and quality of care.

This research project (as indeed does any project) took place within certain (financial, organisational, staffing) constraints: for instance, one researcher holding a temporary appointment in the pay of the hospital, with support from the Eindhoven and Delft Universities of Technology. The research project was carried out independently of the regular processing of incidents reported to the FONA committee. This was considered an essential prerequisite in order to avoid interference with regular practice and to ensure the cooperation of employees and doctors.

So at the beginning of 1994, the Catharina Hospital started a risk management project in the OR which ran until 1997. The next project in the Haemodialysis department took place in 1997 and 1998. Although project evaluation was an integral part of the project from the very beginning, the actual evaluation continued throughout the period 1998–2001.

Two literature reviews carried out at the beginning of 1994, see section 1.4, did not produce a lot of information which was directly applicable to the use of preventive risk management methods in hospitals. Hence a risk management framework was constructed consisting of a number of risk management tools which can be used for the assessment, analysis and prevention of incidents—and, if possible, of complications (see section 3.4, especially figure 3.7 on page 64). These risk management tools—or methods—were used in the OR and Haemodialysis departments.

3 In this thesis, the term ‘risk management method’ is used for a variety of methods, tools and models such as risk assessment methods (e.g. Failure Mode and Effects Analysis (FMEA), Critical Incident Interviews (CIIs)), analysis tools (e.g. Causal Tree Analysis (CTA)), and classification and description models (e.g. the Eindhoven Classification Model (ECM) for classifying causes, a process model for describing the processes within a system).
1.2 The motives for this research

Reasons for risk management research—partly derived from the reasons for risk management in hospitals mentioned in section 1.3.2—are:

- Trying to prevent incidents and complications as much as possible because they can result in high costs for society (e.g. for a hospital), for the insurance companies (both for the third-party and medical insurers), for the patient and the patient’s family, for the doctors and nurses. Prevention is better than cure. In this way, the hospital tries to call a halt to or to have a beneficial effect on the annually increasing costs of third-party insurance for the hospital.

- In order to meet the requirements of new (quality) legislation, the development and implementation of quality control systems is necessary. Risk management and risk management control systems are a necessary (initial) step towards meeting these quality requirements; at the same time, they constitute an important component of these quality requirements. Preventive risk management in particular is a necessary and therefore important part of (quality) management. Both risk and quality management in health care organisations are still largely at the development stage. The focus of this research is on structural causes of process deviations.

- In order to learn from incidents and complications, the management should know the frequency and nature of incidents and complications that occur, and what their structural causes are. One or more methods should be made available to assess and analyse incidents and complications and consequently the risks for patients.

- A model is necessary for the explanation of the development of incidents and complications. The engineering approach using system theory [166] can be used in which incidents and complications are seen both as process deviations and as the result of process deviations.
1.3 Risk management

In this section, a definition of risk management which will be used in this thesis, is given, and reasons why a hospital would commit itself to risk management are presented.

1.3.1 Definition of risk management

In this thesis, risk management is 'the systematic and continuous process of controlling activities to reduce the risk of incidents and complications for patients to a level as low as possible'. From this point of view the term 'risk control' is maybe a better term than 'risk management' but in order to keep this thesis in line with similar research and to maintain its connection with and its relation to (quality) management clearly recognisable, the term 'risk management' is preferred and used in this thesis.

1.3.2 Reasons for risk management in hospitals

Learning from errors To err is human and—unfortunately—often a necessary condition for progress. Making mistakes provides an opportunity for learning, so that in the future the same mistakes will not have to happen again. Errors may lead to medical incidents and to learn from them ideally means that incidents must be analysed and discussed. This is often not possible because errors tend to be suppressed, because of the seriousness of the effects on the patient and the patient's family, for the doctors and nurses, and for the hospital. The culture of medical practice—a powerful emphasis on the perfection of diagnosis and treatment, making mistakes is unacceptable—makes it difficult for doctors to deal with human errors, and to admit and discuss them [64, 90, 95, 186]. So, learning from incidents does not take place. This change in the way of thinking about incidents and a change of internal culture are both a reason and a prerequisite for risk management.

Legal requirements The second reason for risk management is changes in Dutch legislation over the last few years, e.g.:

- The Individual Health Care Profession Act (in Dutch 'Wet BIG': 'Wet op de Beroepen in de Individuele Gezondheidszorg') came into effect on 9 November 1993 [99].

- The Medical Treatment Contracts Act (MTCA or in Dutch 'WBGO': 'Wet op de Geneeskundige BehandelingsOvereenkomst') came into effect on 1 April 1995[100].

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4Based on conventional wisdom of proverbs such as 'experience is the best teacher' (in Dutch 'al doende leert men') and 'practice makes perfect'. See e.g. also [2, 9].
• The Client's Right of Complaint (Care Sector) Act (in Dutch 'Wet Klachtrecht Cliënten Zorgsector') came into effect on 1 August 1995 [101].

• The Care Institutions Quality Act (in Dutch: 'Kwaliteitswet Zorginstellingen') came into effect on 1 April 1996 [101].

• The Participation (of Clients of Care Institutions) Act (in Dutch: 'wet Medezeggenschap Cliënten Zorgsector') came into effect on 1 June 1996 [101].

All this legislation emphasises the importance of good quality management and good quality of care, and lays down general but minimum requirements for quality management. See also chapter 2.

**Increasing insurance premiums** A third reason for risk management is increases in the hospital’s third-party liability premiums over the last few years. By developing and implementing risk management methods, techniques and systems, the hospital attempts to check this trend.

**High costs of incidents and complications** A fourth reason for risk management is the fact that, regardless of whether there is a third-party liability question, the effects of incidents and complications result in high costs (see e.g. [5, 31, 109, 128, 135, 142, 188]).

**Moral duty to develop risk management** The last reason for risk management is that hospitals have, of course, the moral duty to engage in continuous quality management and therefore risk management, for instance to continuously improve the process reliability to minimise the risks for patients. Because fully-fledged, effective quality management and risk management in hospitals are still in their infancy (see also section 1.4), these will have to be designed and developed.

1.4 Risk management in literature and the risk management framework

In this section, a brief overview is given of relevant hospital risk management issues mentioned in literature in general, focusing particularly on the risk management framework which will be discussed in section 3.4. The focus is on preventive hospital risk management based on process control and system thinking, in order to prevent patient incidents: the focus of this research is neither on financial risk management—liability, (complaint) settlement, claims and financial damage control for the hospital—nor on occupational risk management for doctors, nurses and paramedics.
Preventive hospital risk management: not much directly applicable information to be found in literature This research started in 1994 with two literature reviews about preventive risk management in hospitals [148, 150]. The literature reviews were carried out by an article review via Medline and by reviewing human factors literature. The result was disappointing from the view of finding a directly applicable and effective risk management method: little directly applicable information could be found in literature about the use of preventive risk management methods in hospitals. Of course there have been wide-ranging studies of iatrogenic adverse effects like the Harvard Medical Practice Study\(^5\) [18, 89], but this was initiated to address concerns about the economic impact of iatrogenic adverse effects on health care insurers [133] and not about management opportunities from the point of view of the hospital. The Harvard Medical Practice Study is, like the Quality in Australian Health Care Study,\(^6\) a ‘snapshot’ study, and ‘no “snapshot” study to date has been followed by a series of interventions and a post-intervention analysis. One must assume that the impetus that led to the initial studies has passed, and hence that much of their value related to the monitoring of change has therefore been lost’ [181]. Or, put another way, ‘many studies that have been replicated over the years point, over and over again, to the same patterns of error. Yet there is not strong evidence that the findings lead to improved clinical practice’ [103]. Of late—as a result of the public awareness in the USA about patient safety caused by the report ‘To Err Is Human’ [78] released by the Institute of Medicine (see also chapter 8)—the New England Journal of Medicine has begun a series on patient safety [84], see e.g. [14, 22, 56, 87, 91, 168, 173].

Reasons for preventive hospital risk management mentioned in literature Reasons which make it necessary to initiate preventive risk management are found in ample measure in literature [1, 12, 78]. E.g.:

- Realising the reduction of the error rate in medicine which ‘is substantially higher than that tolerated in other risk-laden industries such as aviation or nuclear power’ [103].

- The enormous costs of medical mishaps [138].

- The epidemiology of medical mishaps which is underdeveloped [103].

- Doing research into methods for reducing the number of adverse events [181].

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\(^5\)Retrospective medical record review for more than 30,000 patients hospitalised in 51 hospitals in the state of New York in 1984, see e.g. [89].

\(^6\)Retrospective medical record review of over 14,000 admissions in 1992 [182].
Retrospective medical record review versus voluntary incident reporting  Record review can be used to estimate the extent of under-reporting in the case of voluntary incident reporting: the Quality in Australian Health Care Study shows that only 13% of all adverse events were recorded in the data collection of the Australian Incident Monitoring Study\(^7\) [130, 178, 181], which clearly shows the problem of under-reporting of voluntary incident reporting systems (see e.g. also [137]). Wilson et al. [181] therefore plead for a retrospective review of medical records as the most reliable method for estimating patient injury caused by health care. However, O’Neil et al. [114] compared physician reporting with medical record review and found that reporting uncovered as many incidents as did record review, and that reported incidents are more likely to be preventable. Disadvantages of the retrospective medical record review method are high costs and little contextual information in comparison with incident reports which provide the contextual information necessary to determine the causes of incidents [114, 181]. Because the voluntary incident reporting method is the cheapest method [181], and because of the aim and the limited resources available for this project, its voluntary character [27] and the presence of contextual information about incidents, the voluntary incident reporting method had more advantages for this research than the retrospective record review method. All the more so because the focus of this research is on the detection of structural causes of incidents, causes which are likely to recur because they are built into the system, and not on estimating patient injury (i.e. effects). See also Leape [86] who writes that ‘successful accident prevention effort must focus on root causes—system errors in design and implementation’.

Reason [122, 124] argues that accident reporting systems provide data which are ‘too little and too late’ in the causal sequence. This is why incidents\(^8\) need to be reported and analysed. Near accidents in particular contain valuable information [122, 154] about what can be learned to prevent future incidents, see also chapter 3. However, this research shows that it is possible to determine—even in the case of a single incident—whether certain elements in the cause-effect path have structural elements and are therefore very likely to happen again in the future, resulting in the same—or different—kind of incident. Therefore, a combination of retrospective and prospective methods is used in this research, see the risk management framework in figure 3.7 on page 64.

Lessons from industry  Lessons which can be learned from industry are that the savings from the reduction of errors and accidents more than make up for the costs of data collection and investigation, that much can be learned from cause analysis, and that a

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\(^7\)More than 2,000 reported incidents by 90 Australian hospitals.

\(^8\)See the definition of ‘incident’ in section 3.2.
lot can be learned about ways of adopting a systemic approach to mishaps based on human factors research and cognitive psychology [4, 103, 156], see also chapter 3.

**Health care professionals and dealing with errors**  Professionals in health care may have a problem in dealing with errors [42, 86, 118]. Errors may go unrecognised or may be covered up because the professional is afraid to jeopardise his\(^9\) career or that of a colleague. Because of the responsibility health care professionals have towards patients, they have to strive for perfection. Of course, from this point of view, errors cannot be tolerated. However, every professional knows that perfection is impossible and that errors will be made. Striving for perfection implies learning from (inevitable) errors. This means that errors will have to be admitted. This may be problematic with regard to possible liability, and can even be a danger for the professional’s career. In order to learn from the errors that occur, it should be possible to discuss these errors without the continuous threat of possible consequences for the professional. This was achieved by using the incident data and conclusions for internal purposes only (see chapters 4, 5, 6 and 7, and e.g. section 3.4.9).

It is generally assumed that medical quality is a function of the competence and integrity of individuals [85, 133], but many aspects of patient care are beyond what can be influenced by the professional [133]. The conditions which contribute significantly to the development of incidents are provided by system failure and poor system or job design [133]. Therefore, not (only) individual failure factors but especially system failure must be the focus of risk management. Literature reviews show that system failures contribute significantly to the development of incidents (e.g. [88]).

**Risk management framework for managing errors and incident prevention**  In many studies, like the Harvard Medical Practice Study [90], it is found that most iatrogenic injuries are potentially preventable because they are due to errors [7, 90] and poor system design [85], in other words that incidents and complications\(^10\) are—at least partly—preventable. Leape [90] concludes as a result of the Harvard Medical Malpractice Study that 69% of iatrogenic adverse effects were due to potentially preventable errors. Others also report about the preventability of errors in hospitals. See e.g. for anaesthesia-related errors Cooper et al. [30] about preventable errors causing major adverse events associated with anaesthesia, and Chopra et al. [25] who found that 82% of 549 voluntarily

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\(^9\)For practical reasons, ‘his’ is used but wherever in this thesis ‘he’, ‘his’ and ‘him’ are used, this should be read as ‘he/she’, ‘his/her’ and ‘him/her’ respectively.

\(^{10}\)Because there is no standard terminology, the concepts ‘incident’ and ‘complication’ are used in this thesis—see section 3.2 for definitions—instead of the huge variety of terms which are used in literature to describe medical mishaps and related phenomena [42, 103].
reported observations during a period of 18 months were considered to be preventable. See e.g. for drugs-related errors Bedell et al. [7] about errors in medication which were responsible for preventable cardiac arrests in a study at a teaching hospital, or a study about adverse drug events showing that 42% of life-threatening and serious adverse drug events were judged to be the result of preventable errors [5, 88].

So, if incidents are—at least partly—preventable, it would be advisable to analyse incidents to learn from their structural causes and to put these causes right, and thus to prevent the occurrence of future incidents. An incident can therefore be viewed as an opportunity for obtaining information in order to make a system safer [10, 86].

In order to be able to learn from incidents (see also the above-mentioned thesis by Koornneef [80]), this research presents a framework for assessing and analysing incidents (see e.g. section 3.4). A precondition is that there must be an internal culture in which effective risk management is possible, in other words, there should be an atmosphere of confidence and trust about risk management between management and doctors, nurses and paramedics [103].

But what about incidents which, at first sight, might be expected not to be preventable because some causes cannot be anticipated, e.g. because they are unpredictable or unintended, like ‘forgetting’ [125]? Recent research and insights claim that these causes can also be managed [86, 103]. Reason [125] writes in this context about ‘managing the manageable’: organisational factors which can be influenced by system operators and managers. The focus should not be on individual but on organisational and situational failure.

So, it may be hypothesised that the vast majority of all incidents are preventable because they are caused by one or more preventable causes and therefore can be managed. In order to achieve this, this research presents a risk management framework in section 3.4. The risk management system has to focus on system failure and especially on structural failure factors which cause incidents time and again. This means a focus on the design of systems and processes which cause failure, risks and incidents. Incidents and failure modes are therefore assessed and analysed in order to learn from them: they are a mine of information [12] [42], although largely wasted in practice [103].

The focus on system failure for risk management also becomes apparent from literature [42]. System factors as causes of errors are first and mainly recognised in anaesthesiology, see e.g. [30, 52, 53, 54, 148, 124, 180]. In a study of in-hospital adverse drug events, it was found that system failure accounts for 78% of harmful errors [88].

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11See e.g. also Cromheecke [33] who recently did a multidisciplinary study on the safety management of mechanical heart valve protheses.

12‘Every defect is a treasure’ [10].
Individual failure: system failure  Sharpe and Faden [133] conclude that the design of systems, processes and policies is the principal locus of quality failure, and not the individual: blaming the individual at what Reason [125] calls 'the sharp end' has little or no remedial value.13 Mulcahy and Rosenthal [42, 103] make a plea to look also but not entirely—which is unfortunately often the case—at individual failure. Dearden and Rutherford [38] found that harmful errors were made by inexperienced, junior doctors being on duty outside the regular office hours because of staffing arrangements. Job overload, hospital policy that allows doctors in training to make long working hours, policy that does not provide sufficient supervision of doctors in training, are also mentioned in literature [133, 187] and can, since they are organisational failures, result in system failure.

Including complications in risk management  Complications should also be included in risk management because just like incidents, complications can also lead to harm to patients and may also be preventable,14 see chapter 3.

Risk management is a part of quality management  Quality management focuses on processes and process control to produce the right output. Risk management, in this research, also focuses on processes and process control to get the patient safely through the hospital processes. Because safety is an aspect of the quality of any product or service, risk management is a part of quality management, see also chapter 2. Errors15 and/or process deviations,16 since they are failures within the system, can lead to incidents, see also chapter 3. The focus of this risk management research is—like quality management—on processes and (system) failure and on how to learn from them to achieve better process control—or to prevent future incidents.

Risk management approach  The observation by Mulcahy [103] that 'there is no one simple or universal way to prevent mishaps, and adopting a systemic approach is complicated, expensive and requires a substantial human commitment to be made' was confirmed in this research. A risk management framework—see section 3.4 and figure 3.7 on page 64—had to be constructed on the basis of a process description method, of methods for assessing incidents and failure modes, and of incident description and analysis

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13Reason [125] calls this 'the blame trap'.
14Doctors talk about, e.g., 'avoidable and unavoidable complications' [103].
15An error is a variation in the normal process course.
16A process deviation is a deviation of the normal process course, see section 3.2 for a more extensive definition.
tools. It took more than four years and could not have been done without the help of many people (see appendix A for a list of people who contributed to this research).

This research tried to make a modest start with preventive risk management for patients, based on the point of view that incidents and complications are (the result of) process deviations, see also section 3.3, in particular figure 3.3 on page 54. This means that the focus is on process control, and the way to achieve this focus on process control is by learning from and anticipating process deviations such as incidents and failure modes. Assessments and analysis methods such as Critical Incident Interviews (CIIs), Failure Modes and Effects Analysis (FMEA) and Causal Tree Analysis (CTA) have been combined in a risk management framework which can be used by hospital employees and doctors.

Because of the focus on process control, the research starts by creating a description of the processes within the system so that (quality) management techniques can be used [10], see section 3.4. In order to improve process control, the research focuses on two main methods. The first is a top-down method in which the incident consequences for the patient are analysed in order to find out the causes, by using causal trees based on qualitative Fault Tree Analysis (FTA), see section 3.4.5. This deductive method is used in the case of the Critical Incident Interviews (CIIs) and the Incident Reporting and Management System (IRMS), see sections 3.4.4 and 3.4.7. The other method is a more bottom-up method in which the failure modes of processes are assessed, and the consequences for patients and causes are determined. This more inductive method is used in the case of the Failure Mode and Effects Analysis (FMEA), see section 3.4.3. The results of the methods can be used to improve process control and to minimise the occurrence of process deviations and thus incidents.

1.5 Background

In order to draw a brief sketch of the background to this research, some aspects of the health care system in the Netherlands and some relevant aspects of the Catharina Hospital where the research was conducted are described in this section.

1.5.1 Health care in the Netherlands

In order to give a brief outline of health care in the Netherlands, a number of aspects of the Dutch health care system will be discussed below.

Number and kind of hospitals In the Netherlands, there has been a trend for hospitals to merge for several years now. As a result, the number of hospitals (academic and general)
Chapter 1. General introduction

has been reduced from 237 in 1978 [44] to 114 in 1997 [36]. The reasons for this reduction in numbers and the ongoing process of mergers are scaling-up and the need to control costs in Dutch health care, resulting in a reduction in the number of beds\(^{17}\) and building larger hospitals.

In the Netherlands, hospitals may be divided into three kinds:

- **General hospitals** (n = 105). All of these hospitals have standard nursing and operating facilities. Some of them have 'top clinical' services like radiotherapy and open-heart surgery, conduct some research and have teaching facilities for some specialisms.

- **Academic hospitals** (n = 9). In addition to standard nursing and operating facilities and 'top clinical' services like radiotherapy and open-heart surgery, academic hospitals have extensive research and teaching facilities for specialisms. The hospital is connected to a medical faculty. The Department of Education pays part of the operating costs.

- **Specialised hospitals** (n = 13). These hospitals only focus on one particular diagnosis, e.g. cancer.

**Budget system** Before 1984 the budget system worked with open-end budgets: all costs a hospital incurred were fully refunded. This resulted in rising and uncontrollable health care costs. This is why the government introduced a closed budget system in 1984: hospitals get an annual budget, and if they exceed the budget, there will be no additional refunding.

**Training of doctors and nurses** In the Netherlands, there is a numerus clausus for medical students. Medical students need a certificate of pre-university education in order to gain admitted to medical school. A medical student graduates as a doctor after six years at university, four years of which are theory-orientated and two years of which are practical. For anyone wishing to become a specialist, another four to six years of training (depending on the specialisation) will have to be added. The number of training sites and places available is limited, however, so only a minority can become a specialist.

For nurses there are five different qualification levels. In the near future, the Catharina Hospital aims to have nurses at only two qualification levels: the third level (caring nurse) and the fifth level (highest level, graduates of a School of Higher Nursing Education). The in-service training of nurses (equivalent to the fourth level) has already stopped:

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\(^{17}\)Scaling-up, i.e. larger hospitals, is accompanied by bed reduction because fewer beds are needed, as a result of fewer admissions, a reduction in the duration of admissions, and more policlinic patients.
the nurses already in training will be allowed to finish their training courses but no new student nurses are being admitted. These nurses will in due course receive additional training qualifying them for the fifth level.

An important issue with regard to the training of doctors and nurses in the Netherlands is the shortage of doctors and nurses. Another important issue with regard to the training of doctors and nurses is the question whether doctors and nurses are adequately trained for the duties they have to perform, see e.g. Binnekade, De Mol et al. [13] who examined the quality and safety of care provided to intensive care patients by nurses.

**Professional status** A certain emancipation of the nursing profession has been taking place e.g. by a more prominent profiling of the profession and by the entrance of men into the profession. In general, the professional status of doctors is still exceptionally high.

**Doctor as a woman's profession** Nowadays more women students than men students attend medical school. However, the distribution of male-female medicine students is not (yet) being reflected in the male-female ratio of medical specialists (in particular the surgical specialisms). This is because the medical establishment is not keen to train women instead of men as specialists, because of the risk of career breaks and also because of the risk of the status quo—which is still predominantly male—being undermined.

**Part-time working** Part-time working is becoming more and more common, especially in the nursing profession, something which can easily result in continuity problems in patient care.

**Doctors and employees** Most doctors, especially specialists in general hospitals (like the Catharina Hospital), are not in the pay of the hospital but are self-employed and organised in partnerships per medical specialism. The reduction of working hours as a result of the trend of working part-time and of restrictive legislation should have led to an increase in the number of doctors, but this has not happened. In the course of this research, a distinction is made between doctors who are self-employed and employees who are in the pay of the hospital. The term 'employees' is understood to include both nurses and paramedics.

**Medical and liability insurers** Risks for patients can lead to incidents and complications, resulting in longer or additional admission time for the patient, and in liability claims.
The patient's medical insurance or to a lesser degree the hospital's and/or specialist's liability insurance has to pay for longer or additional admission. The hospital's and/or the specialist's liability insurer may have to pay in case of a patient claim. In the Netherlands, insurance companies are not really actively involved in preventive risk management. In the Dutch market, more than 65 medical insurers\(^{18}\) are operating, and because of the uncontrollable nature of this market,\(^{19}\) there are just 3 liability insurers [63] with whom hospitals can insure themselves against medical errors; only 2 insurers are both medical and liability insurer.

*Error management in hospitals: FONA committees* Koppens [81] gives a historical overview of error management in Dutch health care. In 1968, the NZR\(^{20}\) founded the 'Errors and Accidents Committee'. One of the reasons was that hospitals responded differently and not always effectively to errors and accidents. In 1970 the committee reported about how hospitals should respond to errors and accidents. The report laid down that errors should be reported in order to prevent them in the future. In 1973, a new committee wrote a follow-up report on errors and accidents, and concluded that learning from errors is essential in error prevention. This was the origin of the FONA\(^{21}\) committees in the Netherlands. From 1984 until the introduction of the Care Institutions Quality Act\(^{22}\) [101] in 1996, a FONA committee was mandatory by law in the Netherlands. Although, strictly speaking, FONA committees are no longer mandatory i.e. there is no explicit legal obligation, they still exist—although sometimes under different names—because of the legal commitments of the Care Institutions Quality Act with respect to safe and well-considered care, and because of liabilities with respect to the annual report on the quality of care, which requires the registration and evaluation of incidents. The registration of complications is also gradually becoming a requirement within the scope of the Care Institutions Quality Act.

### 1.5.2 Catharina Hospital

This section provides an overview of the set-up at the Catharina Hospital. The organisation, the reorganisation process and the problem of understaffing and the hospital's FONA committee will be discussed. A brief description of the OR function group and the Haemodialysis department where the research took place will also be given.

\(^{18}\)Source: Zorgverzekeraars Nederland (1998).

\(^{19}\)I.e. there is a trend of increasing costs as a result of more and higher liability claims.

\(^{20}\)NZR stands for 'Nationale Ziekenhuis Raad', in English 'National Hospital Council'.

\(^{21}\)FONA stands for the Dutch acronym 'Fouten, Ongevallen en Near Accidents' which means 'errors, accidents and near accidents'.

\(^{22}\)In Dutch 'Kwaliteitswet Zorginstellingen'.

**Organisation**  The Catharina Hospital (Eindhoven, the Netherlands) is a general hospital (with a teaching function), housing over twenty medical specialisms and 589 beds. The annual turnover of the hospital is more than € 90 million and the number of employees is approximately 2,400. The major part of the medical staff is not employed by the hospital but is organised in partnerships.

The organisation of the hospital consists of a supervisory board at the top with directly below a board of two directors: a financial and a medical director. Six staff services support the board of directors: Human Resources (P & O), Training, Goods Control, Finance, Patient Affairs, and Public Relations (see also figure 1.1 on the next page). In addition, the hospital has a bureau looking after patients' interests. This bureau mediates between the hospital (doctors, nurses, paramedics) and the patient in case of complaints, and inventories these complaints.

**Reorganisation**  In 1995, the hospital reorganised into a function group structure. Patient care is organised in over 30 function groups, each of which corresponds with a medical function [158]. A function group is monodisciplinary (like Urology) or multidisciplinary (like Operating Room). The function group management consists of a medical manager (a member of the medical partnership), a nursing manager and, if necessary, a representative of the paramedics who work for or with the function group. The multidisciplinary function groups also have an advisory committee, the composition of which is in conformity with the multidisciplinary nature of the function group. The function group is largely independent within certain centrally defined constraints. Coordination between the function groups is carried out in conformity with the principles of the negotiation model. The purpose of the reorganisation was to bring costs more under control by making both doctors and employees also accountable for the budget of the function group. At the moment of writing (2000), the reorganisation process was still ongoing.

**Understaffing**  The Catharina Hospital—like almost every other Dutch hospital—is understaffed and has trouble attracting enough qualified staff. This is because of the 36 hour working week which was introduced in 1997, and the increase in part-time work. High work pressure and high absentee rate because of illness aggravate the problem. Sometimes a department is temporarily closed because the department is short-staffed.

**The function group Operating Room and Haemodialysis department**  This research focused on:

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23 A law that obliges employers to permit part-time work at the request of employees ('Wet Aanpassing Arbeidsduur'; in English 'Adaptation of Working Hours Act'), was passed and came into effect on 1 March 2000.
Figure 1.1. Organisational chart of the function group structure of the Catharina Hospital: the Haemodialysis department comes under the function group of Internal Diseases.
1.5 Background

- The function group Operating Room (OR), especially the clinical operating rooms. The clinical section of the function group Operating Room consists of 10 operating rooms and has a total staff of 93 Full-Time Equivalents (FTEs) (1994): 49 FTEs operating assistants, 26 FTEs anaesthesia assistants, 8 FTEs recovery nurses, 3 FTEs management, 1 FTE preparation nurse, 1 FTE technical service and 5 FTEs other staff. There are more than 32 surgeons (excluding the surgeons in training) and 9 anaesthetists, who are members of 11 different partnerships. The specialisms (and partnerships) operating in the OR are anaesthesiology, surgery, heart surgery, plastic surgery, orthopaedics, ophthalmology, neurosurgery, E.N.T., oral/dental surgery, urology and gynaecology. In the clinical section of the OR, about 40 operations a day are performed. In contrast to the Haemodialysis department, the OR has a varying group of patients.

- The department of Haemodialysis which, as a monodisciplinary department, is part of the function group for Internal Diseases. The Haemodialysis department consists of a haemodialysis and a peritoneal dialysis (PD) section and has a staff of 33 FTEs (1998): 28 FTEs haemodialysis nurses, 2 FTEs PD nurses, 1 FTE secretary, 1 FTE management and 1 FTE training coordinator. Two nephrologists (both members of the Internal Diseases partnership) are working in the Haemodialysis department: one of them performs haemodialysis, the other one does PD. There are also two ICU (Intensive Care Unit) specialists (both also members of the Internal Diseases partnership) who work for the Haemodialysis department, both also specialised in nephrology: one of them performs haemodialysis, the other one does PD, and they both are on on-call shift for the Haemodialysis department. The Haemodialysis department has a largely fixed group of patients, see also section 7.2.

**FONA committee** The FONA committee at the Catharina Hospital was founded in 1982 [81]. The aim of the committee is to maintain and, if possible, improve the quality of the hospital's medical care. The committee has four members: three belong to the medical staff and one is a member of the nursing staff. The duties of the FONA committee at the Catharina Hospital are [81]:

- 'Inquiring into the nature and consequences of an incident.

- If necessary consulting with the board of directors and/or with the department managers concerned.

- Drawing conclusions.
• Giving advice to the incident reporter and to the person(s) involved.

• Recording relevant data in an anonymous annual report.

• Giving advice to the board of directors (possible preventive measures and reporting of suspect events to the legal authorities).

More information about FONA and FONA committees can be found in literature [83, 96, 97, 184].

Although, at the Catharina Hospital, it is mandatory to report an incident to the FONA committee, the FONA procedure is not working satisfactorily. Every employee should report an accident, if possible within 24 hours. Near accidents only have to be reported if the reporter feels that preventive measures can be taken.

The FONA committee meets every two or three weeks and draws up classifications of the events. The reports are confidential and the reporter always receives feedback in writing.

1.6 Overview

An overview of this thesis both with regard to its contents and to its research path is given in this section.

1.6.1 Overview of the thesis

The thesis can be divided into three parts:

I. A theoretical section, 'Introduction and methods'. In this section consisting of chapters 1–3, the approach, the methods used and the framework are described. A general introduction to this research is given in this chapter. In chapter 2, the relationship between risk and quality management is discussed. Because the questions of how these incidents occur, of how to learn from them and of how they can be prevented, were underexposed in literature, the development of a risk management framework consisting of models, methods and systems was more or less a requirement and is discussed in chapter 3.

II. A validation section, 'Results and analysis', describing how risk management works in practice. This part comprises chapters 4–7 describing the use of risk management techniques in the OR in chapters 4–6, and in the Haemodialysis department in chapter 7.

24E.g. not all incidents are reported, see e.g. [111], and the type of incidents which are reported is very lop-sided: incidents mainly related to e.g. patients falling down or being administered the wrong medication.
III. A concluding section, ‘Conclusions and recommendations’, consisting of chapter 8 which discusses the conclusions and recommendations as a result of this research.

In order to make this research useful and applicable to other health care organisations, the methods and results at both the OR and Haemodialysis departments will be discussed in great detail.

1.6.2 The research path of the thesis

This section briefly describes where and when the research discussed in chapters 4–7 took place, and contains references to reports published earlier on which this thesis is largely based.

Research path The research project started at the end of 1993 with a literature review [148], and a second literature review at the beginning of 1994 [150]. In April 1994, the EUT M.Sc. thesis research project in the function group Operating Room started with a process description of the clinical operating rooms. Then an assessment of the possible risks for patients was made by using a Failure Mode and Effects Analysis (FMEA). After this, an assessment of the actual risks for patients was made by conducting twenty Critical Incident Interviews (CIIs). A comparison was made between the results of the forecast (FMEA) and the actual risks (CIIs). One of the conclusions was the need for structural risk management, which evolved into the Incident Reporting and Management System (IRMS) [151]. This management system was developed and implemented as an EUT M.Sc. thesis research project by Timmermans [140] in May 1995. More than 520 incidents were reported and analysed by the IRMS in the period May 1995 to April 1997 [140, 144, 145]. In June 1997, a risk management project in the Haemodialysis department was started: a process model of the Haemodialysis department and PD was created, and twenty-five CIIs were conducted. After this, an FMEA was made (April 1998) [153]. For an overview of the methods, tools and models used in this research, see table 1.1 on the following page.

In relating this time path to the chapters 4–7, the following brief outline can be given. Chapters 4 and 5 cover the period February 1994 to April 1997, starting with the process description of the OR, the FMEA, the CIIs and ending with the analysis of over 520 incidents reported to the IRMS. Chapter 6 is about the period between July 1996 and April 1997 and is based on the results of the first and second analysis of in total 345 incidents reported to the IRMS. The project in the OR ended in April 1997, with the third analysis of the last 178 incidents reported to the IRMS. Chapter 7 covers the period June 1997 to April 1998, starting with the process description of the Haemodial-
Table 1.1. An overview of the methods, tools and models used in this research.

<table>
<thead>
<tr>
<th>Method</th>
<th>Additional tools and/or models used with the method concerned</th>
<th>Used in function group/department</th>
</tr>
</thead>
<tbody>
<tr>
<td>• CII</td>
<td>- CTA,(^a) ECM(^b)</td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>- CTA</td>
<td>Haemodialysis</td>
</tr>
<tr>
<td>• FMEA</td>
<td>- process model,(^c) ECM</td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>- process model</td>
<td>Haemodialysis</td>
</tr>
<tr>
<td>• IRMS</td>
<td>- (CTA,(^d) ECM)(^e)</td>
<td>OR</td>
</tr>
</tbody>
</table>

\(^a\)CTA stands for ‘Causal Tree Analysis’, see section 3.4.5.

\(^b\)ECM stands for ‘Eindhoven Classification Model’, see section 3.4.6 and appendix E.

\(^c\)See section 3.4.2.

\(^d\)Mainly used for the analysis of the first 62 reported incidents of the first/original IRMS, see chapter 5.

\(^e\)Only used for the analysis of the first 62 reported incidents of the first/original IRMS, see chapter 5.

ysis department, followed by the CIIs, and ending with the FMEA. The larger part of this thesis was written over the period from April 1998 to September 2001. It was not until this period that a number of the publications cited in the thesis became available. This is particularly relevant in the case of the thesis by Koornneef (2000) [80] which deals with a number of issues which overlap with issues discussed in this thesis. Hence the insights from these sources could not be used in planning and carrying out the research described in chapters 3–7, but they were useful in providing a better understanding and interpretation of the results of this research.

**References to relevant earlier publications** The results on which this thesis is based were presented in a number of earlier publications. The literature review was partly presented in two reports, see [148] and [150]. The research in the OR was presented in four reports [140, 144, 145, 151] and two articles [147, 152]. The research in the Haemodialysis department was presented in one report [153].
Risk and quality management

2.1 Introduction

This chapter describes the relationship between standards, process deviations, risks and process control on the one hand, and the management of care systems, especially quality and risk management systems, on the other. Standards—necessary for providing a fixed frame of reference (both within and outside the organisation) for what is necessary and acceptable, and what is not—are discussed in section 2.2. Section 2.3 is about the approach to risk management this research adopted: the prevention of process deviations in order to reduce risks. The analysis of process deviations, the information resulting from the analysis and the question of how to handle the information are briefly discussed. The control of standards and the risk management information—obtained by analysing process deviations—in care systems are discussed in section 2.4. The question of how risk management and a risk management framework (see also chapter 3) fit into quality management is the subject of section 2.5. Risk management is that part of quality management which is entirely focused on the prevention of process deviations and incidents, and should therefore be integrated into quality management.

2.2 Standards and audits as requirements

Standards and audits are important elements in both quality and risk management: standards stipulate what is viewed as necessary and acceptable, and audits check whether processes and system meet the standards.

Formally, the supplier\(^1\) provides service\(^2\) to the customer:\(^3\) in this case, the patients are the customers [11] who consume hospital care and expect the care to be of a certain quality level. In order to standardise the care to provide a certain quality of care, the care provided must comply with standards which act as a benchmark for everyone—both within and outside the organisation—about what is allowed and not allowed. To test

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\(^1\)"Organization that provides a product to the customer" [3].

\(^2\)"Result generated by activities at the interface between the supplier and the customer and by supplier internal activities to meet the customer needs" [3]. See e.g. also [59].

\(^3\)"Recipient of a product provided by the supplier" [3].
whether the care provided meets the standard, audits are expected to take place. If the care provided does not meet the standard—i.e. comes up to the desired quality level—this should be recognised and acknowledged, and the level of care must be improved, although this often happens—in the absence of a legal basis—on a voluntary basis.

Standards and requirements are postulated in many forms and by many interested parties, and can be divided into standards which relate to the product or to the quality assurance system. Standards which relate to the product—or service—are determined e.g. by the government in the form of legislation such as the Dutch Working Hours Act\textsuperscript{4} which is very detailed about what is acceptable in the case of working hours and what is not, or the Care Institutions Quality Act\textsuperscript{5} which speaks in general terms about quality management. But also branch organisations and professional associations set standards which relate to the quality assurance system—such as the PACE\textsuperscript{6} standards [116] or NEN-ISO\textsuperscript{7} standards\textsuperscript{,8} e.g. [107]—and provide instruments to ensure professional quality such as audits\textsuperscript{,9} certification, education and training, equipment and organisation [29].

In order to be clear to everyone and to be testable, standards must be measurable. Unfortunately, not all standards are operational in such a way that they can be measured unequivocally. This can be a problem because a valid measurement will then not be possible and the standards will be useless for e.g. an audit.

From a rational perspective, it may be assumed that systems and processes, and protocols and procedures work effectively—i.e. perform what they are designed for—sometimes regardless of the standards\textsuperscript{10} standards, included in protocols and procedures, should operate in accordance with the spirit of the system objectives—they must be effective (the effectiveness requirement). It is assumed, therefore, that protocols and procedures are designed effectively and work accordingly. However, this is not always the case: see e.g. the blood-ordering procedure and the supervision of doctors in training.

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\textsuperscript{4}In Dutch 'ArbeidsTijdWet' (ATW) [98].
\textsuperscript{5}In Dutch 'Kwaliteitswet Zorginstellingen' [101].
\textsuperscript{6}PACE is a Dutch acronym which stands for 'Proefproject ACreditatie ziekenhuizen'. In English 'Pilot Project Accreditation Hospitals'.
\textsuperscript{7}NEN stands for 'Nederlands Norm' (in English 'Dutch standard'). ISO stands for 'International Organization for Standardization'.
\textsuperscript{8}The American National Standard [3] uses the term 'Requirements of society: Obligations resulting from laws, regulations, rules, codes, statutes, and other considerations'.
\textsuperscript{9}'Quality audit: Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives' [3]. There are different kind of audits, see e.g. [71], but this lies outside the scope of this thesis.
\textsuperscript{10}An example in which a job is carried out strictly in accordance with standards—i.e. the protocols and procedures—but misfires, is the work-to-rule by Dutch Railways.
mentioned in chapter 6.

Moreover, the medical profession produces and controls its own standards [6], which is not always in the interests of the quality of care and of the patient; audits and the independence of auditors, in particular, may well suffer in consequence. According to Conradi and De Mol [29], 'the auditing system reflects a rather conservative approach to setting professional standards' and 'peers judge errors of colleagues mildly'. They also mention other drawbacks of audits and of expert opinions, such as 'a limited awareness of skill-based and organizational errors', hardly any testing against a 'normative professional standard', and inaccessibility to non-specialists.

A comparison can and must be made both inside hospitals and between hospitals by using standard performance indicators, expressing, for instance, the number of wound infections after a certain operation for a certain patient category. These standard performance indicators can be used for the purpose of comparing both inside the hospital between peers and outside the hospitals between different institutions, and can be provided by the IRMS and CIRMS (Complication and Incident Reporting and Management System).

2.3 Process deviations and risk management

**Process deviations** The focus of this risk management research is on the prevention of process deviations so as to prevent risks. So, in order to control the function of systems and processes, process control is necessary: to improve process control, process deviations must be recorded and analysed. This is done by analysing patient incidents: process deviations are found which cause risks for patients. The circulate process of assessing, analysing and eliminating process deviations will result in a reduction of risks and incidents.

**Analysing process deviations** This analysis can be made in different ways. See table 2.1 on the next page and also section 1.4. E.g.:

- Prospective (e.g. FMEA) or retrospective (e.g. record review, CIIs, voluntary incident reporting).

- Quantitative (e.g. retrospective medical record review) or qualitative (this research). Particularly in the case of a qualitative view on process deviations, risks and risk management, the management makes the decisions with regard to what is important because quantitative data are lacking.
Table 2.1. Overview of a number of methods suitable for risk management, classified in prospective-retrospective and quantitative-qualitative.

<table>
<thead>
<tr>
<th></th>
<th>Qualitative</th>
<th>Quantitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective</td>
<td>FMEA</td>
<td>-</td>
</tr>
<tr>
<td>Retrospective</td>
<td>CIIs with qualitative FTA, voluntary incident reporting</td>
<td>Retrospective medical, record review</td>
</tr>
</tbody>
</table>

In this research, the focus is on assessing structural causes of incidents using qualitative (both prospective and retrospective) methods. This means that the question of how often an incident occurs—i.e. quantitative, retrospective, e.g. by using retrospective medical record review, see table 2.1—cannot be answered. Some figures are given, based on incident reports, but under-reporting means that these figures should be treated with great caution.

**Extracting information from the analysis results** The analysis results must indicate the structural causes of an incident (retrospective approach) or the possible causes—in this case structural elements in the organisation—which may result in an incident (prospective approach).

**How to deal with this information** The management is responsible for (patient) safety and must act accordingly: the management can use the information provided by one or more risk management methods to eliminate structural incident causes.

### 2.4 Care systems

Care systems, especially safety care systems, can be an excellent way of managing standards, recording and analysing process deviations and dealing with the resulting information.

It is important to realise that the integration of care systems—quality, environment and Arbo\(^{11}\)—has its advantages [94, 177].

\(^{11}\)Arbo is a Dutch acronym which stands for 'ARBeidsOmstandigheden', in English 'working conditions' or 'occupational health and safety'.
2.4 Care systems

Care system operates at departmental level  The design of a care system must be based on the processes of a system and not on the organisational structure;\(^{12}\) [177] this implies focusing on processes and process control. However, this creates the possibility that a care system operates across departmental boundaries, which may complicate things. The current function group organisation structure of the Catharina Hospital which corresponds with the medical specialisms is more consistent with the primary processes than the organisational structure before the reorganisation—which is an advantage. Therefore, it is possible to implement and design a care system at function group level—and, if necessary and possible, departmental level\(^{13}\)—based on the primary medical processes in conformity with the medical specialisms, see also section 2.5.3.

Safety care system monitors process deviations  A safety care system must focus on process deviations in a practical way: it must use a workable definition of process deviations, and assess, record and analyse process deviations. In this research, the emphasis is on incidents: a workable definition of incidents is given in section 3.2. The assessment, recording and analysis of incidents is performed by different assessment and analysis methods, see chapter 3.

Risk management methods and care systems  The emphasis of this study is on a managerial approach which focuses on aspects of patient safety and patient incidents. Patient safety, patient incidents and a patient safety care system are related to quality systems\(^{14}\) and to other kinds of safety like occupational safety and occupational incidents.\(^{15}\)

The risk management methods or systems which are described in this thesis are crucial components of safety and quality systems [171] and provide information on how to improve the quality of care [16]. Conversely, quality failures\(^{16}\)—since they are failures—

\(^{12}\)From research conducted by Waszink [177], it turned out that in the case of the development of care systems (i.e. management systems), it is advantageous not to start from the organisational structure but to start from the processes. Moreover, this advantage becomes bigger if meeting the requirements in several result areas is integrated into a system: think of the integration of a care system for, e.g., working conditions, environment and quality. In the case of setting up a care system, it is better to:

- Start from processes. This produces an approach which is simpler and which is characterised by a smaller number of rules than an approach based on the organisational structure.
- Integrate the different care systems. [151]

\(^{13}\)See section 1.5.2 for an explanation of the concepts 'function group' and 'department'.

\(^{14}\)Safety is a part of quality and is accordingly related to quality management.

\(^{15}\)For instance, in the case of a patient who infects a doctor or vice versa.

\(^{16}\)Sharpe and Faden [133] write about this: 'quality failures may be the result of poor system design or management decisions such as unrealistic work loads, over-scheduling, inadequate training, [38] or economic policies that jeopardize patient interests.'
may result in incidents.¹⁷ Risk management can help to identify these flaws. Data collected by risk management methods can be used for auditing purposes e.g. to evaluate the work and performance of quality management in a department or in the hospital. In order to bring about improvements, a quality management improvement path can be designed, e.g. included in a quality plan.¹⁸ Risk management can use the same methods as quality management and might in fact be considered to be a part of quality management: the prevention of (possible) undesirable physical consequences for patients—and doctors and employees, see also chapter 3. The risk management methods or systems which are described in this thesis can be linked to or extended with other formal internal organisational systems, which yield information for reducing patient risks and for improving the quality of care, such as training and accreditation processes, medical and clinical audits, complaints and dealing with claims and epidemiological research [43, 103]—in this way, risk management is linked to quality management [176] and becomes a part of it. Systems drawing on complaint and on claim data for the purpose of preventing future incidents are still in their infancy [103] and this research does not focus on them. However, an analysis of complaints may provide an insight into the standard of care [43] and may be an important source of information in order to improve the quality—including safety—of care. In this context it may be stated that there is no value in recording separately the number of FONA reports and complaints which patients make, and to monitor them over time—they must be integrated into a quality system. Incidents and FONA reports contain information about process deviations and their consequences, and are valuable sources of information for quality and risk management. Complaints may be the result of process deviations and are valuable for quality management, and could be valuable for risk management.¹⁹

2.5 Risk management as a differentiation of quality management

2.5.1 Introduction

Quality management in hospitals is still in its infancy.²⁰ Quality management is a new management aspect for many hospitals, and a comprehensive vision that can be used

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¹⁷ Or, as Dickinson [41] puts it: 'quality improvement offers a positive and constructive approach to the avoidance of medical mishaps'.

¹⁸ 'Document setting out the specific quality practices, resources, and sequence of activities relevant to a particular product, project, or contract' [3].

¹⁹ By way of example, and so as to show the interdependence: incidents can cause complaints.

²⁰ Sandholm [131] presents five phases in the development of quality: dormant phase, awakening phase, groping phase, action phase and maturity phase. Dutch hospitals may be said to find themselves in the first three phases. See also the boxed text on page 31.
to introduce and anchor quality management in hospitals is absent. In Dutch literature, a lot has been written at policy level about the quality circle, in which the link with the primary care processes is mentioned, but the question of how this is put into operation in actual practice in a systematic, efficient, effective and structural way is ignored. See also the boxed text on this page. This section outlines a framework as a starting-point for the development of a quality system both at departmental level and at (top) management level. This framework is limited but necessary for the successful implementation of risk management as a part of quality management. This section makes no claim whatsoever to completeness about quality and quality management: it simply provides a starting-point for risk management as a part of—or lead-in towards—quality management in hospitals.

**Quality improvement in health care services**

'Thus medical care, perhaps even more than other industries, finds itself susceptible to forms of fragmented efforts that impede systemic vision and optimization of the whole. Even more, old habits of work die hard in medicine. Physicians, nurses, and others are trained in highly conservative modes of work; they often regard changes as dangerous until proven to a standard far more stringent than in other industries. The learning cycles (plan-do-check-act) so characteristic of robust quality improvement can therefore feel especially threatening to health care professionals trained, first of all, "to do no harm."

Like other industries that came new to improvement methods, health care organizations often simply do not seem to believe that significant improvement is possible. Many tend to regard disease outcomes as biologically predetermined, patient expectations for comfort and service as "unrealistic," and excessive health care costs as inevitable. (All these constraints are, of course, quite real, unless the processes of work can be systematically changed and improved on the basis of data—unless, that is, quality is managed actively.)

Yet, despite the cultural barriers, the promise of quality improvement in health care remains great.'

A distinction can also be made between quality and risk management. Quality management relates to the production process and tests the normal routine with regard to process and product specifications; quality management starts from normative criteria and tries to exercise control on the basis of these criteria. Risk management can thus be seen as a necessary differentiation of quality management, where risk management
focuses exclusively on risks—in this case patient risks: risk management starts from deviations and tries to control processes from these deviations. The overlap between quality and risk management is that both require that processes are controlled, that this control must be demonstrated and that output must meet customer needs. Add to this the fact that quality management in hospitals is still in its infancy and that the number of medical interventions—e.g. operations—is rising because of an increasingly ageing population, voluntary plastic surgery etc. resulting in more patients being exposed to risks, and the need for risk management is clear.

There are differences between quality management in industry—the cradle of quality management—and in health care. Normally, in the case of an industrial environment, the supplier has a result obligation. In health care, the supplier has an effort obligation: a certain result cannot be guaranteed. But also within the health care system there are differences; for instance, the Haemodialysis department has a limited number of steady state processes with relatively few degrees of freedom while the OR has more complex steady state processes with relatively many degrees of freedom. Generally speaking, this causes the Haemodialysis processes—like industrial processes—to be more controllable and the output to be more certain than is the case with OR processes. However there are also parallels between health care and industry. In both health care and industry, risk management can relate directly to the output (service provided) or product—i.e. patient safety in health care, product safety in industry—or to occupational hazards or to financial risks.

This thesis is about risk management in which risk management is viewed as a differentiation of quality management. This does not mean that risk management has to be implemented from within quality management: risk management can be implemented parallel to quality management, or even as a lead-in to it.

2.5.2 Important definitions

Because risk management is a differentiation of quality management, it may be useful to clarify a number of important quality management concepts. Seven quality concepts are discussed and defined, partly based on the definitions ISO\(^{21}\) [70] gives and adapted if necessary:

**Quality** 'totality of characteristics of an entity (...) that bear on its ability to satisfy stated and implied needs' [70].

\(^{21}\)Although the role of ISO in the professional service sector is under discussion—in particular ISO 9004-2 [19, 20].
Five phases in the development of quality

In Juran's Quality Handbook [71], Sandholm [131] writes about five phases which can be identified in the development of quality in both manufacturing enterprises and service organisations:

‘Dormant phase: Companies do not feel any threat in the marketplace. They earn an acceptable income. Executives are satisfied with the business results. They experience no need to give any special consideration to quality.

Awakening phase: The situation is dramatically changed. Market shares are lost. Income drops. Profit turns into loss. Executives awake and feel that they are facing a crisis.

Groping phase: Upon awakening, executives realize that they have to do something in the field of quality. But what? Trendy tools and methods are there as a possibility, highlighted very much in business literature and at management seminars and conferences. Lacking any sound knowledge in how to manage for quality, executives just select whatever presents itself. The groping phase is a period of trial and error.

Action phase: Some companies discover that the trendy tools and methods do not lead to excellent results. They then start to carry out an effective program for changing the situation. Such a program includes a change of the internal culture, as well as improvements of products and processes.

Maturity phase: A real sign of maturity is when quality is no longer talked about in the enterprise. Full customer satisfaction is achieved through perfect processes in all areas of the organization. The concept of quality applies not only to products, i.e., the goods and services produced and supplied, but also to all supporting activities. A total quality approach is applied, which includes all processes and functions, as well as the involvement of everyone in the organization. Quality is just a natural aspect of the work, permeating the entire organization. Executives regard quality in the same natural way as they regard finances. The maturity phase has been reached by successful Japanese companies. In the West, the list of winners of the Malcolm Baldrige National Quality Award in the United States and the European Quality Award in Europe contains companies that can be fairly considered to have reached the maturity phase.’

As already mentioned in footnote 20 on page 28, Dutch hospitals can be said to find themselves in the first three phases.
Even in such a definition, 'quality' is still a difficult, abstract and personal (subjective) concept, e.g. [77, 175]. The definition of quality and of other definitions relevant to quality management may differ depending on the line of approach.

The quality approach which was chosen in this research is what Kedzierksi and Vlemmix [75] call 'the approach from the producer or service provider': quality is determined by the extent to which a product or service satisfies a (technical) standard. They state that the extent to which the production or service process is controlled largely determines the extent to which the service or product satisfies the standard: 'in case of a controlled process, the quality of the output will be known in advance with a large extent of certainty'.

**Quality management** 'all activities of the overall management function that determine the quality policy (...), objectives and responsibilities, and implement them by means such as quality planning (...), quality control (...), quality assurance (...) and quality improvement (...) within the quality system' [70].

**Quality policy** 'the objectives of an organisation with regard to quality and the ways and means to achieve these objectives' [108]. The quality policy is a part of the total policy of the hospital and is formulated and endorsed by the top management. Quality policy is a management tool and meets the following criteria:

- The presence of a procedure describing the realisation, setting out, evaluation and possible alteration of the quality policy.
- The involvement of all relevant doctors and employees.
- The communication and dissemination of the quality policy to all relevant doctors and employees.
- A policy which is specifically aimed at the quality management of all stages of the entire process (diagnosis, intervention, nursing) and sets clear goals, sets priorities for these goals, describes the means and the way to achieve these goals (i.e. detailed objectives), contains constraints and preconditions which may apply, for instance, to the overall hospital policy, and is included in the quality handbook.

**Quality system** 'organizational structure, procedures, processes, and resources needed to implement quality management' [3].

**Quality handbook/manual** provides a description of the quality system. It contains:

- The quality policy. In addition to the hospital quality policy, the departmental quality handbook contains the quality policy at departmental level.
2.5 Risk management as a differentiation of quality management

- The quality objectives. An objective must be measurable and contains a point in time when the objective must be achieved.

- The structure of the organisation including its responsibilities. This can be represented in the process description.

- A description of the quality system including all elements and all provisions that are a part of it, see e.g. section 3.4 (figure 3.7) and sections 2.5.3 and 2.5.4.

- The quality practices of the organisation.

- The structure and distribution of the documentation of the quality system [69].

According to ISO [69], procedures are not included in the quality handbook but in the document 'procedures'. The appropriate documentation for a quality system consists of the following parts:

- Quality handbook.

- Quality plan.

- Procedures.

- Quality records.

ISO 8402 [70] does not distinguish between protocols and procedures. However, it is useful and important to distinguish between protocols and procedures. The definitions for 'procedure' and 'protocol' are:

**Procedure** 'a reproduction of agreements about routine activities between different departments which are put in writing' [35]. Procedures have a function in the coordination between departments.

**Protocol** 'describes the most efficient method for performing a task' [35]. Protocols provide the coordination within the department. In Dutch, a protocol is also called an 'instructie' (in English 'instruction') or 'werkvoorschrift'.

2.5.3 Quality system at departmental level

A department consists of a flow of (primary) care and medical processes which the patient undergoes, and all the coordinating, controlling, supporting and standard setting elements and processes surrounding it. This has been represented, in an abstract and simplified way, as 'primary process' and 'process control' in figure 2.1 on the following page. The quality system at departmental level is a system within the department and consists of a set of different elements, processes, methods, techniques and instruments to
optimally control the processes in the department and to meet the set quality requirements. Examples are process descriptions, (C)IRM, methods for forecasting risks like an FMEA, document management and quality policy. The elements of a quality system can have an one-off, a permanent, or a partly one-off, partly permanent character. An example of the latter is a training for a quality control method that is periodically used: this training is a one-off element, while the method is a permanent feature of the quality system, which is used periodically. The goal of the quality system is a permanent improvement of the quality of products—in this case the services—by improving the systems and the processes within the system.

The quality system consists of processes and activities aiming at achieving process control over the primary processes and at meeting the expected quality requirements. These requirements may stem both from internal elements (e.g. top management, the management of the department) and from external elements (e.g. patients, legislation). If necessary, measurements taken by the quality system may result in generating a new protocol or in altering an already existing protocol.

The quality system documentation consists roughly of two parts:

- A description of the separate (quality) processes and activities that are included in the (quality) system (quality handbook, quality plan, protocols and procedures).

- The results of the quality system, i.e. the reports and the data which the quality system generates (quality registration/records).

Periodically (e.g. on a weekly or monthly basis), certain parts of the quality system are activated. Some activities in the quality system have a one-off nature, such as creat-
ing an organogram which is included in the quality handbook and is periodically, e.g. annually, tested to find out whether it is still correct. The quality system documentation triggers, periodically or otherwise, the processes and activities in the quality system.

**PACE, NIAZ and the quality system** For almost every hospital department, PACE [116] has a set of standards and an accreditation guide. PACE was tested in the Short Stay department (1995) and turned out to be impracticable because:

- An overall vision and framework of definitions was lacking. A comprehensive vision and clear definitions are necessary to adapt the general standards to the specific situation in a department. E.g. terms like 'quality handbook' and 'quality policy' are meaningless if they are not properly— i.e. unequivocally—defined. An overall vision and philosophy about quality management as contained in ISO, was lacking.

- The PACE standards are not aimed at processes but at organisational structures (i.e. departments). This view of quality management is more or less outdated [177]: the emphasis in quality management has moved in the direction of processes rather than of organisational structures (see also footnote 12 on page 27).

PACE is not explicit about risk management and focuses on the organisational levels of the hospital management and the department, i.e. the first and second level in the model of section 2.5.6 (see also figure 2.4 on page 38).

The NIAZ uses the PACE standards as frame of reference for its quality assurance standard 'quality system' [105] which is used in combination with a testing instrument [106] to determine the state of affairs with regard to quality management in the hospital organisation. The quality assurance standard and the testing instrument of the NIAZ focus on the organisational level of the hospital management, i.e. the first level in the model of section 2.5.6. Just like PACE, NIAZ is not explicit about risk management, either.

### 2.5.4 Central quality system at management level

The quality systems at departmental level must be a part of the central quality system at (top) management level: see figure 2.2 on the next page. The quality systems (at departmental level) are largely autonomous, and operate within the framework that has been

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22 NIAZ stands for 'Nederlands Instituut voor Accreditatie van Ziekenhuizen', in English 'Dutch Institute for the Accreditation of Hospitals'.

23 The quality systems are 'largely autonomous' but not completely. Quality flows from process control. If the process runs across different departments and their quality systems are completely autonomous— i.e. do
created by the central quality system. The central quality system has its own administration and files which perform roughly the same functions as the quality documentation of a quality system at departmental level: they explain and give an overview and description of the operation, functions and objectives of the complete (quality) system of the hospital, the storage of the data and the measures generated by the quality system (or in quality management terms: quality handbook, quality plan, protocols and procedures, and quality registration). The complete quality system consists of the central quality system with its accompanying administration and files, and the quality systems and quality system documentation of all departments.

2.5.5 Quality-orientated organisation

By analogy with successful companies that excel by assigning a central place in the organisation to the aspect of 'marketing'—inherent in every aspect of management—an analogous design is made for a hospital organisation in which the aspect of 'quality' occupies a central position, and which shows overlaps with all other management aspects: see figure 2.3 on the facing page and, for instance, the concept of 'aspect system' in [166]. This approach is the only way to optimally guarantee that the aspect of quality and, with it, the quality requirements, are optimally integrated into the different management aspects of the hospital, and, in so doing, to do justice to the concept of Total Quality

---

24See e.g. [82] for the critical role of marketing in organisations: the same applies to quality.
2.5 Risk management as a differentiation of quality management

Figure 2.3. The quality-orientated organisation: the position of the management aspect of quality in relation to some other aspects of the organisation.

Management (TQM) [58].

In summary: quality management—and therefore also risk management—is a permanent management aspect in hospitals with consequences for the whole organisation.

2.5.6 Model for quality policy in a hospital

The objective is to obtain a structure with matching standards which need to be met in order to achieve process control for the medical, nursing and paramedical processes in a department. For the implementation and interpretation of quality management in a hospital, a model is used.

25Management approach of an organization (...) centred on quality (...), based on the participation of all its members and aiming at long-term success through customer (...) satisfaction, and benefits to all members of the organization (...) and to society' [70].
In this section, a model for a hospital organisation is presented in which three different organisational levels with regard to quality policy are distinguished, see figure 2.4. On the one hand, the rule is that, for the sake of effectiveness and efficiency, aspects are preferably defined, controlled and coordinated in a systematic way at as high and as central a level as possible. On the other hand, this rule must be combined with the rule for risk control which states the opposite, viz. that aspects should be controlled at as low a level as possible unless effectiveness gains by centralisation can be demonstrated. The organisation provides frameworks and controls top-down, and rules and initiatives are coming up from below. For instance, medicine supply management is performed by the hospital pharmacy (from one central point to a large number of departments). In this way, these aspects are regulated for the whole organisation in as unequivocal a way as possible.

The first level is the highest level: the level of the hospital management. At this level, the strategic quality policy which constitutes the basis of the quality policy of the departments is formulated and laid down. This implies formulating and laying down the minimal quality requirements in the form of procedures and working situations which relate, in essence, to every department. It is the task of the top echelon to define in a systematic and unambiguous way the definitions that are used in quality management in the hospital. The top echelon must also specify the frameworks for quality policy at the second, the departmental, level.

The second level is the intermediate level: the departmental level. At this level, the quality policy of the hospital management level is fleshed out and developed further, and then implemented by the department (this includes setting priorities and indicating
how they should be realised in the department).

The third level is the lowest level: the level at which paramedical, nursing and medical processes take place. At this level, the quality policy at departmental level is elaborated and fleshed out in concrete detail, and this has its effect on the organisation and on the way the medical, nursing and paramedical processes are carried out. During the fleshing out of the quality policy at the different levels, a learning process occurs that has its effect on the assessment and analysis of structural process deviations and of process control problems. This may result in advising the first and second organisational level with regard to these deviations and problems, offering suggestions for improvements. At this third level, there are a number of policy decision points [115]: these points are generated by doctors, if possible in consultation with nurses, paramedics and the patient, and have medical, nursing and paramedical dimensions related to the medical, nursing and paramedical care the patient receives.
3

Risk management: definitions and tools

3.1 Introduction

This chapter describes the definitions, models and methods which were used or proposed in this risk management project, see chapters 4–7. For the sake of clarity, section 3.2 explains important definitions and concepts for effective risk management. These concepts and definitions are necessary for an understanding of the models and frameworks in the next sections. Section 3.3 introduces two models to explain the development of process deviations, particularly incidents and complications. Section 3.4 discusses a framework for effective risk management; it describes all the methods, techniques and models which the framework uses. An overview of the methods discussed and described, and of their use in the OR and Haemodialysis department, is provided in table 3.1.

3.2 Definitions

There is no standard term for describing incidents involving patients—many different terms are used, such as ‘failure’, ‘mishap’, ‘adverse outcome’ [42] and ‘(operational) surprise’ [80]—hence, for a clearer understanding of risk management with regard to incidents and complications, a number of important concepts for risk management will be defined in this section. Because this research restricted itself to incidents and complications, the concepts of ‘diagnostic failure’, ‘environmental incident’ and ‘waste’ were ignored. They are mentioned and defined only for the sake of completeness here.

Risk (I) the probability of the occurrence of incidents and/or complications.

However, in the case of e.g. the FMEA, another definition of risk can be given (see e.g. [172]):

\[
\text{Risk} = \text{probability} \times \text{seriousness of the effect.}
\]

The concept of risk thus focuses on the effects: in this thesis, on the (physical) effects on patients. Probability also can be defined as:

\[
\text{Probability} = \text{frequency of occurrence of the process deviation} \times \text{the extent to which a certain cause of this deviation can be corrected or recovered.}
\]
Table 3.1. Overview of the risk management methods which are described and discussed in this chapter as part of a framework for effective risk management (see figure 3.7 on page 64), and of the departments in which these methods were used.

<table>
<thead>
<tr>
<th>Method</th>
<th>Described and discussed in</th>
<th>Used in the</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process model</td>
<td>Section 3.4.2</td>
<td>OR &amp; Haemodialysis (chapters 4–7)</td>
</tr>
<tr>
<td>FMEA</td>
<td>Section 3.4.3</td>
<td>OR &amp; Haemodialysis (chapters 4–7)</td>
</tr>
<tr>
<td>CII</td>
<td>Section 3.4.4</td>
<td>OR &amp; Haemodialysis (chapters 4–7)</td>
</tr>
<tr>
<td>CTA</td>
<td>Section 3.4.5</td>
<td>OR &amp; Haemodialysis (chapters 4–7)</td>
</tr>
<tr>
<td>ECM</td>
<td>Section 3.4.6</td>
<td>OR (chapters 4–6)</td>
</tr>
<tr>
<td>IRMS</td>
<td>Section 3.4.7</td>
<td>OR (chapters 5 and 6)</td>
</tr>
<tr>
<td>CIRMS</td>
<td>Section 3.4.8</td>
<td>—proposed, but not yet used—</td>
</tr>
</tbody>
</table>

In the case of the extent to which a cause can be corrected—which initially focuses only on the visibility, see appendices C and D—it follows that the more a cause can be corrected (i.e. is visible and thus noticed) the lower the assigned value is. This leads to the next definition of risk:

\[ \text{Risk (2)} = \text{seriousness} \times \text{frequency} \times \text{the extent to which a certain cause can be corrected.} \]

(See also [146].) The FMEA uses this definition of risk in the form of the Risk Priority Number (RPN) (see also appendix C).

**Process deviation** every deviation from a normal on-going process.

What is ‘normal’, is determined by standards\(^1\) which stipulate what is set out as necessary and acceptable, see section 2.2. Process deviations can, amongst other things, lead to incidents, complications and health and safety incidents. This implies that (see also figure 3.3 on page 54):

- In the case of incidents and complications, a part of all the elements of the causal path from cause(s) to consequence(s) are process deviations.
- Incidents and complications are a differentiation of the set of process deviations, and will be defined as such, only when (potential) damage to the patient is at stake. Incidents and complications will be defined as complementary concepts further down in this section.

\(^{1}\)When no standards are applicable, the relevant professional group has to lay down the standard.
3.2 Definitions

**Cause** an event, often within a chain of events, which eventually results in an incident and/or complication. Causes can be process deviations or failure factors but also factors that belong to neither category.

An example of such a factor is a characteristic of the patient that can cause an incident and/or complication. Hierarchy and interdependence between causes can be indicated by using terms like ‘root cause’, ‘indirect cause’, ‘direct cause’. Causes can be divided into ‘accidental’ and ‘structural’ causes.

**Process** a series of transformations during the transit of the element (this is the input), resulting in a change of the element as to location, position, form, size, function or any other feature [166].

Such an element can be a patient. Clearly, a process must be controlled, regulated or monitored by a controlling or standard-determining body, and this process can be broken down into subprocesses.

**System** a collection of elements, dependent on the goal set by the researcher, distinguishable within reality. These elements have mutual relationships and (possible) relationships with other elements from the total reality [166].

Because of the goal of process control in this thesis, at least the elements ‘process’ and ‘patient’ are present. Within the framework of this research, a system consists at the very least of a collection of processes. This means that at least the succession of primary processes the patient is passing through (including the controlling and standard-determining processes), are shown.

The concepts of ‘process’ and ‘system’ are inextricably bound up with each other. Systems exist at different levels. E.g. the system ‘hospital’ consists—among other subsystems—of the subsystem ‘OR’. Every system consists of at least one process. The OR, for instance, consists of the processes ‘preparation of the patient’, ‘anaesthesia’, ‘performing an operation on the patient and maintaining anaesthesia’ and ‘recovery’.

**Failure** in a (sub)system does not have to lead to failure of the whole (sub)system—i.e. **system failure**—because failure can be corrected by defences, see ‘adequate defence?’ in figure 3.3 on page 54. The difference between failure and process deviation is that a process deviation could be caused by failure and is located further down the cause-effect path than failure, see figure 3.3 on page 54.

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2 However, a system can also be viewed as a process, e.g. the system ‘hospital’ with the ‘OR’ process. In this case, the concepts of ‘system’ and ‘process’ are interchangeable. In order to be perfectly clear, in this thesis, the hospital is the system consisting of the departments as subsystems; these subsystems each consist of one or more processes.
Defences procedures, protocols and other defence or (quality) control mechanisms, deliberately built in by the organisation, for the purpose of detecting and correcting process deviations.

Recovery factor active (human) intervention and/or coincidence that (could) limit the effects of an incident.

This definition of the concept ‘recovery’ was used during the risk management projects in the OR and Haemodialysis department. Over the years the concept of recovery has evolved, see also the recommendation on page 255 and e.g. [155].

Incident a process deviation that results in (possible) undesirable physical and/or psychological effects on a patient. Its causes are known\(^3\) and the effects can be temporary as well as permanent.

This research focuses mainly on physical harm to patients in the course of their hospital admission. The terms ‘accident’ and ‘near accident’ (or ‘near miss’) are only used during the FMEA and the CIIs in the OR, because it turned out that the effects on patients—over time and physical—are not always clear: the catch-all term ‘incident’ is used instead. During the application of the FMEA and the CII methods in the OR, the following definitions were used for ‘accident’ and ‘near accident’:

Accident a process deviation which is not a complication and leads to temporary or permanent physical effects on the patient.

Near accident a possible accident that either because of active (human) intervention or by coincidence took a turn for the better in the end; in other words, it is an incident which did not result in an accident, though it could easily have done so if the process had not been arrested or diverted.

In order to prevent certain undesirable physical effects on the patient from being viewed neither as incidents nor as complications, the concept of complication has been formulated as an exclusion-definition of the concept of incident. This implies that every process deviation with temporary or permanent physical consequences for a patient is either an incident—cause(s) known—or a complication—cause(s) unknown.

Complication every process deviation with temporary or permanent undesirable physical effects on a patient, the cause(s) of which is(are) unknown, and which (therefore) is

---

\(^3\)Well, not always directly. What is meant is that in those cases in which they are not directly known, they can relatively easily be found out compared with complications (see further on).
not an incident. A complication is the result of an undesirable process, the outcome of which cannot be influenced afterwards.\textsuperscript{4}

This definition does not contain the somewhat fatalistic aspect—which is found in many definitions of the concept of complication—that a complication is intrinsic to medical treatment and therefore inevitable. Casparie and Buruma [24], for instance, give as their most effective definition of the concept of 'complication': 'every harmful effect on a patient resulting from medical treatment that is connected with that type of medical treatment in a known percentage'. The problem with this definition is the limitation and the generality of the term 'medical treatment': this term is too vague because it does not make clear that different kinds of failure can cause complications. If there are, for instance, problems with the air conditioning system in an operating room, then these can manifest themselves in wound infections in patients, i.e. complications. This technical or organisational failure is not covered by the above definition—in fact, they have nothing to do with the real medical treatment. If complications are to be prevented, a definition of the concept of complication which permits the inclusion of preventable causes, is needed. This is why the sort of limited definitions, intrinsically bound up with medical treatment, are not used and the above definition given under the heading of 'Complication' is preferred and used.

A difficult issue is that a complication may be caused by an incident, but is not recognised as such, at least not at the point of time at which the complication manifested itself. An example might be the above-mentioned wound infections caused by the air conditioning system in an operating room. Another example would be that of a patient whose urinary tract has been catheterised; subsequently, the catheter became unsterile because the person who inserted the catheter accidentally had brought the catheter into contact with something unsterile just before inserting the catheter. As a result of this, the patient got an infection of the urinary tract. The incident of the insertion of the unsterile catheter may be recognised as such at that moment, and be reported. However, later on the urinary tract infection will be treated as a complication, though it was caused by an incident—cause(s) known—and if recognised as such, the complication will become an incident (which happened to result in an infection for the patient). This is why complication registration must be accompanied by incident registration and analysis, because their development may overlap, and the concomitant incident may be necessary in order to explain the development of a complication. This does not conflict with the earlier definition of a complication: if the cause is known, it will be an incident; if unknown, it will be a complication (until the cause or causes is/are known). The consequence of this definition of an complication is that if the cause or causes of a complication is/are known, the

\textsuperscript{4}The last sentence was added to the definition to make the definition more acceptable to doctors.
Table 3.2. Overview of the possible effects on a patient when the diagnosis is consistent or inconsistent with reality.

<table>
<thead>
<tr>
<th>Reality</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Good, correct negative</td>
</tr>
<tr>
<td></td>
<td>Undeserved treatment</td>
</tr>
<tr>
<td></td>
<td>and/or intervention,</td>
</tr>
<tr>
<td></td>
<td>false positive (alpha/type I error)</td>
</tr>
<tr>
<td>+</td>
<td>Undeserved no treatment</td>
</tr>
<tr>
<td></td>
<td>Good, correct positive</td>
</tr>
<tr>
<td></td>
<td>and/or intervention,</td>
</tr>
<tr>
<td></td>
<td>false negative (beta/type II error)</td>
</tr>
</tbody>
</table>

*complication becomes*—by definition—*an incident.*

So, in the case of complications, the conclusion is that *complications—at least some of them—are preventable,* and that the causes are unknown and must be found out, for instance via incident and complication registration and analysis: this will be discussed further down in this chapter.

**Diagnostic failure** a process deviation with temporary or permanent (harmful) physical effects on the patient, the direct cause of which is a wrong diagnosis, leading to:

- Inappropriate treatment and/or intervention.
- No treatment and/or intervention.
- Not the right treatment and/or intervention.

A distinction may be made between (erroneously) positive and (erroneously) negative diagnoses, see table 3.2. The focus in the table is on a specific diagnosis, e.g. the protocol to diagnose appendicitis, of which both the diagnosis and the reality have only two values: ‘+’ or ‘−’. A ‘+’ under ‘Diagnosis’ means that the protocol indicates a positive diagnosis, e.g. appendicitis, a ‘−’ means that the diagnosis protocol indicates a negative diagnosis, e.g. no appendicitis. A ‘+’ next to ‘Reality’ indicates that the patient actually has the disorder which the diagnostic protocol is meant to diagnose, e.g. the patient actually has appendicitis, a ‘−’ indicates that the patient does not suffer from the disorder which the diagnostic protocol is testing for, e.g. the patient has no appendicitis. Diagnostic failure is a differentiation of the concept of incident. This research does not specifically single out nor specifically focus on diagnostic failure. The concept was more or less ignored in this research although it is an important part of risk management: for instance, Conradi [28]
analysed 67 errors in his study of errors by GPs, and found that 78% of the errors was related to a faulty diagnosis. The phenomenon of diagnostic failure could be a specific subject for specifically targeted research, for instance into the effectiveness of diagnostic protocols. In order to restrict this research, no specific attention was paid to diagnostic failure.

**Health and safety incident** a process deviation with (possible) temporary or permanent undesirable physical effects on doctors and employees.

A health and safety incident is also called an occupational, working conditions or Arbo incident.

**Environmental incident** a process deviation with (possible) temporary or permanent undesirable effects on the environment.

**Waste** a process deviation that only leads to additional/higher costs for the organisation.

Consequently, it is also possible to have health and safety, environmental and waste complications, the causes of which are unknown. This research does not deal with environmental incidents and waste.

This research describes the different risk management methods and techniques for incidents and occasionally for complications and health and safety incidents.

### 3.3 Models to explain the cause-effect path of incidents and complications

In this section, two models are discussed: a general model to explain the development of process deviations which can lead to damage (section 3.3.1) and a specific model for the development of incidents and complications (section 3.3.2).

#### 3.3.1 Model for the development of process deviations which can lead to damage

For the sake of clarity, this section describes a number of important concepts and definitions, and presents a causation model for the development of process deviations which may result in damage, e.g. incidents and complications.

To minimise patient risks, it is important that the incidence of failures within the system is as low as possible. The failure of system elements can result in process deviations which may in turn lead to incidents and complications (see also figure 3.3 on page 54). Knowing the causes and development of incidents and complications is necessary for preventing future incidents and complications. It is important to know whether a cause
is structural, i.e. whether the cause is likely to happen again in the same context and may lead again to an incident or complication.\(^5\)

In order to determine what must be reported and registered so as to be able to retrieve the causes of incidents and complications, a causal model of the development of incidents and complications is essential. Complications and incidents are the consequence of process deviations. Because of the domino effect of one incident leading to another, an incident may cause a complication. In fact, complications and incidents are the end of a cause-effect path of failure of elements in the system with possible undesirable physical consequences for the patient.

System theory, as described by In 't Veld [166], can help to gain the necessary insight into system failure. In 't Veld models steady state systems. In fact, the system theory In 't Veld describes demands that system theory is only used for steady state systems. A steady state system is a system that is constantly going through the same states again and again.\(^6\) A hospital and a hospital department meet this demand of a steady state system: the system hospital is a steady state system with the different departments functioning as steady state subsystems. A (sub)system consists of a number of processes (see also figure 3.1 on the next page).

Process deviations may cause system failure (including incidents and complications). It is of crucial importance for the prevention of system failure to find out what the causes of system failure are and thus what the causes of process deviations are. Because not every process deviation leads to an incident or complication, the question is which process deviations must be registered and described with a view to preventing system failure. To answer this question, a model has been developed. This pyramidal causation model is presented in figure 3.2 on page 50: the significance of the numbers and letters in round and square brackets is explained further down in this section. The basis for the model are elements of the iceberg model by Hydén [66], of the incident causation model by Van der Schaaf [154], of system theory according to In 't Veld [166] and of general quality management principles. Although the assumption that causal pathways of near misses

\(^5\)Sometimes, one incident is enough to determine whether a cause is structural but it is also possible that a number of incidents is needed. This is supported by Koornneef [80] whose SINS (Systematic Incident Notification System) 'allows learning from one accident and less'. The warning by Lucas [93] about focusing too much on individual incidents—leading to an anecdotal reporting system—instead of focusing on more general patterns of causes in a large database (i.e. a good reflection of reality), is however taken into account.

\(^6\)To be more precise, according to In 't Veld [166], a system is in a steady state when a system has a completely determined behaviour which is recurrent over time, and which is also similar from one time span to another. In addition we also have a steady state system in the case of a stochastic behaviour when the probabilities have a fixed value. In 't Veld also uses the term 'equifinality' [166]: the maintenance of a constant purposiveness on the basis of dynamic balance under varying circumstances, which implies that a certain balanced state can be reached in different ways.
3.3 Models to explain the cause-effect path of incidents and complications

Figure 3.1. The system hospital and its contents (the subsystem(s) department(s)). A (sub)system consists of a number of processes. The patient enters the system (hospital) as input and leaves the system as output.

are similar to those of actual accidents (see e.g. [185]) is still open to debate when it comes to the application, for example, in health care, the model makes it possible to understand incident causation and the role of recovery herein.

The pyramid symbolises all the states of a system, see figure 3.2 on the next page. The bottom and largest category represents the set of all states when the system works within the standards that have been set and when nothing is wrong [A]. The middle and top categories represent the set of all states when a failure of system elements occurs. Because these categories are smaller than the first category, the three sets are symbolically represented as a pyramid. Failure factors and/or other causes\(^7\) (1) give rise to the development of process deviations [B]. Some prevention is achieved in [A] by preventing failure or by removing factors resulting in deviation in [B]. The organisation anticipates the development of process deviations and their (possible) effects by their correction via built-in defences\(^8\) (2): training, protocols, procedures, quality controls etc. These defences correct the process deviations and prevent undesirable effects so that the system can return to its normal state [A]. If an organisation does not anticipate certain process deviations and does not design and build in defences, or if a certain defence fails, a process deviation is not corrected. Such a process deviation can develop into a process deviation with (pos-

---

\(^7\)Causes other than failure factors such as patient-related factors. Patient-related factors [151] are not failure factors, although they are mentioned and classified as such in literature [161, 162]: the system is primarily responsible for the inputted element—the patient—who is temporarily part of the system. See figure 3.3 on page 54 and figure 3.4 on page 56. Patient-related factors are e.g. obesity or an abnormal anatomy which contribute to a complication: a failure in this case may be the fact that a certain patient-related risk factor—such as abnormal anatomy—is not recognised.

\(^8\)Comparable with installing a safety net.
process deviations with (possible) effects

(2) defences by anticipation of the organisation

(5) process deviations

system processes work within the standards

(1) failure and/or other factors lead to process deviations

(3) (accidental) (human) recovery actions full recovery: return system to normal state

(4) (accidental) (human) recovery actions limit the damage

Figure 3.2. The pyramidal causation model: the set of all possible states of a system and the development and possible correction of process deviations.
Table 3.3. Overview and registration of aspects in the development of process deviations.

<table>
<thead>
<tr>
<th>Aspect in the development of process deviations</th>
<th>Registration?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Causes of process deviation</td>
<td>Yes, only of process deviations which have not been detected and corrected by defences</td>
</tr>
<tr>
<td>Process deviation</td>
<td>No, if a defence detects and corrects the process deviation successfully⁵</td>
</tr>
<tr>
<td></td>
<td>Yes, if recovery factors detect and correct the process deviation</td>
</tr>
<tr>
<td>Defences, i.e. the safety net put in place by the organisation to correct process deviations in order to prevent undesirable effects of these deviations⁶</td>
<td>Yes, only if existing defences fail</td>
</tr>
<tr>
<td>(Accidental) (human) recovery factors</td>
<td>Yes</td>
</tr>
<tr>
<td>Process deviations with (possible) effects</td>
<td>Yes</td>
</tr>
</tbody>
</table>

⁵Registration of how often defences are activated and operate can be implemented in systems. The nuclear industry does routinely register how often defences are activated and operate. The normal operation and the frequency of activation of existing defences is not an explicit part of the focus of this research.

It's possible effects (5)[C]. Only the (accidentally) present (human) recovery factors can correct the process deviation (3) or limit the damage (4): recovery then occurs after a defence has been breached—if the process deviation is noted and corrected (3)[A]—or after the process deviation has had (possible) effects (4)[C], respectively. In this last case, recovery can limit the (possible) effects of the deviation, for instance when noticing incorrect artificial respiration by the patient because the patient turns blue. After the operation, the patient seems (apparently) all right. The addition '(possible)' before 'effects' [C] indicates that sometimes effects cannot be determined or that they become visible only after a while or that they may also be of a temporary nature. Recovery can also happen before the process deviation reaches a defence (3): the process deviation is then corrected and the system returns to its normal state [A].

The model provides a framework for the registration of certain aspects of the pyramidal causation model (see table 3.3).

The causation model is also useful for incidents and complications (see section 3.3.2 and figure 3.3 on page 54) and potentially for process deviations which have other effects.
3.3.2 Model for the development of incidents and complications

This section presents a causation model for explaining the development of incidents and complications which are a differentiation of the set of process deviations. The model builds on the model discussed in the previous section, but probes deeper by trying to explain the development of process deviations, particularly incidents and complications. To prevent system failure, it is important to know the causes and to find out:

- Whether these causes are structural and whether it is plausible that they will occur again in the future.
- Whether these causes are accidental and whether it is unlikely that they will occur again in the future.\(^9\)

Process deviation registration and analysis focus on structural causes.

Causes of system failure can be divided into three categories:

I. Failure factors that consist of a combination of technical, organisational and human failure [154] and/or

II. Patient-related factors [151] and/or

III. Factors that are as yet unknown but can be classified in category I or II once they are recognised.

Category I corresponds with the failure of the (sub)system of processes (see I in figure 3.1 on page 49) and category II corresponds with the input—i.e. the patient—of the (sub)system(s) and primary processes (see II in figure 3.1 on page 49). Causes in category I are known\(^{10}\) and in category II may be both known and unknown. Category of causes III (causes unknown)\(^{11}\) occurs mainly with complications. Causes in categories II and III can result in the failure factors of category I, and category III in particular should be subjected to cause analysis (see also figure 3.3 on page 54).

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\(^{9}\)This should be determined by one or more experts in the system processes concerned, e.g. the members of the IRMS committee. The IRMS (Incident Reporting and Management System) will be discussed in section 3.4.7.

\(^{10}\)E.g. based on the incident description, on the expert knowledge of the researcher (who is, for instance, a member of the IRMS committee), or the causes can easily be found out, e.g. by conducting research like interviewing or using CTA (Causal Tree Analysis, which will be discussed in section 3.4.5).

\(^{11}\)If necessary, see by way of illustration the definitions and explanations of the concepts of incident and complication in section 3.2.
3.3 Models to explain the cause-effect path of incidents and complications  

Figure 3.3 on the next page presents a causation model\textsuperscript{12} for system failure and especially for incidents and complications. For an elucidation of the model, see table 3.4 on page 55. This model can also potentially be used for the development of system failures other than incidents and complications.

It is useful to make a distinction between the different categories of causes because this contributes to a precise allocation of the causes, and offers opportunities for process improvements. In the case of complications, it is also advisable to take into account a number of factors, which may contribute to the development of complications, in order to obtain greater insight into these cause(s) (category III). The factors which can be registered, are described in figure 3.4 on page 56. This is an epidemiological approach.

An explanation of some of the factors mentioned in figure 3.4 on page 56 will be given. ‘Protocols’ are (operating) protocols, (operating) techniques, work instructions, operations (subdivided, if necessary, at a later stage). ‘Environment’ is the hardware and the workplace (e.g. anaesthesia cars, the design and layout of the operating room). ‘Materials’ can be divided into equipment and consumables. ‘Location’ may be, for instance, the operating room number. ‘Interfaces’ are, for instance, the interface and communication with other departments. The aspect of ‘organisation’ only matters when comparing different systems such as different haemodialysis centres. Finally, ‘time’ refers, for instance, to the starting and ending time of an operation and special circumstances, e.g. when the operation is the first or last operation in the regular schedule.

The list of factors mentioned in figure 3.4 on page 56 was the subject of a brainstorming session between doctors and employees. In the course of this session, it was decided which concrete factors would be incorporated into the registration of complications. Location (factor 12), for instance, is a factor which may be taken into account in order to find out whether a complication is location-bound or not. For example, let us assume that there are problems with the air conditioning system of a certain operating room but it is not yet clear (category III in figure 3.3 on the next page) that this is being caused by a broken air filter, so that polluted air is blown into the operating room. This may result in a higher number of wound infections for patients who are operated on in this specific operating room. Systematic registration of the complication ‘wound infection’, including the operating location, should make it possible to track down the cause, in this case a problem with the sterility of the air supplied.

Figure 3.3 on the following page shows the causation model for the explanation of process deviations. The model is also a framework for the registration of process devi-

\textsuperscript{12}The causation model is largely a flow chart but it has also features of a more associative model. Figure 3.3 on the following page represents—in an (associative) flow—all possible causal factors/causes, the causal path and possible outcomes for the patient and organisation (persons, means). See also further on in this section.
Figure 3.3. A causation model for the development of incidents, complications and other undesirable outcomes: the model is an extension of the incident causation model by Van der Schaaf [154]. For an elucidation, see the text and table 3.4 on the next page.
Table 3.4. Elucidation of figure 3.3 on the facing page.

<table>
<thead>
<tr>
<th>Nr</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Registration of recovery factor(s) and matching process deviation(s).</td>
</tr>
<tr>
<td>2</td>
<td>These factors are unknown but may subsequently be recognised as failure factors (category I) or patient-related factors (category II). For an overview of the (possible) factors to be registered, see figure 3.4 on the next page.</td>
</tr>
<tr>
<td>3</td>
<td>Registration of:</td>
</tr>
<tr>
<td></td>
<td>• Incidents.</td>
</tr>
<tr>
<td></td>
<td>• Complications.</td>
</tr>
<tr>
<td></td>
<td>• Diagnostic failure.</td>
</tr>
<tr>
<td></td>
<td>• Health and safety incidents.</td>
</tr>
<tr>
<td></td>
<td>• Environmental incidents.</td>
</tr>
<tr>
<td></td>
<td>• Waste.</td>
</tr>
<tr>
<td>4</td>
<td>Focus on a part of quality management. Management determines the defences and decides whether the process deviation which has been detected and corrected by a defence, is selected for the quality management (improvement) process.</td>
</tr>
<tr>
<td>5</td>
<td>Focus on a part of risk management. Incident reporting system registers incidents. System failure like incidents and complications, becomes visible here. Defences (e.g. quality controls) which fail also become visible here. Risk management immediately tracks down weak spots in the system and in the quality system.</td>
</tr>
<tr>
<td>6</td>
<td>If the defence works: register nothing. The process deviations detected and corrected by the defence—e.g. quality control—are predictable. If the defence fails and correction of a process deviation does not take place, the process deviation is possibly detected and corrected further down in the chain. The registration of defence failure and the corresponding causes must take place.</td>
</tr>
</tbody>
</table>
Figure 3.4. Other (possible) factors which are (as yet) unknown but may act as causes of the development of incidents and complications. Number 16 'other aspects/peculiarities' may be further broken down into factors such as 'training'.
3.3 Models to explain the cause-effect path of incidents and complications

ations. This model consists of a flow chart which contains elements of an associative model. A number of examples by way of illustration:

- 'Process deviation' in figure 3.3 on page 54 may relate to a number of process deviations linked to each other by a tree-like structure comparable with a causal tree (see section 3.4.5).

- After the last possible recovery factor when the system can still return to normal without any harm (see 'c' in figure 3.3 on page 54), process deviations can result in a continuum of (possible) undesirable effects on the patient, varying from limited effects (in 'd1' in figure 3.3 on page 54) to lethal effects (in 'd2' in figure 3.3 on page 54).

- Defences can fail by the same theoretical combination of causes that lead to the process deviation they are supposed to stop. The same causation model applies to both the failure of defences and to the system as a whole (defences are, of course, themselves part of the system). Moreover, it is possible to anticipate the failure of a defence in one system (e.g. a nursing department) by building a defence into the other system (e.g. the OR). For example, the preparation of an OR patient takes place in a nursing department. Certain errors may possibly be made, and as a result, the patient is not properly prepared for his operation. Also in the course of checking whether the patient has been properly prepared—i.e. in accordance with the standards—mistakes may also be made. The defence (quality control) fails (this is a process deviation) and the causes or the development of this failure can be modelled with the causation model of figure 3.3. Failure of the patient's end control, i.e. checking whether the patient has been prepared in accordance with the standards, however, may occur more often in this particular nursing department. If the OR is aware of this, an additional defence/quality control can be put in place to check the preparation of the patient. A failure of the defence in the nursing department produces an incident for the nursing department (in conformity with figure 3.3), but a process deviation for the OR. The causes of this process deviation lie mainly in the nursing department, so outside the system OR. The nursing department should identify this incident and should take action to bring about improvements. This identification of the process deviation by the nursing department can also come about as a result of information the OR provides to the nursing department with regard to this kind of process deviations which the OR receives from the nursing department. This example shows clearly that risk management is a part of quality management: risk management results in better quality management.13

13Incident analysis in the nursing department (= risk management) results in better defences/quality control
The three categories of causes appear to the left in the model (in figure 3.3). A combination of causes can lead to a process deviation. In contrast to figure 3.2 in which only the complete path of adequate defences and recovery actions is presented, figure 3.3 shows two paths: the complete and/or longest path, and the shortest\textsuperscript{14}, both represented separately in figure 3.5 on the next page. In the case of the shortest path, failure can lead directly to an incident or complication. In the case of the longest path, a process deviation can be corrected by (accidental) (human) recovery factors (‘a’ and ‘c’), by an adequate defence action (‘b’), or its effect can be limited by recovery (‘d’). If, for example, when replenishing stocks supplies of ampoules in the OR, the wrong ampoule ends up in the ampoule tray (process deviation), then this process deviation can be corrected in three different ways before it leads to possible undesirable effects (see the matching letters in figure 3.3 on page 54):

a. The deviation may accidentally be noticed during a check of supplies by an anaesthesia assistant, and removed before the ampoule is used (recovery factor).

b. The deviation can be eliminated by working in accordance with the protocol, which states that every ampoule label must be read before its contents are aspirated into a syringe (defence).

c. If this defence is skipped during a stressful situation, the deviation may accidentally be noticed by someone who takes the ampoule and reads the label after the ampoule has been aspirated into the syringe. This person then points out the contents of the syringe to the anaesthetist before the anaesthetist injects it (recovery factor).

Thus, correction of deviations can take place in two different ways:

• By deliberately building in defences in advance.

• By recovery factors which happen to be present. These are often (accidental) human interventions but may also be other (accidental) factors.

The deviation, if not corrected, can develop into a deviation with (possible) undesirable effects on the patient and/or the organisation. Subsequently, there are two extreme possibilities (see the matching letters in figure 3.3 on page 54):

\textsuperscript{14}See remarks about associative aspects of the model earlier in this section.
3.3 Models to explain the cause-effect path of incidents and complications

Figure 3.5. A long and short path for the development of incidents, complications and other undesirable outcomes. This figure is based on figure 3.3 on page 54.
d/d1. The deviation can be partially corrected by (a) recovery factor(s), i.e. there are (possible) undesirable, limited effects on the patient and/or the organisation. Recovery moment ‘d’ differs from ‘c’ in the sense that, once the process deviation has arrived at moment ‘d’, it already has (possible) effects whereas at moment ‘c’ this is (still) not the case: compare this with (3) and (4) in the context of [B] and [C] and (5) in the pyramidal causation model in figure 3.2 on page 50.

d/d2. The deviation can take place unchecked and result in (possible) undesirable effects on patient and/or organisation.

The recovery factors (which coincidentally happened to be present) can be made structural (i.e. permanent) by building them into the system (i.e. into the defences of the organisation), e.g. by incorporating the recovery factors into the work instructions and procedures of the organisation. This is why recovery factors, regardless of whether they occur with incidents or complications, should be registered and analysed.

A defence can, like a recovery factor:

- Be successful, i.e. the defence limits the damage (in this case a defence has not been completely effective because it worked, for example, just too late and some damage had already been done but more serious damage is prevented) or it prevents damage (a defence is completely effective).

- Fail or miss, i.e. the defence is in place but is not able to limit or prevent damage.

Undesirable effects on the patient are (see figure 3.3 on page 54):

- Incidents.

- Complications.

- Diagnostic failure.

Undesirable effects on the organisation are (see figure 3.3 on page 54):

- Health and safety incidents.

- Environmental incidents.

- Waste.
3.3 Models to explain the cause-effect path of incidents and complications

![Diagram of cause-effect path]

Figure 3.6. The simplified causation model for the development of incidents, complications and other undesirable outcomes.

The causation model summarised  See figure 3.6. One or more causes can lead to one or more process deviations. Causes can be ‘failure factors’ and/or ‘other factors’ in which one or more ‘other factors’ can lead to a failure factor. These ‘other factors’ are not failure factors but are, like failure factors, causes in the development of process deviations and may be patient-related factors or other factors from inside or outside the system. The set of process deviations consists of a subset of deviations with—on the one hand—no harmful effects (recovered by recovery factors or defences), and—on the other hand—with effects. The subsets ‘incidents’ and ‘complications’ are part of a set of process deviations, in which a subset ‘incidents’ can in turn lead to ‘complications’. Causes do not have to lead directly to an incident. It may also be that a cause leads to a process deviation which in turn leads to another process deviation, and that this chain of process deviations eventually results in an incident—a domino effect.

Useful purposes of the causation model  The value of the development model (figure 3.3 on page 54) is among other things:

- To provide an insight into what a reporting system should register in order to gain a clear understanding of the causes of process deviations like incidents and complications.

- To emphasise the presence of recovery factors and the important role they play in preventing future process deviations. An accidental recovery factor can be made
structural by building the recovery factor into the standard defences of the system, making it an integral part of the defence system. For example, the following recovery factor occurs often: an anaesthesia assistant who happens to observe the anaesthetist during the induction of a patient, corrects process deviations. Subsequently, this ‘accidental observation’ by the anaesthesia assistant during parts of the induction may be incorporated into the protocol for the induction of patients.

- To draw some distinctions, albeit artificial, to show that risk management can be the completion or a part of quality management (see figure 3.3 on page 54 numbers 4 and 5). The model can also be used to account for the development of ‘other undesirable outcomes’, including e.g. waste.

3.4 Framework for effective risk management

3.4.1 Introduction: the risk management framework

This research was planned to assess and analyse patient risks in order to let the hospital organisation learn, and to design and implement improvements in order to prevent future incidents—and, if possible, complications. In order to be able to learn from patient risks, a risk management framework, see figure 3.7 on page 64, based on three requirements (mentioned below) was designed. The risk management tools used for this framework were selected to meet these three requirements. The three requirements were:

- The ability not only to assess the risks of undesirable events which have already occurred—i.e. a retrospective or reactive approach—but also the ability to assess potential risks to prevent undesirable events before they occur—i.e. a prospective or proactive approach. The CIIs and the IRMS (see figure 3.7 on page 64) were used to represent the reactive approach, and are based on incidents. The FMEA represented the proactive approach and is based on failure modes and their possible effects such as incidents. See also table 3.5 on page 65. So, the CIIs and the IRMS make it possible to learn from and take preventive measures on the basis of incidents which have already occurred, and an FMEA makes it possible to take preventive measures before an incident occurs. A process model is necessary for performing an FMEA. The tools which are presented and used in the framework of figure 3.7 on page 64, will be discussed further down in sections 3.4.2 to 3.4.8.

- The ability to assess, analyse and prevent both incidents and complications. Incidents are dealt with via the CIIs, the IRMS and the FMEA. In the case of the FMEA, this is based on the assessment of (possible) failure modes which can result in incidents. Complications can be dealt with via the CIRMS (which was not
implemented; represented as 'complication reports (CIRMS)' in figure 3.7 on the next page and the FMEA (which was not used for this purpose in this research—if used, it would have been based on the assessment of (possible) failure modes which can result in complications). In the Haemodialysis department, CIIs were also used to assess complications: this way of using CIIs is not represented in figure 3.7, see also chapter 7.

- The ability to use a quick, one-off approach to assess and analyse risks and learn from them—via the FMEA and CIIs—and a more systematic way to monitor the occurrence of incidents and complications—assessing, analysing and learning from risks via the IRMS and CIRMS. See also table 3.5 on page 65.

The framework, as presented in figure 3.7 on the next page, assesses and analyses both process deviations (in the form of failure modes via the FMEA) and their results in the form of incidents (via CIIs and the IRMS) and complications (via CIIs—not represented—and the CIRMS, which was never implemented). Notice the connection with process control and with the improvement circle idea of quality management in the framework: collecting data of process deviations, analysing the data and database, and generating measures to prevent future process deviations like incidents and complications.

This research is limited mainly to reactive incident management in the form of CIIs (one-off in nature) and the IRMS (more permanent in nature), and proactive management of failure modes in the form of FMEAs, see also table 3.5 on page 65. Except for an assessment of complications held by the CIIs in the Haemodialysis department, complication management was not implemented but some tools for it were developed. As a bonus, the reporting of health and safety incidents was successfully implemented in the IRMS (see e.g. the reporting form in appendix I), but the results, i.e. an analysis of the health and safety incidents and an evaluation of the results, were left out from this research.

The tools which are presented and used in the framework of figure 3.7 on the next page, will be discussed further down in sections 3.4.2 to 3.4.8.

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15I.e. process deviations with undesirable physical effects on patients—such as wound infections—which are called complications.

16Notice that, for instance, the FMEA, by assessing process deviations, also assesses (possible) incidents (i.e. the effects of the failure modes) and that, for instance, the CIIs, by analysing incidents, also assesses process deviations (i.e. the direct and indirect causes) which resulted in incidents.

17See the definition of risk management in section 1.3.1.
Figure 3.7. Framework for effective risk management improvements from incidents and complications in a hospital. In this chapter, the different methods presented in this framework are discussed. The actual use of these methods will be discussed in chapters 4–7. The CIs were also used to assess complications in the Haemodialysis department, see chapter 7; this is not represented in the framework.
Table 3.5. Overview of the presence and approach of some methods used in the framework for effective risk management represented in figure 3.7 on the preceding page.

<table>
<thead>
<tr>
<th>Method</th>
<th>Approach</th>
<th>Presence</th>
</tr>
</thead>
<tbody>
<tr>
<td>CII's</td>
<td>Retrospective</td>
<td>One-off/periodic</td>
</tr>
<tr>
<td>IRMS, CIRMS</td>
<td>Real-time</td>
<td>Permanent</td>
</tr>
<tr>
<td>FMEA</td>
<td>Prospective</td>
<td>One-off/periodic</td>
</tr>
</tbody>
</table>

### 3.4.2 Process model

It is of crucial importance to create a model of the processes in a system in order to achieve process control to minimise the risks for patients.

Brainstorming sessions were held to establish the requirements for a process model. The result of these sessions was that the model should meet the following requirements:

- The model must accurately describe and provide an insight into the processes that take place in a hospital department.
- The model must include all aspects which are necessary for and relevant to process control. These aspects are the same as the factors mentioned in figure 3.4 on page 56.
- The model should be usable as input into an assessment method for possible patient risks like FMEA or HazOp.\(^{18}\)
- The model must provide an insight to all users, so it can be used as a means of communication between doctors, nurses and paramedics.

Three different process description techniques for making a process model of a hospital department, have been examined:

- The system approach by In ‘t Veld [166], at the core of which is process control. This modelling technique uses different aggregation levels, i.e. different hierarchical levels, the possibility of zooming in and out on concrete systems.
- SADT (Structured Analysis and Design Technique) [62]. This technique can be used for analysing systems, making use of Activity-Factor Diagrams. These diagrams consist of activities grouped in action boxes with four types of factors: inputs, outputs, mechanisms and controls. SADT also has different hierarchical levels.

\(^{18}\text{See section 3.4.3.}\)
• Data flow description techniques in which the data flow in a system is modelled [8, 26, 39]. These methods, which are used in Information Technology, focus on the processes, on process flows, and on data flows.

In 't Veld's system approach is used as a basis for a process description technique to model the processes within the departments. The approach is based on the analysis techniques presented in his book 'Analyse van organisatieproblemen: een toepassing van denken in systemen en processen' [166]. In this book, In 't Veld advocates thinking in systems which might help a manager to get a clearer view and better understanding of what has to be done within his department, and of what the connection is with the departments around him. Thinking in systems creates better opportunities for a multi-disciplinary way of working. To make this possible, In 't Veld offers a number of concepts and insights with regard to systems and processes. The models need no further explanation if the reader is prepared to study the legend and the models for a few minutes. The models are to be found on the CD-ROM, see also appendix B. Reasons for choosing In 't Veld's approach were [151]:

• The method meets all requirements.
• Familiarity with the method.
• The method makes it possible to track the real process flow of the patient through the system.
• The method uses measuring and control loops which fit in with process control.

The other two methods were rejected for the following reasons:

• SADT provides only a limited insight into process flow and process control because there is no (neat) sequence dependence: a factor relationship between different action boxes does not have to refer to a flow, and does not have to indicate a precedence relationship. This tends to result in a spaghetti structure which does not contribute to a greater insight. In addition, 'care must be taken that no boxes “overlap”, i.e. that one activity is assigned to more than one box’ [62]. The In 't Veld method provides an 'easier' insight than SADT which is a bit more complicated because there is no nice sequence dependence such as the In 't Veld method offers. Moreover, the In 't Veld method also seems to be subject to fewer limitations than SADT.

19In English, the title would be: 'An analysis of organisational problems: an application of thinking in systems and processes'.
• The data flow description techniques are mainly focused on one aspect: information. Processes (man or machine), data flows, control flows and data storage can be made visible, but it is not clear whether the other relevant aspects can be modelled by these techniques (e.g. patients, instruments). This approach works well as long as the human activity which is being modelled is mainly information intensive. ‘The approach is not effective when the human processes have significant motor skills or introspective reasoning components’ [26].

For the modelling of certain aspects, it was necessary to make some adaptations or design new symbols. Fortunately, the system approach by In ’t Veld is tolerant of alterations in the modelling technique, and these necessary alterations were in fact made. So, when the focus is, for instance, on process control, it should be clear for each process who is in control of the process. Or, if a process starts every day at a certain time, this was represented by a clock which triggers the start of the process.

The models which were made by means of the adapted In ’t Veld method (see also chapters 4 and 7), can be combined easily with other methods like protocol description techniques such as those of Veen [35, 165] which are commonly used in quality management. The In ’t Veld method produces an associative model of the patient passing through the processes in—and sometimes outside of—the department, i.e. a string of processes the patient ‘flows’ through, with the controlling and standard-setting processes above and below this string.

The process model of a hospital department starts at the highest level: the top aggregation level, see figure 3.8 on the next page for an example. The top aggregation level represents the department and its environment, in which the department is a black box which the patient and accompanying files pass in and out of. In this way the system (i.e. the department) and the system boundaries are clear. Then the black box is opened up, shifting the second highest aggregation level, the main processes the patient is passing through are modelled. Next, these main processes are opened up and the processes within are modelled. This level, the third highest aggregation level, is described, for instance, in the process model of the OR (the model is to be found on the CD-ROM, see also appendix B). At this level, the modelling stops because the level of modelling is adequate for meeting the demands and for assessing the (possible) risks for patients: the level shows the processes the patient is passing through, and who is or are responsible for controlling these processes. Descending one more level of modelling, the fourth highest aggregation level, is the level of the protocols and procedures that are being used. Another modelling technique like Veen’s [165] is probably more appropriate to modelling this level, because it is widely used in quality management for the purpose of describing

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20Veen describes in [165] process control diagrams which are, among other things, useful for work instruc-
protocols and procedures, although it is also possible to describe protocols and procedures in detail using the In 't Veld method.

The validation of the model is effected by discussing the model with experts of the departmental processes and (potential) users of the model.

The reliability of the modelling technique\textsuperscript{21} need not be a problem if clear agreement has been reached in advance about:

- Which aspects are to be modelled (e.g. the patient).

- At what level the modelling has to stop (stopping rule), i.e. at which aggregation level the modelling has to stop. See e.g. the different aggregation levels of the OR

\textsuperscript{21}I.e. the models of the same department

* created by two different model builders and
* created at different points of time (in the case of one model builder)

must be fairly consistent, i.e., they must possess a high degree of reliability. The technique should not be too much bound up with a person nor too time-dependent.
process model in figure 3.8 on the facing page: the modelling of the OR process model stopped at the third highest aggregation level.

- Which other requirements are imposed on the model. For instance, if the purpose of the model is clear, the creator of the process model knows which issues need to be modelled and which do not. Assuming that a model needs to be made which is going to be used for patient risks assessment with an FMEA, it is clear that the model must focus on (and thus model) the control of processes and all relevant issues related to this. The model builder has to keep this in mind while creating the model, and must decide which information and which protocol are important.

For reliability, see also sections 4.2.1 and 7.2.2.

3.4.3 Failure Mode and Effects Analysis (FMEA)

One of the requirements for the selection of risk management tools for the risk management framework mentioned in section 3.4.1, was the ability to assess possible risks in order to prevent undesirable events before they occur. This requirement can be translated into the objective of making a prediction about the nature and frequency of occurrence of possible risks for patients in a department. For this purpose, the Failure Mode and Effects Analysis (FMEA) was used. An FMEA can be used to make an assessment of the possible risks for patients,\(^{22}\) and as such is a valuable and important part of the risk management framework (see figure 3.7 on page 64). An FMEA assesses failure modes of processes within a system, and can be applied to a system which can be divided into individual components [146].\(^{23}\) These components may be hardware or functional blocks. It is essential to have a clear understanding of the function of every component with all inputs and outputs. FMEA examines the failure modes of every component in a systematic way in order to determine the causes and effects of these failure modes [39, 146]. This information—see table 3.6 on the following page for a complete overview—is assessed and recorded on a form during a number of meetings by a multidisciplinary team, i.e. a group of experts on the processes within the system. Such a multidisciplinary FMEA team must consist of one representative of every function, see e.g. section 4.3.1 for the staffing of the FMEA team in the OR. For an example of the FMEA form, see the FMEA manual in appendix C or the Haemodialysis results in appendix H. Finally, when all the required information has been recorded and assessed by the FMEA, the Risk Priority Number (RPN) is determined as the product of the seriousness, the frequency of

\(^{22}\)A comparison was made between the FMEA and HazOp methods [26, 39] after which the FMEA was selected [151].

\(^{23}\)Or e.g. [67, 76].
Table 3.6. The information assessed and recorded by an FMEA team with a brief explanation. See also appendix C.

<table>
<thead>
<tr>
<th>The information assessed and recorded</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The failure mode(s) of every component</td>
<td>For every failure mode a specification is given of what the possible effects on the patient are.</td>
</tr>
<tr>
<td>• The effects of a certain failure mode</td>
<td>The seriousness of these effects are put on the scale and then the (possible) causes of the failure mode are determined. The frequency of occurrence of a certain cause and the extent to which a certain cause can be corrected are determined and put on the scale.</td>
</tr>
<tr>
<td>• The seriousness of these effects</td>
<td></td>
</tr>
<tr>
<td>• The causes of a failure mode</td>
<td></td>
</tr>
<tr>
<td>• The frequency of occurrence of a certain cause</td>
<td></td>
</tr>
<tr>
<td>• The extent to which a certain cause can be corrected</td>
<td></td>
</tr>
</tbody>
</table>

occurrence and the extent to which a certain cause can be corrected,\(^{24}\) this with a view to prioritising, i.e. establishing which causes can and should be dealt with first by the management.

In this research, the FMEA used a process description of the system—i.e. a process description of the OR and Haemodialysis department—for the assessment of failure modes.

A strong point of an FMEA is that a Risk Priority Number (RPN) can be worked out. This simplifies setting priorities with regard to which risks must be handled first. Another strong point is that the results of the FMEA lead to an independent ‘living’ document which over time can easily be adapted on the basis of new failure modes produced by another FMEA.

For more information on FMEA, see the literature, e.g. [67, 76, 146], or the participants’ manual in appendix C.

3.4.4 Critical Incident Interview (CII)

The initial objective of the Critical Incident Interviews (CIIs) was to assess the nature and frequency of actual risks for patients in a department, in contrast to the FMEA which was used for the purpose of making a prediction about the nature and frequency of the possible risks for patients. See figure 3.7 on page 64 for the position of CIIs and FMEA in the risk management framework.

The FMEA and the CIIs are different methods and lead to different results. In order to determine whether the FMEA generates a reliable reproduction of the actual risks, the

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\(^{24}\)See for RPN also the second definition of risk discussed earlier on page 42 or appendix C.
FMEA results must be compared with the results of the CIIs. The CIIs make an assessment of both actual and potential risks, two easily distinguishable categories. The actual risks are linked to the causal tree (see section 3.4.5) via an AND gate, the potential risks via an OR gate. In order to make possible a comparison between the FMEA and CII results, the results of both methods were classified according to the Eindhoven Classification Model of system failure (ECM) (for ECM, see section 3.4.6 and appendix E).

The CII is based on a technique which Flanagan describes in 'The Critical Incident Technique' [48] and which was used for instance by Van Vuuren [159]. Flanagan describes four ways of collecting data; one of them is the interview. By 'critical incidents', Flanagan means events which affect the objective of a certain task in positive or negative ways; these include both failure factors and recovery factors. The CII is an interview technique in which the interviewer and the interviewee discuss an incident, including all causal factors and connections which affected the incident both positively and negatively. The positive factors are the recovery factors, the negative factors are the causes. This research focuses on structural—or permanently present—causes: these structural causes can lead again to incidents in the future and must therefore be prevented. The (accidentally) present recovery factors have been incorporated because they can possibly be rendered structural and in this way may prevent future incidents.

During a CII, the interviewee is intended to talk in an open, confidential interview about an incident, or a complication, which occurred recently and which the interviewee experienced from at first hand. The interviewee must focus attention on his own actions during the interview. The interview concentrates on the (possible) effect(s) on the patient, on the (possible) causes, on the relations between the causes and possible recovery factors.

The interview is confidential and the interviewee is given the guarantee that only the interviewer will have access to the data. The management will only be given a list of structural failure factors of incidents; this should be enough to enable the management to take effective measures and to ensure adequate patient safety, but not enough to trace back the data to their source or to the incident.

Because of the open nature of the interview, the interviewer uses an interview plan for support and standardisation [46]. The interview consists of four phases:

1. An introduction in which a number of things are set out, such as the goal of the interview, the use of the interview plan and the confidential nature of the interview. The introduction concludes by asking whether everything is clear and whether there are any questions.

2. After the introduction, the interviewer asks the interviewee a brief series of ques-
tions to take the interviewee back to the place and the (situational) context in which the incident occurred. This is done in order to jog the interviewee’s memory and increase the chances of the interviewee recalling the events surrounding an incident [47, 57].

3. After this, the interviewee can start by talking about the incident which he recently experienced. Whenever something is not clear, the interviewer should interrupt the interviewee and ask additional questions. For this purpose, the interviewer can use the checklist which is included in the interview plan.

4. Finally, the interview is concluded by discussing a number of things: briefly go over the incident again, check whether the interviewer has properly understood the incident, and whether the interviewee may have forgotten something, and mention when and how the interviewee will be given feedback on the interview.

After the interview, the interviewer draws up a report containing all relevant facts and events. This report is the basis for creating a causal tree (see section 3.4.5) of the incident. Subsequently, the interviewer gives feedback to the interviewee by discussing the report and the corresponding causal tree, and—if necessary—the interviewer amends his report and the causal tree accordingly.

3.4.5 Causal Tree Analysis (CTA)

Causal Tree Analysis (CTA) is a tool that describes events and is based on Fault Tree Analysis (FTA) [159] (or e.g. [68, 76]). A causal tree is a qualitative fault tree and is particularly helpful in describing events with regard to which it is difficult to establish which factors play a role in their development, and to unravel what the underlying connections and relationships are.

CTA describes an event and the development of this event in the form of (the roots or branches of) a tree: see figure 3.9 on the facing page. At the top of the tree is the event called the top event, the development of which is described: in the case of an incident, the top event presents a description of the (possible) undesirable (physical) effects on the patient. The complete tree is built in accordance with the same principle: an event (cause) leads to another event (effect). The cause-effect relations are represented from the bottom to the top of the tree. Recovery factors, if available, are placed on the right-hand side of the tree. Strictly speaking, two kinds of relations exist:

- AND relations, represented in the causal tree by a normal, solid line. All causes mentioned below a certain event are needed to result in an event (= result).
• OR relations, represented in the causal tree by a dotted line. Not all causes mentioned below a certain event are needed to result in an event but one may be enough. OR relations are used if the cause(s) is/(are) unknown.

For examples of a description of an incident in a causal tree, see e.g. Witteveen [183] (based on Bhopal) or Van der Hoeff [149] (based on a cancer radiation therapy machine) both mainly based on cases described in Casey [23], or Van Vuuren [160].

3.4.6 Eindhoven Classification Model of system failure (ECM)

In order to compare the results of the FMEA with the results of the CIIs, the results of both methods must be classified. Van der Hoeff [150] examined four different methods/models for the classification of medical incidents. These models are: the Tripod framework [65, 122, 123], MORT (Management Oversight and Risk Tree) [79], ECM (Eindhoven Classification Model of system failure) [154] and ‘Other models’.

The category ‘Other models’ represents a compilation of methods found in medical literature about research on medical incidents. Most of these ‘Other models’ do not use analytical methods for incident description, do not search for (root) causes, do not use a model to connect causes to measures, and do not evaluate the results of any measures which were taken. Most of the models only count and classify the incidents (e.g. intubation in the oesophagus) and give no—or just a brief—classification of deeper causes
(like ignorance or fatigue), and of the direct effect(s) on the patient (e.g. a lack of oxygen resulting in brain damage). These models, therefore, dropped out of consideration as classification models.

The selection criteria/requirements and the advantages and disadvantages of the remaining three classification models are presented in table 3.7 on page 76 and on page 77. The ECM was chosen as a classification model for incident causes after weighing the pros and cons of this model, as shown in table 3.7 on page 76 and on page 77.

Van der Schaaf [154] developed the ECM for the chemical process industry. The model is a system for the detailed classification of technical, organisational and human failure. The model emphasises the role of human failure which relates to operator error, and is derived from the Rasmussen SRK model. According to this SRK model the performance of a task is based on Skills, Rules and Knowledge.

The reliability of the classification process—i.e. the allocation of incident causes to the classification categories of the ECM—is a weak point, partly due to the general vagueness of the SRK model [154]. Another weak point of the ECM is the emphasis on human failure: this point was later recognised and improved upon by Van Vuuren [161]. The organisational and human failure mentioned in the ECM correspond with the latent and active failure mentioned by Reason (e.g. [121, 125]). The ECM is described further in appendix E.

3.4.7 Incident Reporting and Management System (IRMS)

In contrast to an FMEA and CIIs, an Incident Reporting and Management System (IRMS) is a method for continuously assessing the actual patient risks, see figure 3.7 on page 64 for the position of the IRMS in the risk management framework.

The design of a voluntary IRMS was based on the concept of a near miss management system which was used for reporting and analysing health and safety accidents and near accidents in the chemical process industry [140, 154]. In order to maximise the chance of a successful implementation, the development of the reporting system was based on the participation of the users, so the preferences of the doctors, nurses and paramedics were taken into consideration when designing the system. For this reason, and also for the purpose of actually designing and managing the system, an IRMS committee, consisting of doctors, nurses and paramedics, was set up [140].

The objective of an IRMS is to determine the structural failure factors of incidents with a view to preventing future incidents.

Van der Schaaf [154] gives three different objectives for a near miss management system:
3.4 Framework for effective risk management

* Modelling. The system provides a qualitative understanding of new (i.e. more or less unknown) causes of near misses.

* Monitoring. The system provides a quantitative insight into known causes of near misses.

* Alertness. The system maintains the awareness that compliance with safety procedures is and remains necessary, in spite of measures that may have been taken.

In industry, there is plenty of knowledge of and experience of near miss reporting. According to Lucas [93], the way an organisation thinks about the development of incidents and deals with incidents determines to a large extent the effectiveness of the research process to discover incident causes and of the countermeasures which are taken for the prevention of future incidents. The safety culture must be such that dealing with failures and incidents is aimed at prevention only: an atmosphere of mutual trust between doctors, nurses, paramedics and management is an absolute prerequisite for this. To bring this about, the commitment of the top management is of essential importance. An evaluation of the results of incident research is no problem provided the evaluation is both positive and negative. But what is fatal is if the focus is predominantly on punishment and sanctions. This would be inconsistent with the objective that incident information is only used to learn from, it would be absolutely disastrous for the safety culture and would spell a certain death for the IRMS. Finally, the very existence of the IRMS is threatened if inadequate feedback is given to the reporters on analysis results and improvements of the system.

The IRMS which was designed, is to be found in table 3.8 on page 78. It is partly based on the design of an IRMS for an OR by Timmermans [140]. Table 3.8 on page 78 combines both the IRMS and CIRMS (Complication and Incident Reporting and Management System). Activities two, three and four with regard to complications relate specifically to the CIRMS.

Elucidation of the IRMS in table 3.8 on page 78 (the elucidation of the CIRMS will be given in section 3.4.8):

Activity 1 A course for doctors, nurses and paramedics precedes the start of the IRMS, so that the reporter of an incident knows what incident information is needed and must be reported. In this way, the amount of follow-up research that must be conducted by a member of the IRMS committee for the purpose of collecting more information needed to make a good description of an incident (activity 2), is minimised. Doctors, nurses and paramedics can report an incident by using the reporting form. To lower the threshold for reporting, the reporting form is designed by the IRMS committee (see also appendix I).
Table 3.7. An overview of the criteria/demands three classification models must meet, and the advantages and disadvantages of these three classification models [150].

<table>
<thead>
<tr>
<th>Model</th>
<th>Directly applicable?</th>
<th>Recognisability?</th>
<th>Translation of classification to measures possible?</th>
<th>Insight into the development of incidents?</th>
<th>(Other) advantages and remarks</th>
<th>(Other) disadvantages and remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECM</td>
<td>Yes, model largely fixed; model can be expanded if necessary</td>
<td>• High, by using examples from own organisation • SRK model is easily understood and is widely accepted and used</td>
<td>Yes</td>
<td>Yes</td>
<td>• Deals with all relevant failure factors • Software under development</td>
<td>• General vagueness of the SRK model • Emphasis on human behaviour/failure</td>
</tr>
<tr>
<td>MORT</td>
<td>Yes, model fixed</td>
<td>Moderate, user must continuously make a translation to his own situation</td>
<td>Yes</td>
<td>Yes</td>
<td>• Complete • Software available, helping with recording and judgement</td>
<td>• Complexity and size can scare off user • Analysis is time-consuming and too comprehensive (too heavy an instrument in most cases)</td>
</tr>
</tbody>
</table>

*continued on next page*
<table>
<thead>
<tr>
<th>Model</th>
<th>Directly applicable?</th>
<th>Recognisability?</th>
<th>Translation of classification to measures possible?</th>
<th>Insight into the development of incidents?</th>
<th>(Other) advantages and remarks</th>
<th>(Other) disadvantages and remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tripod-delta&lt;sup&gt;a&lt;/sup&gt;</td>
<td>No, custom-made for every situation (checklist); time-consuming</td>
<td>High, model is custom-made</td>
<td>No (does indicate where problem is)</td>
<td>No</td>
<td></td>
<td>No validation for items as indicators for fault types for an ICU department [174]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Directly applicable</th>
<th>Recognition</th>
<th>Measures</th>
<th>Insight</th>
<th>Complete</th>
<th>Time per analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECM</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>MORT</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Tripod-delta&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>?</td>
<td>+</td>
</tr>
</tbody>
</table>

<sup>a</sup>This overview was made in 1994, and concerns Tripod-delta originally developed as an audit tool. In Tripod-beta—the current Tripod version for incident analysis—some of these disadvantages have been obviated, but this version was not available at the time this research started.
Table 3.8. (Complication and) Incident Reporting and Management System ((C)IRMS). The IRMS described is the final IRMS (see also section 5.2).

<table>
<thead>
<tr>
<th>Activity</th>
<th>Carrying out activity</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reporting incidents and complications.</td>
<td>Doctors and employees</td>
<td>Daily</td>
</tr>
<tr>
<td>2. Incidents: describing incidents of past week.</td>
<td>Member(s) (C)IRMS committee, if necessary, involvement of doctors and/or employees</td>
<td>Weekly</td>
</tr>
<tr>
<td>Complications: describing complications. This is already done by activity 1 if the complication is reported via the computer.</td>
<td>Doctors and employees</td>
<td>Daily</td>
</tr>
<tr>
<td>3. Incidents: clustering incidents of the past week to their cause(s).</td>
<td>Member(s) (C)IRMS committee</td>
<td>Weekly</td>
</tr>
<tr>
<td>Complications: counting number of complications per category.</td>
<td>Computer</td>
<td>Weekly</td>
</tr>
<tr>
<td>4. Incidents: examining all incidents and, if necessary, altering clusters and/or making new clusters. Generating list of structural failure factors. Trend analysis.</td>
<td>All members (C)IRMS committee</td>
<td>Periodically(^a)</td>
</tr>
<tr>
<td>Complications: generating list with number of complications per category. Trend analysis and, if possible, generating a list of (possible) causes of complications.</td>
<td>All members (C)IRMS committee</td>
<td>Periodically(^a)</td>
</tr>
<tr>
<td>5. Drawing conclusions and making recommendations.</td>
<td>Members (C)IRMS committee</td>
<td>Periodically(^a)</td>
</tr>
<tr>
<td>6. Proposing, initiating and securing improvements.</td>
<td>Management of the department, if necessary, with the cooperation of the members of the (C)IRMS committee and/or the hospital management</td>
<td>Periodically(^a)</td>
</tr>
<tr>
<td>7. Evaluate (C)IRMS, if necessary, adapting (C)IRMS procedure.</td>
<td>Members (C)IRMS committee</td>
<td>Periodically(^b)</td>
</tr>
<tr>
<td>8. Giving feedback on analysis results and improvements to doctors and employees.</td>
<td>Members (C)IRMS committee</td>
<td>Periodically(^a)</td>
</tr>
</tbody>
</table>

\(^a\)Frequently, e.g. every three months.
\(^b\)Less frequently, e.g. every six months.
Activity 2 The IRMS committee makes a description of the incident containing:

- The (possible) effect(s) on the patient.
- The causes.

CTA can be used if the development of the incident is complicated.

If the information on the reporting form does not suffice for making a description of the incident, follow-up research in the form of an interview takes place between the reporter(s) and an IRMS committee member.

Activity 3 The incident described is classified into one or more of the clusters. These clusters are categories of all frequently occurring causes of incidents, and are, if possible and necessary, divided into subclusters giving a clearer view of what and where the structural causes of incidents are.

Activity 4 Periodically, the IRMS committee must consider whether:

- New (sub)clusters can and need to be created.
- Existing (sub)clusters can and need to be altered or adapted.

The IRMS committee does this by examining all the incidents. In this way, the (sub)clusters always indicate clearly what the causes of the incident are.

Subsequently, a list of structural failure factors of incidents is generated.

Trend analysis takes place by tracking over time whether certain (sub)clusters become larger or smaller, particularly the (sub)clusters against which measures have been taken.

Activity 5 Conclusions can be drawn from the structural causes that are found and from the results of the trend analysis. If possible, the IRMS committee can make recommendations to the management of the department.

Activity 6 It is the task of the management (of the department), if necessary in consultation with the IRMS, to initiate and guarantee improvements to prevent the structural causes which have been found from occurring again in the future. Particularly if a cause is found outside the department boundaries, if the department does not have the staffing capacity to deal with the cause, or if the cause is of an organisational (hence 'politically' sensitive) nature, it may be necessary for the management of the department to consult with the hospital management.

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25 Clustering is the iterative process of joining similar incidents and incident causes together in groups (clusters) and subgroups (subclusters). This is done by the IRMS committee.
Activity 7 Periodically, say every six months, the IRMS committee critically evaluates the operation and operating procedures of the IRMS, and, if necessary, adapts the operating procedures.

Activity 8 The IRMS committee gives, for instance every three months, feedback on analysis results and improvements to employees and doctors: this is essential for maintaining the willingness of doctors, nurses and paramedics to continue to report incidents.

The IRMS framework resembles in most important aspects the incident reporting framework developed by Koornneef [80] in his research which was conducted in parallel with this study. This research was not known to the author of this thesis at the time.

An IRMS can be used for reporting and analysing many different process deviations like complications and working conditions incidents. In the next section, complications will be added to the IRMS concept, resulting in a Complication and Incident Reporting and Management System (CIRMS).

3.4.8 Complication and Incident Reporting and Management System (CIRMS)

Complication registration is necessary because:

- The occurrence ratio of complications must be closely monitored. Knowing the frequency and nature of complications is the beginning of and the basis for an effective complication policy. In this thesis, this is called *level 1 registration*.

- The aim is to minimise the occurrence of complications. This means that in addition to reporting and registering complications, all possible causal factors must be registered and analysed. In this thesis, this is called *level 2 registration*.

This section describes a Complication and Incident Reporting and Management System (CIRMS) which could be used for the continuous assessment and analysis of both incidents and complications. In the risk management framework of figure 3.7 on page 64, this is represented as ‘voluntary incident reports’ and ‘complication reports’.

The CIRMS is in fact an IRMS with additional elements for the reporting and analysis of complications. The objective of an IRMS was to determine the structural failure factors of incidents in order to prevent future incidents (see section 3.4.7). The objective of the CIRMS is more or less the same as the objective for the IRMS, but it now includes both incidents and complications. In other words, the objective of a CIRMS is to determine the structural failure factors of incidents in order to prevent future incidents, to

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26 Or after a report such as [144, 145], see e.g. section 5.4.
measure the frequency of occurrence of complications, and to try to prevent complications by registering possible causes/factors. These possible causes/factors are registered and analysed to determine the causes for the development of complications. If the causes are known, complications may be prevented.

In accordance with the definitions of incident and complication in section 3.2 and with the causation model presented in figure 3.3 on page 54, it is clear that incidents and complications should be registered and analysed together, because:

- Incidents and complications both result in undesirable physical harm for patients, and should both be registered and analysed in order to be able to prevent this harm.

- Incidents may result in complications and for a complete understanding of the causal path of complications, it is necessary that both incidents and complications are registered.

So, it may be concluded that the registration and analysis of incidents and complications should not be done separately from each other. However, defining the deviation as an incident (causes known, see the definition on page 44) or a complication (causes unknown, see the definition on page 44) results in different registration and analysing paths. Complications must be registered and analysed differently from incidents because the causes are (largely) unknown. This means that the data which have to be registered and the data analysis are different, i.e. all factors which may have contributed to the development of a complication should be registered, and the determination of whether a factor is a cause in the development of a complication must be performed by statistical analysis.27 This amounts to an epidemiological approach to complications as opposed to a causal-deterministic approach to incidents.

The aim is, eventually, a level 2 registration for all complications. For this purpose is needed:

- A list of all possible complications.

- For each complication, a list of factors that should be registered.

This list of complications and factors can be obtained by:

- Brainstorming session(s) with doctors, nurses and paramedics.

---

27 E.g. there may be a positive correlation between the complication wound infection and the operating room (i.e. the factor location, see figure 3.4 on page 56) in which patients were operated on, which may indicate that there is a sterility problem (i.e. an indication of a cause) in this particular location.
• Periodically updating the list in the course of the operational use of the registration system.

Alternatively, the complication registration may have to be limited for reasons of restricted staffing capacity. However, a level 1 registration for all complications is a minimum requirement. An extension of this with a level 2 registration may be initiated, based on the results of this level 1 registration. Level 2 registration implies that many different reporting forms are necessary, since every complication may require, at least in theory, the registration of different factors. For practical reasons, the registration of the complication data and, of course, their analysis justify the use of a computer with supporting dedicated software.

Table 3.8 on page 78 presents a description of a Complication and Incident Reporting and Management System (CIRMS). The description is based on the IRMS presented in section 3.4.7.

An elucidation of a CIRMS described in table 3.8 on page 78:

**Activity 1** The reporting of incidents is performed by filling in a reporting form in which the reporter can give a description of the facts of the incident and of the (possible) effects on the patient (see also appendix I).

The reporting of complications is performed by entering the relevant data on a ‘form’. This ‘form’ consists of several fields on a computer screen and the data are fed directly into the computer. A computer is used for efficiency reasons because, for instance, the number of different forms may be large. Complications are classified into categories in which every category describes the (physical) effects on the patient and every ‘form’ contains at least one category.

**Activity 2** The effects on the patient are described of both incidents and complications. In the case of incidents the causes, and in the case of complications the relevant factors, are included in the description.

**Activity 3** Each week, the incidents are classified on the basis of their structural causes into clusters. Complications are clustered per category and counted automatically by the computer the moment the complication is fed into the computer (activity 1).

**Activity 4** Periodically, all incidents are examined and, if necessary, new clusters are created and/or existing clusters altered or adapted. A list is generated of structural failure factors of incidents, of the number of complications per category and—if possible—of (possible) causes of complications.
Trend analysis of incidents and complications can and must be performed, such as, for instance, comparing standard performance indicators of complications and incidents:

- Over time.
- Between departments of different organisations.

As a result of trend analysis, conclusions may be drawn.

**Activity 5** As a result of the list with the structural failure factors, and the trend and cause analysis of incidents and complications, conclusions can be drawn and recommendations can be made.

**Activity 6** Improvements can be generated, initiated, implemented and guaranteed.

**Activity 7** Periodically, e.g. after an analysis, an evaluation of the system can be made:

- An evaluation of the data which have been registered, both for incidents and complications. An evaluation of complications, for instance, can be made by consultations between doctors and employees about the possible addition and/or elimination of causal factors that have been registered.
- If necessary, altering or adapting the reporting form.
- If necessary, the implementation of other improvements to the system.

**Activity 8** The feedback on analysis results and improvements to doctors and employees is essential for the willingness to (continue to) report.

### 3.4.9 Legal aspects of incident and complication registration

Conditions for a successful complication and incident registration are:

a. The information which the nurse, paramedic and/or doctor report must be treated as confidential and must be used exclusively for learning purposes.

b. The registration is conducted in such a way that follow-up research is possible. This implies that the patient’s name or number is included in the registration.

For incidents mainly condition a is relevant, while for complications it is both conditions a and b. The question is to what extent conditions a and b are in conflict with each other and can cause legal problems. Can the patient demand access to and thus come into possession of the information contained in a CIRMS because the patient’s name,
number or any other (indirectly) identifying mark is present? If so, what ways are there of solving or getting round this problem?

In the Netherlands, data—for instance those from a CIRMS—can be protected via two laws:

- The Medical Treatment Contracts Act (MTCA or, in Dutch, ‘WGBO’: ‘Wet op de Geneeskundige BehandelingsOvereenkomst’) [100].
- The Data Protection Act (DPA or, in Dutch, ‘WPR’: ‘Wet PersoonsRegistratie’) [102].

These acts are cumulative i.e. patients can derive a right from either law, whichever of the two is the most comprehensive or sweeping.

The MTCA was incorporated into the civil law (in Dutch ‘BW’: ‘Burgerlijk Wetboek’) in March 1995. From this, it is evident that:

- The patient has the right to inspect his patient file.
- ‘Patient files’ include all forms of registration that are used by doctors, nurses and paramedics.

The patient can examine all the data which are part of the patient’s file. The question whether complication registration is a part of the patient file and comes under the MTCA, depends on the answer to the question whether complication registration is a registration which is related to the care of the individual patient. It may be argued that complication and incident registration as well as the FONA registration have no relation to the care of an individual patient. In that case, at best the provisions of the DPA are applicable.

Another but less elegant option is to interpret the registration as ‘work notes’. In this view, these work notes by the doctor in attendance do not need to be included in the medical file. This view has come in for a lot of criticism, especially since notes are meant for use between colleagues and therefore should be in the patient file.

The DPA stipulates that the person concerned must be informed of registration, and, on request, must be given access to the information. The question is whether the condition of ‘the notification of registration to the person concerned’ has been met, if—on being admitted to the hospital—the patient is informed that his data will be included in the registration system. A number of exceptions have been introduced in the DPA, in

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28 Complication and incident registration are aimed at analysing complications and incidents in order to learn from them, and to prevent future complications and incidents. The registration of a complication or an incident for this purpose has no direct relation to the care of an individual patient at that moment.
conformity with which a patient's request for access to his file can be turned down. This is possible, for instance, when the keeper of the registration has an interest of overriding importance.

In summary, the patient's right of inspection does not apply to complication and incident registration:

- If the registration does not relate to the care of the individual patient (MTCA).
- In the case of an interest of overriding importance; i.e., in this case, research into the causes of complications and incidents with the objective to learn from them in order to prevent future complications and incidents.

Maybe, on admission to the hospital, the patient should be notified in advance and more explicitly that all relevant information will be entered into the hospital registration system, and that for research reasons the patient's information can be entered into a complication and incident registration system. However such a formal notification may have the wrong effect and might scare patients off, so one should proceed with caution here.

The methods described in this chapter were used in the OR and in the Haemodialysis department, except for the CIRMS which was never implemented. The results and conclusions will be presented in the following chapters.
Part II

Results and analysis
Prospective and retrospective approach in the OR: FMEA and CIIs

4.1 Introduction

The previous chapter discussed the theoretical framework: the definitions and methods which were used for the risk management framework, represented in figure 3.7 on page 64. The present chapter will discuss the actual implementation of a prospective (by means of FMEA) and retrospective method (by means of CIIs) in the OR, see also table 3.5 on page 65. Chapter 5 will discuss the implementation of the IRMS; an IRMS which—in contrast to the methods discussed in the present chapter—is permanently present and in the context of which doctors and employees can report incidents directly ('real-time') to the IRMS. Chapter 6 will discuss risk management adjustments in the OR.

Sections 4.2 to 4.4 of this chapter will give a description of the following aspects of each of the methods used:

- The use of the method in the OR. A number of important aspects, considerations and experiences which have resulted in evaluations and adaptations of the methods, are also included in the description.

- The results, i.e. the patient risks which were found.

- An evaluation of and a discussion about the experiences in using the method within the scope of risk management in the OR.

The chapter ends with a concluding section, in which a comparison is drawn between the FMEA results and those obtained through the CIIs.

This risk management research started in the function group Operating Room (OR)\(^1\) in February 1994. The decision to start the research in the OR was made by the hospital management, for reasons connected with organisational politics. The research in the OR was mainly concerned with the clinical part of the OR.

\(^1\)The OR \emph{department} as it was called at the time, see section 1.5.2.
Table 4.1. The main processes of the clinical OR and their location in the OR.

<table>
<thead>
<tr>
<th>Process</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of the patient</td>
<td>Preparation room</td>
</tr>
<tr>
<td>Patient receives anaesthetic</td>
<td>Operating room/recovery</td>
</tr>
<tr>
<td>Operating and maintaining the anaesthesia</td>
<td>Operating room</td>
</tr>
<tr>
<td>Recovery</td>
<td>Recovery</td>
</tr>
</tbody>
</table>

4.2 Process model

This section describes the creation, the validation and the reliability of the OR process model, next (briefly) the result—i.e. the process model which is to be found on the CD-ROM—and finally the conclusions which could be drawn and the recommendations which could be made.

4.2.1 Creation of the OR process model

In section 3.4.2, the reasons for choosing the modelling technique by In 't Veld [166] were given. The model was designed after a guided tour of the OR which followed the patient’s passage through the department, after a set of four interviews with the assistant manager of the OR, and after attendance at three operations. The modelling started at the highest level: the function group OR in its direct environment. At this level, the OR is a black box. The focus was on the clinical part of the function group OR. The outpatients’ part was ignored, as was also, for instance, the ICU. The black box was opened up, and the four main processes patients pass through and their locations were modelled, see table 4.1.

These main processes were also opened up and the processes within were modelled. The result was a process model that sufficed for the FMEA to assess the possible risks for patients. The process model of the OR is on the CD-ROM, see also appendix B.

Validation of the model The validation of the model was performed by discussing the model in four meetings with the assistant manager of the OR (since the model was created as a result of interviews conducted with the assistant manager), and by presenting the model to OR employees who possessed the relevant expert knowledge, but had not been involved in the modelling process. See table 4.2 on the next page.

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2At the beginning of this research, the OR had an assistant manager who eventually became manager.
Table 4.2. Parts of the OR process model and the functions which have validated the parts.

<table>
<thead>
<tr>
<th>Function</th>
<th>Preparation</th>
<th>Anaesthesia</th>
<th>Operating</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation nurse</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Anaesthesia assistant</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Operating assistant</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Recovery nurse</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

The relevant parts of the model were distributed among former FMEA participants. The reason for this was because, during the FMEA meetings, the participants of the FMEA meetings had been given a first draft version of the model and they had already gained some experience of working with the model. All four employees were asked to study the model and, in individual appointments, to give feedback on deficiencies and omissions in the model.

**Reliability of the model** The reliability of the model had to be determined because the model was also intended for later use outside the OR, for instance in a future project in the Haemodialysis department (see chapter 7). The reliability may hypothetically be determined by examining whether there is a significant difference when another individual performs the modelling or when the model is created again by the same individual after a certain lapse of time. The differences and thus the reliability must not be too personal or too time-dependent if the model is going to be used more often. Reliability does not need to be a problem if clear agreement has been reached in advance about which aspects have to be modelled, where the modelling has to stop (stopping rule), and which other requirements have to be imposed on the model.

**Understanding the model** The "In 't Veld" model of the OR processes is designed to provide greater insight into the OR processes for OR employees. During the validation discussions of the model with four OR employees (as mentioned above), they were asked—after studying the model at home—whether they understood the model. All four participants understood the model and could 'read' it, although initially the size of the model scared them off and it took a while before the employees understood it.
Table 4.3. Risks found during the creation of the OR process model.

<table>
<thead>
<tr>
<th>Problems encountered with insufficiently controllable protocols and procedures</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Count instruction instruments:</td>
<td>Instruments are counted but their number is not recorded</td>
</tr>
<tr>
<td>2. Lack of clarity with regard to the blood-ordering procedure:</td>
<td>Who orders the blood? Who checks whether blood has been ordered and whether it is available in the OR? Who checks the availability of the blood right before the operation?</td>
</tr>
</tbody>
</table>

4.2.2 OR process model

The process model represents the actual state of the system (‘Ist’) or how the system should be (‘Soll’). Although the primary goal of the process model is not to assess risks, the discrepancy between the ‘Ist’ and the ‘Soll’ does lead to an assessment of problems. The focus is on the problems which can potentially result in incidents for patients. During the creation of the model, it became clear that two processes were insufficiently controlled, and could result in incidents; the first problem had to do with an ineffective protocol, the second with an ineffective procedure, see table 4.3. The complete process model of the OR is on the CD-ROM, see also appendix B.

<table>
<thead>
<tr>
<th>Summary of the data and data processing: OR process model</th>
</tr>
</thead>
<tbody>
<tr>
<td>The n of charts = 9 (including 1 legend and 1 overview chart). The n of risks found = 2.</td>
</tr>
</tbody>
</table>

4.2.3 Conclusions and recommendations

In this section, conclusions will be drawn from the results of and from the experienced gained in working with the OR process model. Recommendations are made on the basis of these conclusions and experiences.

**Conclusions about the process description of the OR** The process description method based on the—adapted—method by In ’t Veld [166], has proved useful for describing the processes in the OR, and is for that reason probably also useful for describing other hospital departments.

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3During the creation of the OR process model, it became clear that a discrepancy existed between how things were actually done—indicated by the German word ‘Ist’—and how things were supposed to be done—indicated by the German word ‘Soll’.
Strong points of this method are that:

- The model presents the processes in their natural order i.e. the processes are shown in the order in which the patient passes through the different processes.

- The model has different aggregation levels.

- The model uses measuring and control loops with standards.

This results in an unequivocal description of the processes in a department.
During the creation of the model of the OR, it turned out that:

- Before an operation, instruments are counted but their number is not recorded, in contrast to gauzes (the number of which is recorded).

- There are no clear rules with regard to ordering blood for an operation and with regard to the control of this procedure.

**Recommendations about the process description of the OR** The model of the OR can be used:

- To identify weaknesses in patient care. In this way:
  - Nothing is forgotten, omitted or overlooked.
  - It is clear which duties are carried out by whom.

For these reasons, the model can be used with an FMEA but also with other risk assessment methods like HazOp [61].

- To realise process control with the results of e.g. an FMEA or CIIs. Certain measuring and control loops may, for instance, be set up.

- To serve as a starting-point for further analysis. For instance, certain processes can be opened up for further analysis.

- To serve as basis for an overview of all processes in the OR and as an overview for the main flows of information between them. This is a requirement which the Information Service of the Catharina Hospital imposes on the OR as a precondition for making a start with the computerisation.

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4In Dutch: ‘Dienst Informatie Voorziening’ or ‘DIV’.
• To serve as a basis for a quality assurance system for the OR (PACE project, see section 2.5.3). For this purpose a model is needed which makes clear the connection between different aspects that are necessary for quality assurance.

• In the case of consultation between different function groups, for the purpose of reorganisations etc. in which an overview over the OR-event is needed in order to achieve a good result.

The "In 't Veld" method could be used more extensively because only a small number of the methods described by In 't Veld [166] were actually used in this research.5

The model is in need of maintenance, i.e. changes with regard to processes and their control must be carried through.

It is useful to use the model also if there are problems or if processes have to be designed. It is merely a tool which can produce an excellent overview of which aspects are relevant and of which connections exist between them. If necessary, a certain process can be opened up to obtain a clearer view of how to solve certain problems. However, it should be used sensibly like every model: it is a simplification of reality (this makes it attractive) and it is never complete (i.e. it contains only a limited number of aspects).

The model shows straightaway that:6

• Instruments must not only be counted but their number must also be recorded.7

• (If necessary,) the ordering of blood before an operation and control of this must be properly organised.8

These problems of a lack of control should be dealt with.

To increase the clarity and accessibility of the model, the model can be printed in colour. The main flow, and the measuring and control loops, will then stand out immediately.

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5For instance, in the case of procedure failure (ECM: OP) of a certain process, the standard for this process can be opened up to examine what exactly is wrong with the procedure. At that moment, 'the control loop of the standard setting' can be used which is not used in the current OR model but is described by In 't Veld. The model could also be further developed into a comprehensive model of an aspect system. This model could increase the insight into the structures and into the functions of the management and planning. In such a model, the steady state model is in the operational plane, and the so-called 'innovation model' is at a right angle to this [166].

6i.e. during the creation of the OR process model—in this case mainly during interviews (keeping process control in mind) and less during the drawing of the model—the following risks were found straightaway. See also table 4.3 on page 92.

7See also process number 44 in the file Opereren.cht on the CD-ROM (appendix B).

8See also process number 70 in the file Algemeen.cht and e.g. process number 67 in the file Algemeen.cht, process numbers 72 and 74 and measuring and control loop C in the file AnesthI.cht, and process number 29 in the file Opereren.cht on the CD-ROM (appendix B).
Table 4.4. Composition of the two FMEA groups in the OR.

<table>
<thead>
<tr>
<th>First group</th>
<th>Second group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation nurse</td>
<td>Anaesthetist</td>
</tr>
<tr>
<td>Secretary preparation</td>
<td>Two anaesthesia assistants</td>
</tr>
<tr>
<td>Two recovery nurses</td>
<td>Surgeon</td>
</tr>
<tr>
<td>Anaesthesia assistant</td>
<td>Two operating assistants</td>
</tr>
</tbody>
</table>

4.3 FMEA

This section describes the use of the FMEA in the OR, the results of the FMEA, the conclusions which could be drawn and the recommendations which could be made about the FMEA.

4.3.1 Use of the FMEA

The FMEA used the process model of the OR in order to assess the patient risks. Two FMEA rounds of four meetings each were held. The original FMEA set-up worked with one group which consisted of one representative for every function. For the OR this meant that the FMEA group consisted of seven people: a preparation nurse OR, a secretary preparation OR, a recovery nurse, an anaesthesia assistant, an anaesthetist, a surgeon, and an operating assistant. About 10% of the OR patients are passed on to the ICU. The ICU was excluded from the FMEA because it is outside the system boundaries of the OR.

According to Van Aalst [143], the maximum time for an FMEA meeting is between 1½ and 2 hrs. Four FMEA meetings of 2 hrs. each were planned.

Because of the number of participants needed for the FMEA, the limited time of a meeting and the number of meetings, the group was divided into two smaller groups, see table 4.4.

In order to maximise the chance of success, the assistant manager of the OR was asked to select the most suitable persons for the two FMEA groups.

A team was put together to support the FMEA meetings. The team consisted of:

- A project manager. The project manager was responsible for:
  - Preparation of the meetings.
  - Acting as panel chairman.
  - Processing and working out in detail results of the meetings.
The reporting of the FMEA project as a whole.
- Giving feedback on the results.

- Three coaches. The coaches were responsible for:
  - Taking minutes of the meetings.
  - Acting as additional panel chairmen.
  - Supporting the progress of the meetings.

- The OR assistant manager. The OR assistant manager was:
  - A participant as an anaesthesia assistant.
  - An additional panel chairman.

Because no one had any practical experience of working with an FMEA, the decision was made to hold all the meetings of the first group first, next to evaluate these meetings, and only then to proceed with the meetings of the second group. Another reason for starting with the first group, was that the first group could be composed more easily—the participants were more readily available, so no advance meetings between participants about possible participation (OR advisory committee) were needed. The meetings were held outside working hours. Four meetings were planned for each FMEA group:

- The first meeting, held for both FMEA groups together, was a general briefing about what would happen, why and how. See also the participants' manual in appendix C. During this meeting, the 'preparation' and 'recovery' of the OR process model were discussed by way of example.

- During the second meeting, the failure modes and possible effects were generated and their seriousness were classified.

- During the third meeting, the causes were determined, the frequency of occurrence of a cause and the extent to which a certain cause could be corrected were classified, and the RPN was also calculated.

- During the fourth meeting, measures were generated and guaranteed in order to prevent the future occurrence of causes (with the highest RPN, e.g. all causes with an RPN > 100).

The project manager asked the participants to prepare in advance the second, third and fourth meeting, and also to hand in their homework in advance. This with a view to:
• See whether all the participants had grasped the goal of the meeting. If not, this could be adjusted at the beginning of the meeting.

• Prevent the meeting from stalling because the brainstorming process got bogged down.

The FMEA meetings The planning was adjusted in the course of the FMEA rounds. The reasons for this for each group were:

• First group.

  – The homework that had been set at the end of the first meeting for the next meeting, surpassed expectations, i.e. the number of failure modes generated was too large to discuss within the meeting time planned. Because of this, it was not possible to discuss during the meeting all the failure modes which had been generated during the homework. In order to incorporate these failure modes, an additional meeting was held (duration: 1 hr. 45 min.) between the project manager and a recovery nurse in which the remaining failure modes, their effects and seriousness were discussed and then recorded, so that they could be incorporated into the remaining FMEA meetings.

  – After the third meeting, the process of generating all possible causes for the failure modes and classifying the frequency of occurrence of a certain cause and the extent to which a certain cause can be corrected, was not over. An additional meeting was held (duration: 1 hr. 30 min.) attended by one of the coaches, the assistant manager of the OR, two recovery nurses and the project manager. This meeting failed to generate causes for all the failure modes. It was decided to use the fourth meeting also for this purpose.

  – After the fourth meeting, it turned out that this meeting had also been too short to bring to light all the causes for the failure modes found. In the course of this meeting, measures were generated for the causes with an RPN > 100 for the process preparation-secretariat. It was decided to hold an additional meeting (duration: 3 hrs.) in which the two recovery nurses and the project manager participated. After the fourth meeting, it was also agreed that the measures should be generated by the participants themselves with the assistant manager of the OR acting as panel chairman. The plan was for feedback on the results to be passed on to the project manager who would incorporate the results into the reporting. The generation of measures by the participants did not materialise.
• Second group.

- During the first meeting, the briefing, only one participant (an operating assistant) of the second group was present with the effect that during the second meeting:

  * The anaesthetist's expectations were wrong.
  * The surgeon left the meeting at 5:30 p.m. because he did not know that the meeting was going to last until seven o'clock in the evening.

Apparently, neither had properly studied the manual (appendix C) which had been handed out, and misinterpreted the informal briefing by the assistant manager of the OR. The wrong expectations, in particular, which had been created in the case of the anaesthetist, led to such strong irritation during the second half of the meeting that one of the coaches even suggested terminating the meeting. In the end, this did not happen, but it was decided to continue the FMEA, with the proviso that:

  * There would be free brainstorming without using the model.
  * The black box of the specialist was enlarged to include all medical acts (e.g. 'the insertion of a drip', see process number 5 in the model on the CD-ROM (file Anesth1.cht), see also appendix B) and was excluded from the FMEA meeting.

The strongest objections voiced by the anaesthetist were that:

  * The anaesthetist did not see the point of discussing with laymen issues relating to professional matters.
  * The anaesthetist mainly wanted to discuss organisational problems in the OR.

By taking the above aspects into account, the FMEA meeting could be continued and completed. Another objection by the anaesthetist was that generating measures in consultation with laymen/non-experts was not very efficient. In the anaesthetist's opinion, this could only be done by the department itself because otherwise he would constantly have to give explanations to non-experts. For this reason and because of the limited duration of a meeting in which it was not possible (as was the case with the first group) to make up for lost time with additional meetings beyond the planned number of meetings, it was decided that generating measures should be left to the department itself. Just as with the first group, the assistant manager would act as panel
chairman and gave feedback on the results to the project manager who incorporated it into the report. The generation of measures by the department did not materialise.

- After the fourth meeting, it turned out that classifying the frequency still remained to be done. This task was eventually performed by the assistant manager of the OR, partly with the help of an operating assistant and of an anaesthesia assistant of the FMEA group.

*Use of the process description during the FMEA* The idea was to use the process description model of the OR as a guideline during the FMEA meetings. In this way, no process would be overlooked and, additionally, the model would at the same time be validated by using it during the FMEA meetings. However, this aim was achieved only to a certain extent because:

- In the case of the first group, as early as the second meeting it became apparent that, because of the limited duration of the meeting, it was not possible to generate the possible failure modes from process to process. It was then decided that the failure modes would be dealt with in the order in which the participants had generated them while doing their homework—and subsequently in the course of the meeting—and to drop the model.

- In the case of the second group, dropping the model—as mentioned above—was a precondition for removing the irritation felt by the participants and for making the FMEA meetings a success.

- The validation of the model therefore was realised only for the processes of preparation and recovery, but not for the processes of anaesthesia and operating (for the validation of the model, see also section 4.2.1).

### 4.3.2 Results of the FMEA

The FMEA groups were probably not exhaustive in generating possible failure modes because of the limited duration per meeting and the limited number of meetings. This was also because the model was only partly used as a guideline; this meant there could be no certainty that no process had been overlooked. Because of the lack of time, it was not possible to use the six Ms\(^9\) as a guarantee that no causes had been overlooked. The use of both the model and the six Ms would have slowed down the FMEA meetings, which would have been undesirable, given the limited time available and the tensions

\(^9\)See appendix C and figure C.1 on page 292.
which surfaced during the second meeting by the second group. A recommendation to
get round this problem is made in section 8.2. However, because the FMEA meeting
is a group event, it more or less ensures that the most important—in the view of the
participants—failure modes (risks) are indeed mentioned.

<table>
<thead>
<tr>
<th>Summary of the data and data processing: OR FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>The n of failure modes = 85. The n of causes = 997. After removal of the failure modes which lead to psychological effects on patients and effects on doctors and employees, the n of failure modes = 66 and the n of causes = 637. These causes were classified according to the ECM in which some causes were classified in more than one classification category. The n of classified causes for the complete FMEA = 834. The n of classified causes for the anaesthesia-operating part of the FMEA = 297. These classified causes were used for comparison with the classified causes of the CIIs, see table 4.14 on page 130. The results of the FMEA—e.g. the n of classified causes—can be corrected for the frequency with weighting factors, see table 4.12 on page 127. The n of classified causes for the complete FMEA with weighting factors = 1394. The n of classified causes for the anaesthesia-operating part of the FMEA with weighting factors = 377. These classified causes were used for comparison with the classified causes of the CIIs, see table 4.14 on page 130. See also table 8.1 on page 256.</td>
</tr>
</tbody>
</table>

The failure modes that were found, are presented in table 4.5 on the facing page and following. For all of these failure modes the effects and causes were determined. The causes that were found were processed in the way described in section 4.5. The results indicate that the majority of the causes are organisational and human failures, see the pie chart in figure 4.1 on page 104. The three largest ECM classification categories were wrong management priorities (ECM: OM), inadequacy or absence of procedures (ECM: OP), and choosing the wrong working method or working with the right method but carrying out the work in the wrong order or incompletely (ECM: HR 5) (see appendix E for ECM). See the bar chart in figure 4.2 on page 104.

The results of the classification of the causes of the FMEAs are presented in figure 4.1 on page 104 for the four main classification categories: technical failure, organisational failure, human failure and X (i.e.: unclassifiable).

The detailed classification results are given in the frequency distribution of figure 4.2 on page 104, and in the relative frequency distributions of figure 4.3 on page 105.
Table 4.5. The failure modes that were found during the FMEA meetings for the four main processes in the OR.

<table>
<thead>
<tr>
<th>Failure modes that were found with the FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process: preparation-secretariat</strong></td>
</tr>
<tr>
<td>1. Patient too late (&gt; 15 min.)</td>
</tr>
<tr>
<td>2. Surgeon too late</td>
</tr>
<tr>
<td>3. Patient ordered too late</td>
</tr>
<tr>
<td>4. Wrong patient ordered</td>
</tr>
<tr>
<td>5. Absence of data/documents</td>
</tr>
<tr>
<td>6. Wrong document</td>
</tr>
<tr>
<td>7. Operation cancelled (patient already ordered)</td>
</tr>
<tr>
<td>8. Operation of patient who has already been ordered starts late</td>
</tr>
<tr>
<td>9. Ward nurse forgets information</td>
</tr>
<tr>
<td>10. Patient not properly prepared</td>
</tr>
<tr>
<td>11. Ignoring patient's wish to see a specialist</td>
</tr>
</tbody>
</table>

| **Processes: anaesthesia-operating**       |
| 1. Incorrect description of operation:     |
| - different terms used for identical operation |
| - incomplete description of operation       |
| 2. Notification of change of operation too late, or additional activity during operation |
| 3. Wet instrumentarium                      |
| 4. Net not present in time                  |
| 5. Net incomplete                           |
| 6. Wrong net (sticker does not match contents) |
| 7. Net damaged (damaged packing)            |
| 8. Patient not present                      |
| 9. Not present on time:                     |
| - employees OR                              |
| - surgeons                                  |
| 10. Confusion about scheduling times        |
| 11. Unrealistic scheduling in view of the capacity of instrumentarium |
| 12. Understaffing OR                        |
| 13. Too many patients scheduled             |
| 14. Too few patients scheduled              |
| 15. Incomplete files (patient goes to operating room) |

*continued on next page*
Failure modes that were found with the FMEA

16. Anaesthesia assistant does not check equipment or checks too infrequently (protocol stipulates there should be daily checks)
17. Patient incompletely prepared (by anaesthesia assistant)
18. Scheduling information not known in the case of (last-minute) changes
19. Anaesthetist starts induction without connecting (and/or examining) ECG and RR
20. No monitoring during transport
21. Protheses not present
22. Missing gauze/needle
23. Incorrect handling of sample
24. X-ray machines are not working well/not present
25. Mixing up medicines (similar label/ampoules etc.)
26. Operating room not properly prepared for the first operation
27. Inventory lacking in cabinets
28. Team members operating room missing
29. External team members (disciplines) absent
30. Relevant data not/too late available for OR scheduling (special instrumentarium)
31. Unfamiliarity with operating technique (operating assistant)
32. Anaesthetist unavailable (for the purpose of induction)
33. Anaesthesia assistant calls anaesthetist too late (for the purpose of induction)
34. Anaesthetist too late
35. Alarms off (after induction)
36. Anaesthetist cannot be contacted (during maintenance phase)
37. Problems with anaesthesia equipment
38. No clear indication of presence of blood
39. Failure to order blood
40. Next patient is ordered too late (during last phase of anaesthesia)
41. Anaesthetist engaged with other patient (for the purpose of last phase of anaesthesia)
42. Inadequate communication about progress of operation (between anaesthesia assistant and surgeon)
43. Shortage of medications and/or materials (before start of OR program/operation)
44. Bad/late decision process about adjusting the scheduling
45. Failure to use the right protocol/misapplication of the right protocol (septic patient)
46. Team does not function well (teamwork)
47. Inefficient use of materials
48. Inadequate stock-taking instrumentarium (counting)
Failure modes that were found with the FMEA

49. Violating sterility

Process: recovery

1. Insufficient number of beds available
2. Failure to announce patient in need of artificial respiration
3. Delivering patient with unstable condition (weak, poor inhalation)
4a. Bad communication (e.g. reanimation, MRSA) => missing information on (anaesthesia) list
4b. Bad communication (e.g. reanimation, MRSA) => inadequate oral communication
5. No communication (during peak hour: failure to connect patient to monitoring equipment)
6. Delivering patient in bad/wrong position
7. Bad communication by intercom + beeper
8. Medication order unclear/not present
9. Incorrect adjustment of equipment
10. Incorrect information or incomplete information
11. Wrong document
12. Absence of data
13. Patient insufficiently prepared for OR
14. Understaffing after six o’clock in the evening
15. Insufficient checks/observations in recovery
16. Inferior/shortage of material
17. Anaesthetist/surgeon cannot be contacted
18. Administering local/regional anaesthetic too late
19. Local regional anaesthetic insufficient
20. Lack of attention by specialist
21. Specialist too late for patient’s treatment
22. Insufficient compliance with hygiene regulations
23. Making comments about the nurse or the patient in the presence of the patient
24. Failure by the ward to pick up the patient (> 30 min.)
25. Taking patient too soon to recovery (before 8:30 a.m.)

4.3.3 Conclusions and recommendations

Conclusions about the FMEA The result of the FMEA meetings for the FMEA participants was that the enthusiasm for and the commitment to risk management increased. This was perhaps the most important benefit of the FMEA meetings because the internal
Organisational failure: 44%

Technical failure: 6%

X: 9%

Human failure: 41%

Figure 4.1. Distribution of the classified causes per main classification category of both OR FMEA groups: n of causes = 834. ‘X’ means unclassifiable.

Figure 4.2. Frequency distribution of classified causes per classification category of both OR FMEA groups: n of causes = 834. The classification categories are explained in appendix E.
Figure 4.3. Comparison of the relative frequency distributions of classified FMEA causes per main classification category of the main processes of the OR: n of causes preparation-secretariat = 29, n of causes anaesthesia-operating = 297, n of causes recovery = 508. ‘X’ means unclassifiable.
culture (or culture change) in a department was an important aspect of the introduction of a voluntary IRMS.

If the results of the two FMEA rounds are combined, then organisational failure is the largest failure category in the OR, followed by human failure. The three ECM classification categories into which most causes were classified, are in descending order (so from large to small): the organisational factors of 'management priorities' (ECM: OM) and 'operating procedures' (ECM: OP), and the human behaviour factor of 'planning' (ECM: HR 5) (see appendix E for the ECM).

**Recommendations about the FMEA** The results of the FMEA meetings can be used in the department to:

- Generate measures in the case of causes generated by participants.

- Create a 'living' document on the basis of the results of the FMEA meetings. This can be done by classing the results of the FMEA (both problems and solutions) in a database which may then be consulted, for instance, for the purchase of new equipment, the alteration of rooms, the purchase of new material(s) and in the case of reorganisations.

To improve the results, in future FMEAs it would be necessary to:

- Organise an additional meeting or additional meetings to try to:
  - Use the complete model.
  - Check the causes against the six Ms (see participants' manual in appendix C).
  - Evaluate the results (all FMEA columns) again to examine whether additions are necessary, formulations need to be tightened up, etc.

- Use the results of the existing FMEA meetings (as input or starting-point) for future meetings.

- Before the FMEA starts, establish clearly what the requirements with regard to the FMEA are, i.e. to put the emphasis on process deviations with e.g. physical effects or psychological effects on the patient. This can be done by examining whether the effects meet the requirements of the FMEA, just after the failure mode has been generated. If the requirements have not been met, the effects which did not meet the requirements are deleted. The failure mode is deleted if none of the effects meet the requirements.
• Incorporate the results of the meetings into a ‘living’ document.

The FMEA can also serve other fields like health and safety.\textsuperscript{10} During the FMEA, the participants already generated failure modes in the field of health and safety which, because of the purpose of the FMEA, could not be taken into account.

When a department makes a start with risk management, an FMEA can be used as an introduction, to introduce risk management to the department and to initiate the required change of internal culture which is necessary for an IRMS [93].

In the future, an FMEA can be used to predict risks in the case of changes in the processes or in the case of designing new processes within a department. The FMEA would then be used as a forecasting method based on the experiential knowledge of system experts. Because the assessment method is already known, opposition to using the method will be low and the method will be used more efficiently.

During the classification of FMEA causes, the classification team has a wide margin of interpretation because the description of the causes is concise. In the future, it would therefore be better to include the classification as a part of the FMEA meeting. It would also be advisable to validate the results of the FMEA in the future. This validation can be performed, for instance, by having someone who has not been not involved in the FMEA classification process of the causes classify the causes independently, and then to compare the results and discuss possible differences in the classification of causes.\textsuperscript{11}

\textbf{4.4 CIIs}

\textbf{4.4.1 Use of the CIIs}

Before being interviewed, all interviewees received an information letter [151] and a case worked out in detail [149]. The letter explained the purpose of the interview; the case illustrated how an incident was registered and analysed, and at the same time showed how an organisation could learn from analysing incidents.

Because it was an open interview, an interview plan was used, in order to:

\textsuperscript{10}In Dutch ‘Arbo-zorg’ (‘Arbo’ care).

\textsuperscript{11}Later on in this project—to be precise during the analysis of IRMS reports 1–325 (see table 5.2 on page 150)—it became clear that classifying had a number of drawbacks, see the heading ‘Classifying’ on page 141 and following.

(\text{It may also be noted that the unreliability of classification will not be so bad if the classification is made by the same person(s) over a brief period of time. Classifying only made sense for the purpose of comparing the results of the FMEA with the CIIs in the OR, see section 4.5 on page 125 and following. In the daily practice of organisational learning [80], classifying causes in accordance with the ECM is not really useful, and too laborious and unreliable (a classification is made over too long a period of time).})
Table 4.6. Overview of the number of planned and realised interviews per function, and the number of analysed interviews per function in the OR.

<table>
<thead>
<tr>
<th>Function</th>
<th>Number of interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Planned and realised</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>4</td>
</tr>
<tr>
<td>Surgeon</td>
<td>4</td>
</tr>
<tr>
<td>Anaesthesia assistant</td>
<td>4</td>
</tr>
<tr>
<td>Operating assistant</td>
<td>3</td>
</tr>
<tr>
<td>Preparation nurse</td>
<td>2</td>
</tr>
<tr>
<td>Recovery nurse</td>
<td>3</td>
</tr>
<tr>
<td>Total number</td>
<td>20</td>
</tr>
</tbody>
</table>

- Standardise the interviews.
- Give the interviewer a plan to hold on to and to prevent him from forgetting certain aspects.

The number of interviews should be large enough to be representative of the nature and frequency of incident causes. The number of interviews held was twenty. For practical reasons, it was not possible to conduct more interviews.

To maximise the independence of interviewees and to obtain an objective comparison between the results of the FMEA and the CIIs, an attempt was made to restrict the selection of interviewees for the CIIs to people who had not taken part in the FMEA. This did not apply to preparation nurses; because only two preparation nurses worked part-time in the OR, both were interviewed even though one of the two had already participated in the FMEA.

The interviewees were chosen from all OR functions in order to ensure a reliable picture of the nature and frequency of incident causes in the OR. The numbers of interviews per function are given in the column ‘Planned and realised’ in table 4.6.

Seventeen of the twenty CIIs were analysed. Three interviews were not incorporated into the research because two interviews were about common process deviations (see also figure 3.3 on page 54) which occur frequently, and one interview was about a process deviation which occurred at the ICU. The distribution of the number of analysed interviews is presented in the column ‘Analysed’ in table 4.6.

In order to maximise the chances of success, the assistant manager of the OR was asked to select the most suitable persons for the interviews. The interviews were conducted in random order, depending on the availability of interviewees. All the interviews
were recorded on the same standard form by using an interview plan. After finishing all the interviews, they were analysed by describing each incident in a causal tree, see also sections 3.4.4 and 3.4.5.

4.4.2 Results of the CIIIs

In this section, the results of the CIIIs are presented. Because the objective of the CIIIs was to assess the actual risks for patients, the results in this section are presented for the actual causes (see section 3.4.4).

<table>
<thead>
<tr>
<th>Summary of the data and data processing: OR CIIIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>The original n of interviews = 20. The n of interviews used for analysis = 17 which means in this case that the n of discussed and analysed incidents = 17 (each interview yielded one incident). The data below relate to this number of 17 interviews/incidents. The n of causes = 98 of which the n of actual causes = 84 and the n of possible causes = 14. After classification of these causes according to the ECM—in which some causes were classified in more than one classification category—the n of actual causes = 96 and the n of all causes (i.e. both actual and possible) = 113. The n of recovery factors = 22 of which 14 were successful. The classified causes were used for comparison with the classified causes of the FMEA. For comparison with FMEA causes relating to the anaesthesia-operating part of the FMEA, the n of CIIIs which relates to the anaesthesia-operating part of the CIIIs = 13, the n of classified actual causes = 81, and the n of all the classified causes (i.e. both actual and possible) = 92. See also table 8.1 on page 256. The n of structural causes found = 20, see table 4.7 on page 112.</td>
</tr>
</tbody>
</table>

For reasons of reliability, the causes that were found by the CIIIs were classified by the same persons who classified the causes of the FMEA and under the same conditions, see section 4.5. In order to determine to which classification category a cause could be assigned, the description Kanse [72] gave of the classification categories of the ECM was used and adapted by Van der Hoeff [151], see also appendix E. The classification results were examined by Van der Schaaf, researcher at the Eindhoven University of Technology (EUT), to validate the results. As a result of this, sixteen alterations were made in the classification categories of the causes in question.

The results of the classification of the causes of the CIIIs are presented in figure 4.4 on the following page for the four main classification categories: technical failure, organisational failure, human failure and X (i.e. unclassifiable).

The detailed classification results are given in figure 4.5 on the next page.

The causes and the recovery factors that were found by analysing the CIIIs are presented in two tables. The causes are presented in table 4.7 on page 112 and the recovery factors in table 4.8 on page 113. Both the causes and the recovery factors were
Figure 4.4. Distribution of the classified OR CII causes per main classification category: n of CII s = 17 and n of causes = 96. ‘X’ means unclassifiable.

Figure 4.5. Frequency distribution of classified OR CII causes per classification category: n of CII s = 17 and n of causes = 96. The classification categories are explained in appendix E.
anonymized and generalised because of the confidential nature of the CIIIs.

Of the 22 recovery factors mentioned, 8 did not result in successful actual recovery.\textsuperscript{12} It turns out that recovery factors (read: remarks) were missed because of people's failure to pay attention to each other. On the one hand, recovery factors should be taken advantage of, and taking advantage of them should be encouraged; on the other hand, if a recovery remark was made, it was often ignored, even though the reluctance to make these recovery remarks was great. This reluctance was due to the gulf between doctors and employees.

All 17 incidents had one or more recovery factors. This emphasises the importance of an optimal use of these factors which may have a favourable effect on the outcome of an incident.

During the CIIIs, information was collected that resulted in additional analysis. These research questions concerned:

1. Making \textit{FONA reports} of incidents.
   a) How many of the incidents were reported to the FONA committee?
      Out of a total of 17 incidents that were analysed, 6 were also reported to the FONA committee.
   b) What was the distribution of the incidents which were reported and those which were not reported to the FONA committee, if a distinction is made between incidents with demonstrable temporary or permanent physical effects (accidents) on the one hand, and incidents with no demonstrable effects on patients (near accidents) on the other hand?
      This question was answered although:
      - It is difficult to determine whether or not an incident has effects on a patient, and what these effects are.
      - It is difficult to determine the effects on patients indirectly via an interview.

In order to determine to what extent incident types were reported to the FONA committee, the number of FONA reports per incident type is presented in table 4.9 on page 113.

The results in table 4.9 on page 113 were tested by means of the Fisher exact probability test\textsuperscript{13} which showed no difference between the distributions

\textsuperscript{12}I.e. if attention had been paid to such a recovery remark, then the outcome of an incident—the top event—would probably have been less serious for the patient.

\textsuperscript{13}In this research, all data were tested using the SAS software version 6.12. For every test, the value for the level of significance or alpha was 0.05.
Table 4.7. Overview of the structural incident causes which were found using the CIIIs in the OR.

<table>
<thead>
<tr>
<th>Structural incident causes found using the CIIIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• On the anaesthesia list there is no specific space to report incidents</td>
</tr>
<tr>
<td>• There is no uniformity of medicine stickers on ampoules and syringes</td>
</tr>
<tr>
<td>• Doctors ignore remarks made by nurses</td>
</tr>
<tr>
<td>• There is no proper protocol that keeps everyone in the OR informed of which medicines are new and in which concentration they are available</td>
</tr>
<tr>
<td>• Filling in the different medical records before a patient is operated on is mandatory but is often not performed</td>
</tr>
<tr>
<td>• Surgeon leaves the operating room too casually while the patient is being operated on</td>
</tr>
<tr>
<td>• Turning off the alarms during the induction phase and forgetting to turn them on again afterwards</td>
</tr>
<tr>
<td>• Inadvertent failure to make FONA reports*</td>
</tr>
<tr>
<td>• Failing to take action about the dangerous situation of the ‘forgotten switch’b (this is/these are) one/two switch(es) which people forget to turn on/off: the respirator is then hand-operated instead of in the ventilation state, and the patient is not insufflated)</td>
</tr>
<tr>
<td>• No involvement of anaesthesia assistants in the purchase of anaesthesia equipment</td>
</tr>
<tr>
<td>• Not calling in a surgeon outside one’s own discipline for assistance when faced with problems during an operation though the need for assistance is obvious</td>
</tr>
<tr>
<td>• Assigning patients to a certain discipline is based on which day of the week it happens to be and not on the availability of a surgeon who is sufficiently competent to carry out the operation</td>
</tr>
<tr>
<td>• Although antibiotics should be supplied during operations, they were not</td>
</tr>
<tr>
<td>• X-ray technician is not experienced enough</td>
</tr>
<tr>
<td>• Only one X-ray examination tube available in the OR</td>
</tr>
<tr>
<td>• Equipment in the recovery is not uniform</td>
</tr>
<tr>
<td>• Because surgeons habitually blame the instrumentarium for setbacks during the operation, complaints about the instrumentarium are not always taken seriously by the operating assistant which results in defective instrumentarium continuing to be used. By not always taking the surgeon’s complaints seriously, the operating assistant prevents instruments from being unnecessarily replaced only because of the surgeon’s irritation</td>
</tr>
<tr>
<td>• Mixing up the data of patients with the same name but different dates of birth</td>
</tr>
<tr>
<td>• Equipment in the ICU makes too much noise which leads to errors because people misunderstand each other (NB: this cause relates to the ICU, of course)</td>
</tr>
<tr>
<td>• Failure to perform a check in a given situation because doing so would annoy a colleague because he has already checked</td>
</tr>
</tbody>
</table>

*aBecause: – it was an error, and was not omitted on purpose; – it was not considered necessary; – no attention was given to it; – it was considered the specialist’s job; – FONA was not considered an important issue (the (departmental) management did not consider this necessary); – after the operation, it was hoped that things would go all right: the complication did not emerge until later; – the incident was caused by equipment; – the incident was recognised in time, and it concerned a near accident. 

bThis is the term used by the staff (in Dutch ‘verget-eknop’).
Table 4.8. Overview of the recovery factors which were found using the CIIIs in the OR.

Recovery factors found using the CIIIs

- Drawing attention to the fact that an injection is being given into artery instead of into vein
- Patient is intubated by chance
- Drawing attention to patient being injected with painkiller rather than with sleep-inducing drug
- The box containing the prothesis is opened by chance, and the prothesis appears to be unsterile
- Patient’s thorax is open which made direct heart massage possible
- Heart-lung machine is connected
- A report that a gauze is missing
- Missing gauze is finally found
- Pre-oxygenate patient with 100% oxygen
- Observing sallow face and blue lips
- Observing blue lips
- Making remarks that method for inserting object into patient is wrong
- Making remarks about not working in compliance with sterility requirements
- Correct ideas about possible diagnosis
- Finding out by chance that patient does not wish to be operated on
- X-ray examination tube is accidentally already being used to position patient instead of when the patient is already under surgery: it turns out that X-ray examination tube is not working
- Finding out that alarm is off by checking the print-out of the time recorder
- During earlier operations, it had already been noticed that instruments were not working correctly (but nothing was done about it)
- Putting medications ready so as to have them to hand
- Observing that patient’s medical record is incorrect: left and right turn out to have been switched round
- Observing that there is a mismatch between patient’s medical record and reality
- By accidentally putting a question to the patient, it is noticed that patient’s data have been mixed up

Table 4.9. The number of FONA reports per incident type discussed during the OR CII: n of discussed incidents which were classified as accidents = 11 (with n of causes = 73), n of incidents discussed which were classified as near accidents = 6 (with n of causes = 23), n of CIIIs where a FONA report was made of the discussed incident = 6 (with n of causes = 46), n of CIIIs where no FONA report was made of the discussed incident = 11 (with n of causes = 50).

<table>
<thead>
<tr>
<th></th>
<th>Accident</th>
<th>Near accident</th>
</tr>
</thead>
<tbody>
<tr>
<td>No FONA report</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>FONA report</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 4.10. The number of FONA reports, and the number of FONA reports omitted, of incidents discussed by doctors and employees during the OR CIIIs: n of CIIIs where a FONA report was made of the incident discussed = 6 (with n of causes = 46), n of CIIIs where no FONA report was made of the discussed incident = 11 (with n of causes = 50), n of doctors interviewed = 6 (with n of causes = 26), n of employees interviewed = 11 (with n of causes = 70).

<table>
<thead>
<tr>
<th></th>
<th>FONA</th>
<th>No FONA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Employees</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>

(p = 0.3334). Table 4.9 on the preceding page shows that the greater part of the accidents and near accidents were not reported to the FONA committee.

c) Is there a difference between doctors and employees with regard to the number of FONA reports they make?

The results in table 4.10 were tested with the Fisher exact probability test (p = 1.0000), showing that, comparatively speaking, doctors and employees are equally bad at or remiss in reporting incidents to the FONA committee.

d) What are the causes found by the FONA committee with regard to the incidents which were both discussed during the CIIIs and reported to the FONA committee?

The results of the 6 CIIIs, the incidents of which were also reported to the FONA committee, were compared with the classification and conclusions of the FONA committee. For 4 of the 6 CIIIs, FONA reports were found in the FONA archives; the remaining 2 were not found. This may mean that these incidents had never been reported to the FONA committee, although the interviewees said they had been. On the basis of the data on the FONA reporting forms, it was only partly possible to reconstruct the 4 incident descriptions. So, it is possible that the FONA committee drew the wrong conclusions, also because there was often no consultation between the reporter(s) and the FONA committee. The distribution of the causes per main classification category of incidents with and without a FONA report, is presented in figure 4.6 on the facing page. The Fisher exact probability test was used to test the data of figure 4.6 on the next page. The test shows that there are no grounds for establishing a difference between the two distributions (p = 0.1457).
Figure 4.6. Relative frequency distributions of the classified OR CII causes per main classification category in the case of incidents in which there was a FONA report and those in which there was no FONA report. In the case of a FONA reports, n of CIIs = 6 and n of causes = 46, and in the case of no FONA reports, n of CIIs = 11 and n of causes = 50. 'X' means unclassifiable.
Table 4.11. The number of accidents and near accidents discussed by doctors and employees during the OR CIIs: n of incidents discussed which were classified as accidents = 11 (with n of causes = 73), n of incidents discussed which were classified as near accidents = 6 (with n of causes = 23), n of doctors interviewed = 6 (with n of causes = 26), n of employees interviewed = 11 (with n of causes = 70).

<table>
<thead>
<tr>
<th></th>
<th>Accidents</th>
<th>Near accidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Employees</td>
<td>7</td>
<td>4</td>
</tr>
</tbody>
</table>

2. *Incidents.* The distribution of incidents in accidents and near accidents, and the reporting of different kinds of incidents by doctors and employees.

The results of reporting different kinds of incidents by doctors and employees are presented in table 4.11. The ratio of accidents and near accidents discussed during the CIIs is about the same for doctors and employees (Fisher exact probability test, p = 1.0000).

The distribution of incident causes in which there is an accident or a near accident, is presented in figure 4.7 on the next page. The Fisher exact probability test was used to test the data of figure 4.7 on the facing page. The test shows that there are no grounds for establishing a difference between the two distributions (p = 0.2934).

3. The effects of *haste* and *fatigue*.

The CIIs can be divided into incidents in which there was ‘fatigue’ and ‘no fatigue’, and into incidents in which there was ‘haste’ and ‘no haste’.

‘Haste’ is understood to refer to ‘emergency operation’. This was the case in three incidents which all occurred in the evening.

‘Fatigue’ is understood to refer to a situation in which an operation was still going on after four o’clock in the afternoon or was performed in the evening. In the case of all three incidents in which there was haste, fatigue also played a role too (i.e. in this case the emergency operations were performed in the evening, see above). The distributions of incident causes in which there is haste and fatigue are presented in figure 4.8 on page 118 and figure 4.9 on page 119. The Fisher exact probability test was used to test the data of figures 4.8 on page 118 and 4.9 on page 119. For figure 4.8 on page 118, the Fisher exact probability test shows that there are no grounds for establishing a difference between the two distributions (p = 0.2634).
Figure 4.7. Relative frequency distributions of the classified OR CII causes per main classification category in the case of incidents which were classified as accidents and those which were classified as near accidents. In the case of accidents, n of CII\s = 11 and n of causes = 73, and in the case of near accidents, n of CII\s = 6 and n of causes = 23. 'X' means unclassifiable.
Figure 4.8. Relative frequency distributions of the classified OR CII causes per main classification category in the case of incidents in which there was haste and those in which there was no haste. In the case of haste, n of CII s = 3 and n of causes = 25, and in the case of no haste, n of CII s = 14 and n of causes = 71. ‘X’ means unclassifiable.

For figure 4.9 on the facing page, the Fisher exact probability test shows that there is a convincing difference between the two distributions \( p = 0.0189 \), and cell chi-square shows no cell which contributes in a convincing manner to this difference. In this research, the value chosen to call a cell informative in the case of cell chi-square is 6¼ \[129\]. (Among statisticians, there is no unanimity about this value for the determination of informative cells. The value of 6¼ corresponds to a probability of 0.012 of calling a cell erroneously informative. Other values common among statisticians are 3.84, 4 and 9, so 6¼ is quite a safe value.)

4. Incidents discussed by doctors and employees.

Figure 4.10 on page 120 shows the distributions of causes of incidents discussed by doctors and employees. The Fisher exact test shows that there are no grounds for establishing a difference between the two distributions \( p = 0.607 \).
Figure 4.9. Relative frequency distributions of the classified OR CII causes per main classification category in the case of incidents in which there was fatigue and those in which there was no fatigue. In the case of fatigue, n of CII = 6 and n of causes = 56, and in the case of no fatigue, n of CII = 11 and n of causes = 40. 'X' means unclassifiable.
Figure 4.10. Relative frequency distributions of the classified OR CII causes per main classification category in the case of incidents which were discussed by doctors and which were discussed by employees. In the case of doctors, n of CII = 6 and n of causes = 26, and in the case of employees, n of CII = 11 and n of causes = 70. ‘X’ means unclassifiable.
4.4.3 Conclusions and recommendations

Conclusions about the CII s In the OR, human failure is the largest failure category, followed by organisational failure. The three classification categories in which most causes are classified are in descending order (from large to small): the organisational factor of 'operating procedures' (ECM: OP), the human behaviour factor of 'planning' (ECM: HR 5) and the organisational factor of 'management priorities' (ECM: OM) (see appendix E for the ECM).

For the Fisher exact probability tests performed for the tables 4.9 on page 113, 4.10 on page 114 and 4.11 on page 116, it should be noted that a larger number of incidents—the number of 17 incidents is quite small—may lead to different test results.

Although the Fisher exact probability test shows no difference between the distributions in table 4.9 on page 113, the data in table 4.9 give an indication that, in the case of the near accidents, the vast majority is not reported. This could be explained by the fact that, in accordance with hospital policy, doctors are requested to report accidents also to the FONA committee.

Table 4.10 on page 114 shows that the willingness to report incidents to the FONA committee is the same for doctors and employees.

The fact that only 6 of the 17 incidents were reported to the FONA committee (table 4.9 on page 113), may indicate that the number of FONA reports is not a good indicator of the real number of incidents in a department. However, in the FONA database only 4 of these 6 incidents reported to the FONA committee were to be found. It is possible that 2 interviewees were wrong and that only 4 (instead of 6) FONA reports were made of the 17 incidents. A comparison of the results of these 4 CII s with the corresponding 4 FONA reports, shows that it is not possible to get a clear and complete picture of an incident on the basis of the FONA report. This is because of the use of a standard form which provided only a concise impression of the nature of the incident and of the circumstances in which it took place, which makes it impossible to retrace the real causes on the basis of just the information on the form. The FONA committee can obtain any additional information which may be required by interviewing the persons concerned. However, in all 4 FONA reports, the reporter had indicated on the form that he did not desire an interview with the FONA committee.

When comparing the data about the causes of an incident obtained by a report of an incident on a FONA form with the data obtained by a detailed CII and a description of the incident by the means of a causal tree, the added value of an interview with a causal tree appears to be clear. This added value is realised in two areas:

- The CII finds the root causes in contrast with the FONA form which often only
reports the direct cause(s).

- The CII yields more causes and therefore gives a much completer and more comprehensive view of which events ultimately led to the incident.

The distributions of classified causes per main classification category for incidents which were and those which were not reported to the FONA committee (see figure 4.6 on page 115 for the relative frequency distribution) tested with the Fisher exact probability test showed no significant difference between the distributions.

However, the data of figure 4.6 on page 115 may show that there is an indication that incidents of which a FONA report was made contained relatively more organisational failure factors and fewer human failure factors than incidents of which no FONA report was made. Apparently, incidents with relatively many organisational failure factors and relatively fewer human failure factors are more often reported to the FONA committee. The preference for making FONA reports of incidents with relatively more organisational failure factors and fewer human failure factors may indicate that reporters believe that the FONA committee is better at dealing with—in particular—organisational failure, or that organisational failure is deemed to be less personal and thus safer to report for a reporter.

According to the Fisher exact probability test, there are insufficient grounds for rejecting the hypothesis that the distributions are the same, i.e. for detecting a difference between the distributions in figure 4.7 on page 117. However, the distributions in figure 4.7 may show an indication that in the case of a near accident, technical failure factors occur relatively more often than in the case of an accident: it appears that more successful and complete recovery is easier to achieve in the case of technical failure. In the case of near accidents there may be an indication that organisational failure factors occur relatively less often than in the case of accidents: apparently accidents are better at ‘finding’ the weaknesses in existing organisational defences. (By definition a near accident is repairable, with accidents this is not so clear-cut.)

Table 4.11 on page 116 shows that during the CIIs, doctors and employees contributed, relatively speaking, just as many accidents as near accidents. This might indicate, for instance, that neither group has a specific preference for either reporting accidents or near accidents.

The Fisher exact probability test found for the distributions in figure 4.8 on page 118 that there is no difference. However, figure 4.8 may give an indication that in the case of an incident in which there is ‘haste’, organisational failure factors may occur relatively more often than in the case of incidents in which there is no urgency; in the case of incidents in which there is no haste, there are relatively many human failure factors. This
may indicate that organisational protocols or procedures with regard to haste situations must either be drawn up, or (if they are already in place) improved.

The Fisher exact probability test shows that there is a convincing difference between the distributions of figure 4.9 on page 119. Figure 4.9 shows that in the case of an incident in which there is ‘fatigue’, human failure factors occur relatively more often than in the case of incidents in which there is no fatigue (see e.g. Sexton [132] for the perception of stress and fatigue).

For the distributions in figure 4.10 on page 120, the Fisher exact probability test found no difference. However, figure 4.10 may give an indication that, in contrast to doctors, employees discussed incidents containing, relatively speaking, more human and less organisational failure.

The list of recovery factors shows that:

- Escalation is often prevented (by chance).

- Recovery is sometimes not successful because in the case of bottom-up communication, people do not listen to each other, and ignore matters to which their attention has been drawn and advice which has been given.

- Recovery would not be necessary if compliance with protocols improved.

The list of structural failures shows that:

- All structural failures and, therefore, all incidents can be prevented.

- Although certain errors occur regularly (after all, they are structural) and are already known, nothing structural is done about them.

**Recommendations about the CIIs**  In general it is true of CIIs that conducting more interviews is better: more interviews, i.e. more incidents, may result in other and additional results, conclusions and recommendations.

The percentage of near accidents and accidents reported to the FONA committee should be and could be much higher. In particular the near accidents which occur more frequently than accidents and from which a lot can be learned [154], are important for the purpose of a better control of the OR processes. Because near accidents in the OR are hardly reported to the FONA committee, this should be all the more reason to aim at the introduction of a voluntary IRMS in the OR.

It would be advisable to change the FONA form in such a way that the reporter can give an as clear and complete as possible picture to the FONA committee of the causes which—according to the reporter—have led to the incident.
It would be advisable to aim at a uniform way of working by both the FONA committee and the IRMS. In this way it could be prevented that the same work is done twice over, because the data which have to be collected are in principle interchangeable. However, there is an underlying problem. Before this could be done, the blaming bias of the FONA system should be eliminated first. If it is not possible to get rid of this blaming bias, the two systems should be kept very separate administratively—only the classification methods should be uniform.

Further research, i.e. a better research set-up and the analysis of a larger number of incidents, is necessary to determine whether the conclusions drawn earlier in this section remain the same,\textsuperscript{14} for instance, with regard to the following issues:

- The relations between (no) FONA report on the one hand, and organisational or mainly human failure factors (see figure 4.6 on page 115) on the other hand.
- The relations between accidents or near accidents on the one hand, and technical and organisational failure (see figure 4.7 on page 117) on the other hand.
- The relations between haste or no haste on the one hand, and organisational or mainly human failure factors (see figure 4.8 on page 118) on the other hand.
- The relation between fatigue and human failure factors (see figure 4.9 on page 119).
- The relations between doctors or employees and the discussion of incidents with more or less organisational and human failure (see figure 4.10 on page 120).

Further research is also necessary into the following questions:

- Are the chances of successful and complete recovery better in the case of technical failure?
- Are specific organisational lines of defence in place in the case of near accidents which are not in place in the case of accidents?
- Is a near accident the effect of a repairable situation and an accident the effect of an irreparable situation? Or, have near accidents and accidents the same causes?

The recovery factors show that the communication between doctors and employees should be improved in order to prevent errors.

\textsuperscript{14}E.g. with none of the distributions of figures 4.6 on page 115 to 4.10 on page 120 a chi-square test was possible because too many cells had expected counts of less than five and a further combining of cells was not possible.
4.5 Comparing the FMEA results with the CII results

It would be advisable to encourage making remarks which lead to recovery in order to take maximum advantage of these recovery factors.

It is necessary to learn from the recovery factors found (see table 4.8 on page 113), and to examine how, by making changes in the organisation, recovery factors will become a structural (rather than accidental) part of the organisation, and then to implement these alterations.

The structural failure factors show that uniformity of equipment is important, because starting up and adjusting equipment is a routine procedure, and this may lead to errors in the case of non-standard equipment. To the structural failure factors (see table 4.7 on page 112), the same applies as to the recovery factors: organisations should learn from the structural failure factors found. These structural factors should be discussed with all persons concerned and then the situation should be changed so that these structural failures cannot occur anymore.

For both the recovery factors and the structural failure factors, it is quite possible that certain processes must be altered or redesigned. This alteration or redesign of processes should be done in such an unequivocal way that the process becomes controllable. The process model and the method “In ’t Veld” can be used for this purpose.

It would also be necessary in the future to register and analyse recovery factors, preferably systematically rather than just through CIIs, see also section 8.2.

To sum up for the FMEA and the CIIs To all the technical, organisational and human failure factors that were found by the FMEA and the CIIs applies that they are preventable. In addition, both the FMEA and the CIIs show that organisational and planning failure is responsible for the largest part of the failure modes and incidents found. As a result, it is necessary to get a better and more complete understanding of the causes of these failure modes and incidents. To bring about this understanding, an Incident Reporting and Management System (IRMS) should be implemented—and was implemented, see chapter 5—to which incidents can be voluntarily reported. The FMEA and CIIs provide a basis for the implementation of an IRMS.

4.5 Comparing the FMEA results with the CII results

This section tries to answer the question whether the prospective FMEA method finds the same kind of causes as the retrospective CII method.

Because the two methods are different, the results yielded by the two methods must be adapted to make a comparison of these results possible. CTA (see section 3.4.5 and figure 3.9 on page 73) which was used in the case of the CIIs, is an approach that starts
with the effects (top events) and then determines the main causes, the causes and finally the root causes. The FMEA is an approach that begins with the possible process deviations (the so-called ‘failure modes’ of the processes), next determines the possible effects for every process deviation/failure mode, and eventually determines the possible causes that lead to a certain failure mode-effect combination. The methods differ in the sense that:

- The CIs are based on a recall and retrospective analysis of actual incidents, and produce a frequency distribution of both actual causes and possible causes. (Although only the actual causes were used in the CII data analysis, the possible causes were also used during the comparison, see further down in this section.)

- The FMEA is based on a prediction of possible failure modes with possible effects and produces a frequency distribution of possible causes.

To answer the question to what extent the frequency distributions of the predicted FMEA causes and the CII causes correspond, the results of the FMEA and CIs were adjusted and classified as described further on in this section, in order to make the comparison of the frequency distributions of the FMEA and the CIs. The classification of the causes of the FMEA and the CIs was made by the same three persons. They tried to classify a cause in as few categories as possible and they had to come to an agreement about the classification category or categories for each cause.\(^{15}\)

The FMEA results had to be adjusted because the CIs lead to specific detailed causes while the FMEA leads to predicted risks with somewhat less well-defined causes. Another reason is that the FMEA adopted a broader approach: not only the physical effects on patients but also the psychological effects on patients, and effects on employees and doctors were assessed. The CIs were held after the FMEA was made and only assessed the physical effects on patients.

The results of the FMEA were processed as follows:

- First, a sifting of the FMEA results took place. The failure modes leading to psychological effects on patients and effects on doctors and employees, were removed.

- Second, the causes of the remaining failure modes were classified in accordance with the ECM. Every cause was classified in at least one classification category of the ECM.

\(^{15}\)Classification in accordance with the ECM will be shown later to be unreliable in an absolute sense, see section 5.2. However, the classification of the FMEA and CII results was made by the same three persons over a short period of time, so the bias as a result of this unreliability was kept as small as possible. See also [151].
Table 4.12. Weighting factor for each frequency category. The frequency categories are given in appendix C.

<table>
<thead>
<tr>
<th>Frequency category:</th>
<th>1–4: never–rarely</th>
<th>5–7: regular</th>
<th>8–10: often–(nearly) always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighting factor:</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

- Finally, the classified causes were corrected for their frequency with a weighting factor in conformity with table 4.12—the classified causes were multiplied by this factor. This in order to compensate the FMEA causes for the estimated frequency with which they occur. Because the range of the estimated frequency values assessed during the FMEA was considered too wide to be used as a compensation factor (range from 1–10, see appendix C), a weighting factor was introduced with a smaller range (range from 1–3). This weighting factor was derived directly from the FMEA frequency category, see table 4.12.

As the weighting factor used here was somewhat arbitrary, the FMEA results are presented both with and without weighting factors in order to show their effect.

The comparison of the FMEA and CII results was made for the following distributions, see table 4.14 on page 130:

- The FMEA results with and without weighting factors.

- The CII results subdivided into the actual causes only and all causes (actual + possible). Causes connected with the causal tree by an OR gate—i.e. the possible causes—were left out from the analysis of the CII results on page 109 et seq. However, in order to answer the question of how well the FMEA assesses causes in comparison with the CIIIs, and to prevent the arbitrary exclusion of CII causes which the FMEA might identify, the distribution of all the CII causes was also taken into account. To sum up, the CII results are presented in two ways: (1) the actual CII causes are compared with the possible FMEA causes in order to make a comparison of actual with possible risks, and (2) all CII causes are compared with the possible FMEA causes, in order to make a comparison of the results produced with both methods.

- The FMEA and CII results for both the complete OR and for the anaesthesia-operating part only. A separate comparison of the results of the anaesthesia-operating part of the FMEA and the results of the CIIIs for the anaesthesia-operating part was made, because the number of actual causes of the CIIIs for this part was—in absolute and relative terms—large enough to justify such a comparison, see
Table 4.13. Composition of the classified FMEA and CII causes to that part of the OR they are related to (FMEA, n of causes = 834; CII, n of causes (actual) = 96).

<table>
<thead>
<tr>
<th></th>
<th>Preparation-secretariat</th>
<th>Anaesthesia-operating</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMEA (n of causes)</td>
<td>3% (29)</td>
<td>36% (297)</td>
<td>61% (508)</td>
</tr>
<tr>
<td>CII (n of causes (actual))</td>
<td>8% (8)</td>
<td>84% (81)</td>
<td>7% (7)</td>
</tr>
</tbody>
</table>

'Table 4.13. ‘CII’s for the anaesthesia-operating part’ means the CII’s of the functions anaesthetist, surgeon, anaesthesia assistant and operating assistant.

The parts preparation-secretariat and recovery were not compared because the number of CII’s for the part preparation-secretariat was two, and the number of CII’s for the part recovery was also two. These numbers are too small to produce a frequency distribution of classified causes that results in a reliable reproduction of the nature and frequency of the patient risks.

A comparison of the above-mentioned distributions leads to eight different comparisons, see also table 4.14 on page 130 and figures 4.11–4.18 (pages 131–134). Each comparison compares the relative frequency distributions of the results of the FMEA and the CII’s: the results are the classified causes of both methods. For the classification of the causes, the ECM was used, see also paragraph 3.4.6 and appendix E. The overview in table 4.14 on page 130 shows which parts of the clinical OR the comparison relates to, whether all CII causes were used or only the actual causes, and whether the FMEA results for that part were corrected with a weighting factor or not. To test whether the FMEA and CII results are coming from the same basic distribution, chi-square tests were used. However, in most comparisons, too large a number of cells had expected counts of less than five. Fisher exact tests were not possible—i.e. the computational complexity was too large for the present computer and software (SAS version 6.12)—and there was no alternative for the chi-square test. To minimise the number of cells with expected counts of less than five, the TC, TE and TM cells were combined.\(^\text{16}\) Cell chi-square was also performed and presented in table 4.14 for all classification categories with a value larger than 6\(^{1/2}\) [129]—i.e. the number of causes in the cell (classification category) is different from what could be expected in the case of the frequency distributions

\(^{16}\)However, even this does not result in a table which meets the chi-square requirements, see table 4.14. Combining HS1 was not possible except if HS1 were combined with HK1, HK2, HR1, HR3–HR6. This would result in combining too many cells and a reduction of distinguishing power, and therefore this was not done. In spite of these problems, the results of the chi-square test are presented, since they are so significant that this breach of the requirements cannot lead to an incorrect conclusion.
of the FMEA and CII results being the same. In all eight cases, the distributions were significantly different. So, the prospective FMEA does not reveal the same categories of causes as the retrospective CII.

A comparison of the main classification categories for both the FMEA and the CII in the pie charts of figure 4.1 on page 104 and figure 4.4 on page 110 respectively, shows that the largest main classification categories differ: the largest category according to the FMEA is organisational failure, the largest category according to the CII is human failure. The three categories with the largest number of causes are the same for the FMEA and the CII, but not in the same order: the organisational factors of 'operating procedures' (ECM: OP) and of 'management priorities' (ECM: OM), and the human behaviour factor of 'planning' (ECM: HR 5).

So, the conclusion may be drawn that the FMEA does not reveal the same (categories of) causes as do the CII. An assessment as to which of the two methods is to be preferred, is given in chapter 8, after the presentation of findings in the Haemodialysis department.
Table 4.14. Overview of the 8 comparisons made for the FMEA and CII results, and of the results of the chi-square tests. The following information is shown in brackets, separated by semicolons:
- The percentage of cells which have expected counts of less than 5 in those cases in which this was considered to be too large by the software (SAS issues a warning if the percentage of cells with expected counts of less than 5, is greater than or equal to 25%).
- The classification categories which had a cell chi-square larger than 6%.
- The accompanying figure.

<table>
<thead>
<tr>
<th>Parts of the clinical OR</th>
<th>CII causes</th>
<th>FMEA</th>
<th></th>
<th>FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Without weighting factor</td>
<td>With weighting factor</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>Actual</td>
<td>&lt; 0.0001 (25%; HK2, HS1; fig. 4.11, p. 131)</td>
<td>&lt; 0.0001 (25%; HS1; fig. 4.12, p. 131)</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>All</td>
<td>&lt; 0.0001 (N/A; HS1; fig. 4.13, p. 132)</td>
<td>&lt; 0.0001 (25%; HR1, HS1; fig. 4.14, p. 132)</td>
<td></td>
</tr>
<tr>
<td>Anaesthesia-operating</td>
<td>Actual</td>
<td>&lt; 0.0001 (38%; HK2; fig. 4.15, p. 133)</td>
<td>&lt; 0.0001 (38%; OM, HK2, HS1; fig. 4.16, p. 133)</td>
<td></td>
</tr>
<tr>
<td>Anaesthesia-operating</td>
<td>All</td>
<td>&lt; 0.0001 (33%; HK2; fig. 4.17, p. 134)</td>
<td>&lt; 0.0001 (33%; HS1; fig. 4.18, p. 134)</td>
<td></td>
</tr>
</tbody>
</table>
4.5 Comparing the FMEA results with the CII results

Figure 4.11. Relative frequency distributions of the classified causes of the complete OR FMEA without weighting factors (n = 834) and of the classified actual causes of all OR CII (n of causes = 96, n of CII = 17). The classification categories are explained in appendix E.

Figure 4.12. Relative frequency distributions of the classified causes of the complete OR FMEA with weighting factors (n = 1394) and of the classified actual causes of all OR CII (n of causes = 96, n of CII = 17). The classification categories are explained in appendix E.
Figure 4.13. Relative frequency distributions of the classified causes of the complete OR FMEA without weighting factors (n = 834) and of all classified causes of all OR CII's (n of causes = 113, n of CII's = 17). The classification categories are explained in appendix E.

Figure 4.14. Relative frequency distributions of the classified causes of the complete OR FMEA with weighting factors (n = 1394) and of all classified causes of all OR CII's (n of causes = 113, n of CII's = 17). The classification categories are explained in appendix E.
4.5 Comparing the FMEA results with the CII results

Figure 4.15. Relative frequency distributions of the classified causes of the anaesthesia-operating part of the OR FMEA without weighting factors (n = 297) and of the classified actual causes of the OR CIs relating to the anaesthesia-operating part (n of causes = 81, n of CIs = 13). The classification categories are explained in appendix E.

Figure 4.16. Relative frequency distributions of the classified causes of the anaesthesia-operating part of the OR FMEA with weighting factors (n = 377) and of the classified actual causes of the OR CIs relating to the anaesthesia-operating part (n of causes = 81, n of CIs = 13). The classification categories are explained in appendix E.
Figure 4.17. Relative frequency distributions of the classified causes of the anaesthesia-operating part of the OR FMEA without weighting factors \( (n = 297) \) and of all classified causes of the OR CIIs relating to the anaesthesia-operating part \( (n \text{ of causes} = 92, n \text{ of CIIs} = 13) \). The classification categories are explained in appendix E.

Figure 4.18. Relative frequency distributions of the classified causes of the anaesthesia-operating part of the OR FMEA with weighting factors \( (n = 377) \) and of all classified causes of the OR CIIs relating to the anaesthesia-operating part \( (n \text{ of causes} = 92, n \text{ of CIIs} = 13) \). The classification categories are explained in appendix E.
Real-time approach in the OR: IRMS

5.1 Introduction

This chapter describes the application of the Incident Reporting and Management System (IRMS) in the OR. In contrast to the CIIs and FMEA discussed in the previous chapter, which are held once-only and assess risks retrospectively (in the case of CIIs) and prospectively (in the case of the FMEA), the IRMS is permanently present and doctors and employees can report incidents directly to the IRMS. For the place of the IRMS within the risk management framework, see table 3.5 on page 65 and figure 3.7 on page 64. Just as with the risk management methods discussed in the previous chapter, the following aspects will be discussed:

- The use of the IRMS in the OR. Important aspects, considerations and experiences which led to evaluations and alterations in the IRMS, are also included.
- The results, i.e. the patient risks which were found.
- An evaluation of and a discussion about the experiences with the IRMS within the scope of risk management in the OR.

Chapter 6 will discuss risk management adjustments in the OR.

This chapter starts by describing the use of the IRMS. Next, the original IRMS, the reasons for altering the original IRMS—with regard to the classification of causes in accordance with the ECM and the use of Causal Tree Analysis—and the resulting final IRMS will be discussed in section 5.2. Section 5.3 presents experiences with and recommendations about the ECM and CTA. The IRMS results of three data analyses are presented and discussed in section 5.4. This chapter ends with section 5.5 in which conclusions and recommendations based on the IRMS results are presented.

5.2 Use of the IRMS

An IRMS was designed and implemented as a permanent method for doctors and employees to report and analyse incidents [140]. For a description of the operation of an IRMS, see section 3.4.7 which describes the activities of the final IRMS. Incidents were
reported voluntarily to the IRMS, and the IRMS had to operate in a self-supporting way: no assistance from outside the department would be needed.

Over several meetings, the IRMS committee (see also section 3.4.7) was trained to work in accordance with the eight modules of the IRMS. Initially, the committee consisted of four OR employees (covering the four main parts of the clinical OR: preparation, anaesthesia, operating and recovery), a surgeon and an anaesthetist [140].

The IRMS is an independent system which works in isolation from the hospital's FONA ('Fouten, Ongevallen en Near Accidents', in English 'errors, accidents and near accidents') system.

The description of the activities of the IRMS that was given in section 3.4.7, was the state of the IRMS between the second and the third incident analysis and evaluation moment of the IRMS. The first analysis and evaluation moment was after two months, the second was after fourteen months (or 345 incidents), and the third after twenty-three months (or 523 incidents): see table 5.2 on page 150. The first incident analysis and evaluation moment coincided with the ending of the final project of Timmermans [140], the second took place a year later, and the third coincided with the ending of this research project in the OR. The operation of the IRMS was adapted once, when the first or original IRMS became the final IRMS, see also table 5.2 on page 150. The mode of operating of the IRMS was altered significantly after the IRMS had been in place for two months. The reasons for adapting the IRMS protocol are discussed further down in this section on page 139.

The original IRMS

The differences between the activities in the final IRMS and the modules of the original IRMS are briefly described in table 5.1 starting on the facing page because the original IRMS was only in place for a relatively short time, and every incident that was analysed by the original IRMS was also analysed by the later—the final—IRMSS.

After two months, the IRMS had resulted in the analysis of 62 incidents. At that moment, the IRMS consisted of the seven original modules in the development and implementation of which the IRMS committee had participated. The seven modules of the original IRMS are described in the right-hand column of table 5.1 together with the differences with the final IRMS which was presented in table 3.8 on page 78.

---

1The original IRMS was designed by Timmermans [140].
Table 5.1. The differences between the final IRMS and the first/original IRMS [140].

<table>
<thead>
<tr>
<th>Activity of the final IRMS (see table 3.8 on page 78, and explanation in section 3.4.7)</th>
<th>Modules of the first/original IRMS [140]: difference(s) with the activity of the final IRMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reporting incidents.</td>
<td>1. Detection module</td>
</tr>
<tr>
<td></td>
<td>Every reporter got a written confirmation.</td>
</tr>
<tr>
<td>2. Describing incidents of last week.</td>
<td>2. Selection module</td>
</tr>
<tr>
<td></td>
<td>The purpose of the selection module was to determine which incidents were described by CTA.</td>
</tr>
<tr>
<td></td>
<td>The selection of incidents was mainly made on the basis of whether an incident had already</td>
</tr>
<tr>
<td></td>
<td>been analysed thoroughly before. The objective was to control the workload for the IRMS</td>
</tr>
<tr>
<td></td>
<td>committee with regard to describing incidents, and nevertheless to produce a balanced and</td>
</tr>
<tr>
<td></td>
<td>usable database. Incidents selected for description by CTA were, in general, incidents that</td>
</tr>
<tr>
<td></td>
<td>were either new or serious.</td>
</tr>
<tr>
<td>3. Description module</td>
<td>3. Description module</td>
</tr>
<tr>
<td></td>
<td>All incidents which were selected were analysed by CTA. For all these incidents, follow-up</td>
</tr>
<tr>
<td></td>
<td>research took place in the form of an interview between the reporter and a committee member</td>
</tr>
<tr>
<td></td>
<td>to produce a correct and complete CTA.</td>
</tr>
<tr>
<td></td>
<td>The incidents which were not selected, were described only by their top event and their (prob-</td>
</tr>
<tr>
<td></td>
<td>able) main cause. The data of the reporting form were used for this purpose. There were no</td>
</tr>
<tr>
<td></td>
<td>additional interviews.</td>
</tr>
<tr>
<td>3. Clustering incidents of the last week to their cause(s).</td>
<td>4. Classification module</td>
</tr>
<tr>
<td></td>
<td>All the (main) causes of the incidents were classified in accordance with the ECM.</td>
</tr>
</tbody>
</table>

continued on next page
Activity of the final IRMS (see table 3.8 on page 78, and explanation in section 3.4.7) Modules of the first/original IRMS [140]: difference(s) with the activity of the final IRMS

4. Examining all incidents and, if necessary, altering clusters and/or making new clusters. Generating list of structural failure factors. Trend analysis.

5. Data analysis module
The database of classified (main) causes was analysed. This was done by analysing the largest cause categories. These categories were broken down to make the specific incident information visible which was necessary for drawing conclusions and generating measures. This meant that all incidents that had contributed with one or more causes to a certain classification category, had to be re-examined in order to describe the classified cause in concrete detail.

5. Drawing conclusions and making recommendations.

6. Interpretation module
The goal of this module was to make proposals for improvement on the basis of information and ideas obtained from results of the data analysis module. Evaluation criteria were adopted by means of which the implemented proposals for improvements could be evaluated. All the OR employees and doctors were informed of the measures that were taken.

6. Proposing, initiating and securing improvements.

7. Evaluate IRMS and, if necessary, adapt IRMS protocol.

7. Evaluation module
The evaluation criteria of the previous module were used to determine whether the measures of the last period had been effective. The results of this evaluation could, for instance, result in generating new measures.

8. Giving feedback of analysis results and improvements to OR employees and doctors.

From the beginning, the IRMS committee actually consisted of three OR employees (one recovery nurse, one anaesthesia assistant and one operating assistant) instead of the proposed composition of four OR employees, plus an additional surgeon and an

---

2The availability of the preparation nurses was a problem. The preparation part of the OR was covered by the anaesthesia assistant who was sufficiently conversant with the preparation process. At the start of the IRMS committee, the OR manager was temporarily added to the IRMS committee [140].
anaesthetist. All members were rostered to be off duty together on the same afternoon for 4 hrs. a week. The senior staff members, a surgeon and an anaesthetist, who should have been part of the IRMS committee, were unfortunately not able to plan a couple of hours off on a weekly basis.

The data analysis was made by Timmermans (see [140] for more details) and is briefly described in table 5.1 on page 137 and following. The database of the (main) causes of incidents, contained:

i. An overview of the classification categories per incident report.

ii. Information about the occurrence of recovery factors.

iii. An overview of the (cumulative) counts for each classification category.

Reasons for altering the original IRMS After the IRMS had been in operation for two months, the support for the IRMS committee from outside the OR ceased because Timmermans’s final project was completed [140]. After nine months, it appeared that the IRMS committee was not able to carry out all its weekly activities: a structural backlog of work in describing incidents and classifying causes had built up. Two reasons for this were:

- The three IRMS committee members were often not able to roster the 4 hrs. per week per person off. This was caused by understaffing in the OR.

- Describing incidents in a causal tree and classifying the causes was too laborious and time-consuming.

Additional staff, two FTEs (one full-time researcher, two part-time researchers), from outside the OR were brought in to eliminate the backlog: describing the incidents, classifying the causes, performing data analysis, generating measures for improvements, making a report. However, a number of problems occurred:

a. The incidents on the reporting forms were often described inadequately. It was not possible to make a correct and complete causal tree based on these descriptions.

b. The causal trees that were created by the IRMS committee were incomplete: causes turned out to be missing. This had already been found by Timmermans [140]. According to Timmermans, IRMS committee members did not describe incidents completely for two reasons:
Incidents could involve another discipline, and because knowledge about this discipline might be inadequate, describing the incident completely was a problem.

An insight into causes and effects on the basis of which other causes, too, could be suspected, was missing.

c. It was not possible to remedy the shortcomings mentioned under points a and b. This was because:

- The number of incidents was too large. The staff available could not cope with this.

- It was not possible for the researchers to conduct follow-up research in the OR. This would be too much of a burden for the employees and doctors because:
  
  * The number of incidents was too large.
  
  * A feedback interview with the reporter(s) would take a (relatively) long time because the researchers were not OR employees or doctors.

- The IRMS committee members did not have the time to review the causal trees critically, to conduct follow-up research and to make the causal trees more complete.

d. In the causal trees, causes and/or top events were described wrongly, causes were incorrectly situated in the tree, had been merged incorrectly or had—mistakenly—not been merged.

e. In the case of incidents which were not described by CTA, the top events and the main causes were often described incorrectly. Causes were wrongly viewed and treated as top events, or effects were left out.

f. The classification of causes was inconsistent.

g. The classification of causes was sometimes incorrect.\(^3\)

\(^3\)I.e. in accordance with the researchers' interpretation of the ECM during a review of the causal trees created by the IRMS committee. It should be noted that the researchers used the same standard version of the ECM as was used by Van der Hoeff [151] which was slightly different from the version Timmermans [140]—called ECM Medical—used for the original IRMS. Timmermans' version had two extra classification categories: EX for EXternal, and PRF for Patient-Related Factors. For patient-related factors see also [151], and footnote 7 on page 49 about patient-related factors and failure factors.
h. An analysis of only a part of all incident causes—only the largest categories of causes were analysed—would lead to a loss of important information, so all incident causes should be analysed. Moreover, a discrepancy existed between the nature of the causes of the incidents which were analysed by CTA and those which were not.

In the original IRMS, the amount of effort which had to be made to eliminate the backlog of work in describing incidents and classifying causes was too large, considering the way the IRMS operated and the level of staffing available. Since, at that moment, the number of staff available was expected to decrease even further in the future, because of pregnancy leaves and a general staffing shortage, the solution had to be found in a more efficient way of working without making any concessions to effectiveness.

Classifying A solution in the form of additional training for IRMS committee members in order to eliminate the classification problems mentioned under points f and g, would have been useless for two reasons:

- The classification of incident causes is personal and unreliable. In a pilot study which Van Vuuren conducted among researchers—all of them experienced users of the ECM—in which causes in a causal tree had to be classified, less than 70% were correctly classified. The objective of the pilot study was to determine how easily recognisable new classification categories (abstract, general) were in practice (concrete, specific) by using a number of incidents which were worked out in causal trees. This did not really differ from the situation in the OR: assigning classifications to causes. Classification categories must be defined in concrete terms by using a number of examples (see also appendix E) but in practice this is not enough. The same goes for the adapted model, the ECM Medical [161, 162]: examples are used to define the different categories. These examples should be tailored to the specific situation of each hospital department, but doing this provides no guarantee for preventing fruitless disagreements. Moreover, the ECM Medical incorrectly categorises patient-related factors [151] as (system) failure [140, 161, 162], see also section 3.3.1.

4See e.g. Van der Schaar[154]: a formal test in which two judges classified causes according to the seventeen subcategories of the ECM, yielded a degree of overlap of 36%. The problems Van der Schaar discusses with regard to incident cause analysis and classifying causes in accordance with the ECM, were also encountered in this research: the corrections which had been suggested by Van der Schaar—such as explaining the entire classification scheme again to each ‘judge’—were not convincing.

5This pilot study was initiated by Van Vuuren. The results of this pilot study have not been published.
Moreover, after some time it turned out to be difficult or impossible to explain why a cause had been classified in a certain category: this applied both to classifications made by a third party and those made by the researcher himself. The reason for assigning a cause to a certain classification category was forgotten and later on was found no longer to be so obvious. The reliability and in this case therefore also the validity was low: a cause was not classified as it should have been classified.

• As long as causes have to be classified, the workload will remain too large.

The solution had to be a more efficient way of describing incidents. In addition to the two disadvantages mentioned before, classifying has two other drawbacks:

• In the data analysis module of the original IRMS (see table 5.1 on page 137 and following in this section), classifying becomes ineffective. In the case of, for instance, the data analysis of 345 incidents, the conversion from abstract (the classified cause) to concrete (the actual cause) had to be performed about 2,000 times,\(^6\) for it is impossible to determine on the basis of an abstract classification what the concrete cause is and whether it is a (possible) structural cause. The reason for analysing all the incidents was that the selection of incidents resulted in a biased database (see above in this section under point h), and that for reasons of carefulness every reported incident should be included in the data analysis. In this way the problem mentioned above under point h is resolved: when all the incidents are analysed, the problem of analysing only a part of the incident causes is solved. Furthermore, there is no longer a selection of incidents and therefore the problem of discrepancy is also solved (see above under point h on the preceding page).\(^7\)

\(^6\)The 17 incidents of the CIIIs yielded 96 causes in all (i.e. classified actual causes, cf. the original 98 causes, see the boxed text 'Summary of the data and data processing: OR CIIIs' on page 109). The average number of causes per incident is about 5.6 (96 divided by 17; cf. the value of '5.76' for the 'mean n of causes per incident' in table 8.1 on page 256 which is based on the original number of 98 causes, see again the boxed text 'Summary of the data and data processing: OR CIIIs' on page 109). For e.g. 345 incidents, this would mean that the conversion from abstract (the classified cause) to concrete (the actual cause) must be performed close on 2,000 times.

\(^7\)In summary and by way of explanation: in principle all incidents were described by the original IRMS. The very decision whether or not to select incidents for analysis by means of CTA caused a discrepancy between the nature of incident causes of those incidents which were analysed by means of CTA and those which were not. Thus, for instance, no incident which was (co-)caused by technical failure was selected for analysis by means of CTA [140]. Subsequently only the causes belonging to the largest cause categories were analysed. As a result a part of the incident causes—and therefore probably also the incidents themselves—were not included in the analysis and important information is not used and therefore is lost. See also the descriptions of the modules of the first IRMS in the right hand column of table 5.1 on page 137 and following.
• The corollary to this is that classifying is unnecessary, see also the boxed text ‘Context of incident’ on the following page. In practice there is no point for an IRMS to classify the cause in an abstract category, such as e.g. OP, and lose all context information, if later on all these abstracts categories have to be converted back to their context, i.e. concrete cause(s). So, the ECM was useful for comparing different risk management methods (in this research FMEA with CIIIs), but has no value in the IRMS. The classification of causes in the ECM was therefore removed from the IRMS. Instead of classifying causes into abstract ECM classification categories, the clustering of incidents to their cause(s) took place on the basis of similarities, see further down in this section and table 5.4 (see pages 152–154) and table 5.6 (see pages 160–163). These clusters were then used by the IRMS committee to learn from, i.e. to draw conclusions and make recommendations.

The low reliability of the ECM with regard to the classification of causes also became evident from the long discussions about the classification of causes the researchers had among themselves and with the researchers from the Eindhoven University of Technology (EUT) which developed the ECM. As long as classification takes place in consensus by the same group and over a limited period of time, its reliability is probably adequate. However, this is very time-consuming and demanding. The classification of the results of the FMEA and the CIIIs was performed like this. But all through the process the group had to argue again and again why a certain cause was classified into a specific category.

**Causal Tree Analysis** Not only classifying—i.e. the classification of causes—is unreliable (see the above-mentioned points f and g), but also the quality of a causal tree depends strongly on the experience and knowledge of the creator of the causal tree (see the points mentioned above under b and d; the above-mentioned point e is to do with the description of the top event of a causal tree and of the main cause of incidents not described by CTA).

Validity and reliability are important in determining the quality of a causal tree:

• **Validity.** Does the causal tree describe all the relevant elements to explain the development of an incident?

• **Reliability.** If different persons create a causal tree of the same event, to what extent do the same causes and top event recur in the same configuration? Or if the same person creates a causal tree of the same incident at two different moments: to what extent do the same causes and top event recur in the same configuration?

The problems described above, such as points b, d and e, indicate that the validity and
Context of incident

Just to be perfectly clear, by 'classifying' is meant classifying causes according to the classification categories of the ECM. This is unnecessary in the case of the IRMS as it was used in the OR. What is not meant by 'classifying' is 'clustering' which has been used subsequently instead of 'classifying'. 'Clustering' is understood to mean the process of clustering incidents to their cause(s) on the basis of similarities. For examples of clusters see table 5.4 (see pages 152–154) and table 5.6 (see pages 160–163). The clustering process is also described further down in this section. A cluster contains more context information than an ECM classification category: e.g. see the cluster 'Incidents concerning NedSter: dirty sets or instruments' (cluster a1: see both table 5.4 (see pages 152–154) and table 5.6 (see pages 160–163)) with the classification category 'Organisational factor: Operating procedures' (see OP in figure E.1 on page 303). The loss of context which occurs in the case of clustering is later compensated for by the IRMS committee—since they are what Koornmeef [80] calls 'domain experts'. The compensation for the loss of context by the IRMS committee is needed in order to be able to draw conclusions and make recommendations as a result of the clusters obtained.

Loss of context also occurs in the case of incident reporting by the reporter or reporters to the IRMS. This loss can also be compensated for by the IRMS committee (as domain experts). This is done during the description of the reported incident, see also further down in this section under the heading 'The final IRMS'.

To sum up:

• Loss of context occurs in the course of reporting and clustering of the incident. The loss of context during the clustering of causes into concrete clusters is not as serious as during the classification of causes into abstract classification categories such as the ECM categories, where the context is completely lost.

• Compensation for the loss of context by the IRMS committee occurs in the course of the description of the incident after the incident report, and in the course of drawing conclusions and making recommendations as a result of the clusters obtained. With regard to the incident description: the loss of context during the reporting stage can be compensated for by the domain knowledge of the IRMS committee members, and by additional research (e.g. interviewing). With regard to drawing conclusions and making recommendations: the IRMS committee can easily compensate directly for the loss of context in the case of concrete clusters on the basis of their domain knowledge which is impossible in the case of abstract classification categories. If necessary, the incident descriptions concerned can be consulted.

NB: Loss of context also takes place while making an incident description (making an incident description is described further down in this section). With regard to describing incidents, the intention was to describe—of each incident—the effects on the patient(s) and the most important causes. The IRMS committee—being domain experts—can compensate for the loss of context which occurs in the case of an incident description, see also [80]. However, if this loss of context caused by the description of the incident is a problem (i.e. the loss of context cannot be compensated for by the IRMS committee), then consultation of the incident report in question (and, if present, of additional information sources such as interviews) by the IRMS committee would also be a possible way of compensating for the loss of context. This may occur when the IRMS committee is drawing conclusions and making recommendations as a result of the clusters obtained.
reliability of CTA are not very high. The validity and reliability could possibly be improved by gathering together experiential knowledge about creating causal trees into a number of general guidelines for creating a correct causal tree (see also section 3.4.5). Problems in creating a causal tree are, for instance, that:

- Creating a causal tree is partly a matter of knowledge, partly a matter of skill, and is personal. Some researchers use one-on-one relations in a causal tree while others do not. Some aspects of creating a causal tree may be easily corrected by training (this applies to not using one-on-one relations), while others may be much harder to correct, such as a lack of logical insight resulting in the omission of causes, a lack which was mentioned by Timmermans [140] (see also above in this section under the heading 'Reasons for altering the original IRMS').

- The formulation of a cause requires great care and precision. Isolated formulations, as in a causal tree, can easily be placed in a wrong context or be misconstrued, resulting in different classifications of a cause. Again, experience shows this, both within the hospital—the users in practice—and outside the hospital—experienced researchers of EUT.

All this makes clear that the combination of describing an incident by means of a causal tree and subsequently classifying the causes is not very reliable and valid. Nevertheless, the objective was to make the description method for incidents, the creation of a causal tree and the classification of the causes more efficient and at the same time sufficiently effective. In other words, a description method that takes as little time as possible and at least achieves its goal. But what is the goal of an incident description method? A good incident description method aims at the prevention of future incidents, aims at completeness of description, in particular completeness in describing structural causes (and not so much completeness in describing all causes). It is structural causes which can lead to the development of future incidents. Once structural causes are prevented, the incidents in question can no longer occur via that causal path.

Completeness in a description cannot be attained only by using a causal tree, though its use may contribute to this completeness. A causal tree is an instrument that can be used to gain a clear view of the causal path. However, it is:

---

8What is meant by a 'one-on-one relation' is when one cause leads to one effect without using an AND gate or an OR gate. Some researchers, like the present researcher in his research in the OR, put this cause and effect together in one combined description, leading to one block of text in the causal tree instead of two. Following this convention results in causal trees in which two or more causes always result in an effect via an AND gate or an OR gate: each level of the tree is connected via AND gates and OR gates. See also under the point 'CTA' on page 203.
• A laborious method that has added value only for incidents with a complex causal path.

• A strongly personal method. The result—the quality of the causal tree—is determined by the knowledge of and experience of the method, familiarity with the department and its processes, the perception which the user has of the incident, and the ability of the user to recognise risks. This applies to all incident description methods like a CII, regardless of whether it is described by means of a causal tree or not. Training is possibly a way for improving this.

A method which guarantees that an incident is completely described does not exist, although models like MORT, ECM and Tripod, when they are used as a checklist during a description, probably come pretty close. However, these models would be too laborious in the case of large numbers of incidents. Completeness remains a weak point but this can be achieved in sufficient measure by means of careful description, familiarity with the department and its processes, experience in the creation of incident descriptions, and the ability to recognise risks.

Completeness in describing incidents is only important for structural causes, less so for accidental causes. The difference between a structural cause and an accidental cause is that a structural cause can occur again in the future, causing an incident to occur again. It is possible that a structural cause is mistakenly viewed as an accidental cause, but by asking whether a cause is structural (i.e. whether the cause can happen again), it is possible to determine with sufficient certainty whether a cause is structural or accidental. Structural causes are often related to a complete protocol or procedure. If a failure of a part of the protocol or procedure is a cause then it is possible that—and this relates in particular to procedures which by definition exceed the system boundary of the department—the complete protocol or the complete procedure needs to be re-examined for structural failure, and may need to be redesigned in order to exclude suboptimal improvements. An example of this would be the blood-ordering procedure which is discussed in chapter 6.

A description of the incident with the (possible) effects on the patient and the (most important) (structural) causes in which the focus, the essence of the incident, is maintained, is sufficient. This is possible in a description of two to eight lines (cf. the concise case descriptions in Koornneef’s thesis [80]). The advantages of such a description are that it is not laborious and the context of the incident with all accompanying information is not lost, as is the case with the classification of the causes into abstract ECM categories. The clustering of incident causes also proceeds more efficiently and smoother in this way because it is easier to recognise (new) clusters in large numbers of incidents.
This clustering still needs to be done by hand and cannot (easily) be performed by a computer. Clustering of incident causes and classifying incident causes to these clusters is an iterative process, in which clusters and subclusters are formed and adapted, and causes are classified into these clusters. In order to provide an insight into the process of clustering and classifying incidents into clusters, the three incidents on which the cluster n with the subclusters n1 and n2 were based, are given by way of example. See the boxed text ‘An example of the creation of clusters and the classification of incidents into clusters’ on the following page. The incidents are part of the last 178 incidents reported to the IRMS, see section 5.4 and in particular table 5.6 (see pages 160–163).

To sum up:

- Completeness in the case of an incident description is difficult to realise but a causal tree may help.
- The focus should be on the assessment of structural failure factors.
- The combination of creating causal trees of incidents and classifying the causes found is a laborious process.
- Because creating causal trees of incidents and classifying the causes found into abstract categories each have a low reliability and validity, both methods used together can create an—undesirable—appearance of reliability.\(^9\)
- Moreover, classifying causes into abstract categories for other purposes other than for comparing methods, is not meaningful.

The final IRMS This analysis was adequate for adapting the mode of operation of the IRMS. After all, the effectiveness of the IRMS lies in preventing incidents. To this end, the IRMS should provide an insight into structural failure factors so that improvements can be implemented. However, the IRMS bogged down on the data analysis. The solution was found in the form of a redesign of the IRMS:

1. No selection was made and all incidents were used for the analysis in order to find structural causes.
2. Of each incident reported a description was given of the effects on the patient(s) and of the most important cause(s).
3. Structural causes of the development of incidents were identified.

\(^9\)E.g. a reliability of 0.7 for both methods—i.e. creating a causal tree and classifying causes found in accordance with to the ECM—results in a total reliability of 0.49 when both methods are simultaneously used.
An example of the creation of clusters and the classification of incidents into clusters

The following three incidents led to the creation of cluster n 'Incidents concerning on-call shift procedure' with subclusters n1 and n2, which then resulted in the classification of these three incidents as such. For the meaning of cluster n, see the table below. For the meaning of the cluster codes other than n, see table 5.6 (see pages 160–163).

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Incidents concerning on-call shift procedure</td>
</tr>
<tr>
<td>n1</td>
<td>Patient not announced in accordance with protocol</td>
</tr>
<tr>
<td>n2</td>
<td>Staff not called up in accordance with procedure</td>
</tr>
</tbody>
</table>

* Incident 471
Patient not optimally taken care of by OR, and the staff of the Delivery Rooms did not act in accordance with the mandatory rules for hygiene. The patient was taken into an operating room for a Caesarean section without an announcement on the duty beeper: because of this, proper preparation was not possible. In the end, it was a normal delivery. The staff of the Delivery Rooms had their hands covered with blood and/or faeces, and did not take off their gloves after use as a result of which everything they touched became contaminated.
Clustered in: n1, s3.

* Incident 474
The quality of care in case of patient was not optimal in case of a rethoracotomy at the ICU, because:
- The thorax spreader was not assembled correctly by the Central Sterilisation Department (CSD).
- The defibrillator was broken.
- *The ICU doctor did not know how the on-call shift procedure worked and did not know which doctor was on duty.*
- Communication was bad at the ICU, and the nursing staff did not know how the OR's defibrillator worked.
Clustered in: a8, f8, j6, n2, q6, s3.

* Incident 477
Calling up OR staff on duty goes wrong 2 times. In one case, *the telephonist called up the wrong shift of anaesthesia staff* (the B shift instead of the A shift). In the other case, initially only half of a surgery team was called up, as a result of which one person turned up later than intended.
Clustered in: n2.
4. These structural causes were grouped into subclusters (see also footnote 25 on page 79).

5. These subclusters were then grouped into main clusters.

6. During the classification of the incidents into clusters, new sub- and main clusters were added and existing sub- or main clusters altered.

The final IRMS resulting from this is represented in table 3.8 on page 78.

In summary The views about how to carry out risk management changed after the first analysis of the IRMS. In the original IRMS, a selection of the incidents reported and a time-consuming classification of the root causes found in the abstract classification categories of the ECM—which resulted in abstract profiles—were made. In the final IRMS, the risk management approach was changed: no selection of incidents (so no selection bias), brief descriptions of incidents with a classification of the main causes of incidents into more concrete clusters. In contrast to the ECM classification categories, the clusters are based on the actual processes and elements within the system, and are generated after studying a large number of incidents by the IRMS committee. The results of the analysis of IRMS reports are described in section 5.4.

5.3 Experiences with and recommendations about ECM and CTA

The Eindhoven Classification Model (ECM) is useful for classifying causes of system failure in the OR that were found via the FMEA and the CIIs. This made possible a comparison of the results of the two different methods. Because of the low reliability, the results should be classified by the same person or persons over a short period of time. The (resulting) low validity of the ECM is another drawback. The ECM is often used in combination with Causal Tree Analysis (CTA) (e.g. in this research in the case of the CIIs in the OR and the first IRMS). Because CTA also carries a low reliability and (therefore) a low validity, the combination of ECM and CTA is not ideal but there was no alternative. Classifying causes in accordance with the ECM is a laborious process, and turns out to be impractical when applied on a regular basis in combination with CTA in the IRMS.

In future research, it would be advisable to examine the specific extension of the ECM with regard to the organisational factors (which frequently occur in the OR) 'operating procedures' (ECM: OP), 'management priorities' (ECM: OM), and to the human behaviour factor 'planning' (ECM: HR 5). The team that made the classification of the causes was under the impression that these categories were often used as a kind of
Table 5.2. Overview of the incident analysis and evaluation moments of the IRMS.

<table>
<thead>
<tr>
<th>Analysis after</th>
<th>Analysis of</th>
<th>n of months after start IRMS</th>
<th>Analysed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>62 incidents</td>
<td>The first 62 incidents (reports 1–62)</td>
<td>2</td>
<td>Original IRMS</td>
</tr>
<tr>
<td>345 incidents</td>
<td>The first 345 incidents (reports 1–325)</td>
<td>14</td>
<td>Final IRMS</td>
</tr>
<tr>
<td>523 incidents</td>
<td>The last 178 incidents (reports 326–504)</td>
<td>23</td>
<td>Final IRMS</td>
</tr>
</tbody>
</table>

*Some incident reports consist of more than one incident.

*bOne report was blank.

catch-all term or residual category. Research into the expansion of the ECM with organisational factors has since been conducted by Van Vuuren [161]. Van Vuuren expanded the organisational categories of the ECM for the medical domain from two to five. These new categories could not be used because the classification took place in 1994 and 1995, and Van Vuuren published his thesis in 1998 [161].

In the case of making a CTA, it is important to focus on the purpose for which a causal tree is used. If the purpose is to analyse an incident, then the (possible) physical effects on the patient should be taken as a starting point, the so-called ‘top event’ (see also section 3.4.5). In order to be able to classify a cause into the right classification category—thus improving the reliability and validity of the combined use of CTA and the ECM—it is also of crucial importance to describe all events in the causal tree as completely and carefully as possible.

To increase the reliability of classifying incident causes in accordance with the ECM, it is important that the classification is made by a group within a limited time span and in conformity with the guidelines for making a CTA (see also section 3.4.5).

5.4 Results of the IRMS

The data of the IRMS were analysed 3 times over a period of almost 2 years. The first analysis was made with the original IRMS, the second and third analysis with the final IRMS. The second analysis also included all the incidents analysed during the first analysis with the original IRMS, see table 5.2. The results of these analyses are given in this section.
Summary of the data and data processing: IRMS

The total number of incidents reported = 523. Because some incident reports consisted of more than one incident, the total number of incident reports = 504. The analyses were made after 62, 345 and 523 incidents, and related to the first 62 incidents (reports 1–62), the first 345 incidents (reports 1–325) and the last 178 incidents (reports 326–504). See also table 5.2 on the facing page for more details. In addition to the analysis of the incident reports, an analysis was also made of complaint cards about NedSter. This was done twice. Each time an analysis was made of the complaint cards collected over a period of 34 weeks. The n of complaint cards of the first analysis = 364 and the n of the second analysis = 334. The n of different structural causes found was 9 for the first 62 incidents, 53 for the first 345 incidents and 51 for the last 178 incidents.

Table 5.3. Overview of the different structural causes found by the IRMS after the analysis of 62 incidents [140].

<table>
<thead>
<tr>
<th>Structural causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating room was not well prepared</td>
</tr>
<tr>
<td>Progress in the OR was allowed to prevail over the safety of the patient</td>
</tr>
<tr>
<td>Failure to pass on information about the availability of surgeon</td>
</tr>
<tr>
<td>Failure to pass on information about necessary resources</td>
</tr>
<tr>
<td>Inducing patient with no surgeon present</td>
</tr>
<tr>
<td>Surgeon absent/arrives too late in the OR</td>
</tr>
<tr>
<td>No blood available in the OR and no cross-matched sample in the laboratory</td>
</tr>
<tr>
<td>Incomplete information in the OR</td>
</tr>
<tr>
<td>Problems with the availability of materials to be supplied by NedSter</td>
</tr>
</tbody>
</table>

Results after 62 reported incidents  This analysis was made by Timmermans [140] using the original IRMS. The structural causes that were found are presented in table 5.3. The analysis was made of 62 incidents: 30 incidents were analysed by means of CTA, 32 incidents were described by their top-event and their (probable) main cause.

Results after 345 reported incidents  This analysis was made by the IRMS committee with assistance from the department of Patient Affairs [145]. In addition to the analysis of the 345 incidents reported, the analysis also concerns the 364 complaint cards about NedSter which were reported to the IRMS. NedSter was established in 1993 as a joint venture of the Catharina Hospital and NedLin, and is the successor to the Central Sterilisation Department (CSD). By using a form (complaint card), the IRMS committee recorded how many sets were incorrectly delivered by NedSter. This was done because
the committee had received complaints about NedSter. The complaint cards which the IRMS committee collected were processed separately from the IRMS reports. It is not known how much overlap there is with IRMS reports about NedSter.

The 345 reported incidents The structural causes that were found after analysing 345 incidents are subdivided into 13 clusters and 53 subclusters, see table 5.4 on this page and following.

Table 5.4. Overview of the different structural causes found by the IRMS after the analysis of 345 incidents. In square brackets are the causes/clusters which were not found during the analysis, but are described here, all the same, because the purpose of this table is also to elucidate the meaning of (sub)clusters.

<table>
<thead>
<tr>
<th>Structural causes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>a Incidents concerning NedSter</strong></td>
</tr>
<tr>
<td>a1 Dirty sets or instruments</td>
</tr>
<tr>
<td>a2 Wet sets</td>
</tr>
<tr>
<td>a3 Sets not packed in accordance with protocol</td>
</tr>
<tr>
<td>a4 Failure to indicate absence of instruments on packing</td>
</tr>
<tr>
<td>a5 Wrong contents of set or wrong instrument</td>
</tr>
<tr>
<td>a6 Weighing nets (deviation &gt; tolerance)</td>
</tr>
<tr>
<td>a7 Regulations about (emergency) sterilisation are not always complied with</td>
</tr>
<tr>
<td>a8 Instruments not checked properly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>b Blood-testing and -ordering procedure (no blood, no cross-matched sample)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>c Incidents concerning patients arriving from the ward</strong></td>
</tr>
<tr>
<td>c1 Patient not prepared properly (e.g. set of false teeth not removed)</td>
</tr>
<tr>
<td>c2 Incomplete patient file</td>
</tr>
<tr>
<td>c3 ECGs missing</td>
</tr>
<tr>
<td>c4 X-rays missing</td>
</tr>
<tr>
<td>c5 Mixing up patient data (e.g. similar names, dates of birth)</td>
</tr>
<tr>
<td>c6 Laboratory results missing</td>
</tr>
<tr>
<td>c7 Pre-operative screening not performed properly</td>
</tr>
</tbody>
</table>

| **d Incidents concerning patients arriving from the preparation room** |
| d1 Patient not prepared properly (e.g. false teeth not removed) |
| [d2 Incomplete patient file] |

continued on next page
5.4 Results of the IRMS

continued from previous page

Structural causes

d3 ECGs missing
[d4 X-rays missing]
d5 Mixing up patient data (e.g. similar names, dates of birth)
d6 Laboratory results missing

e Doctor absent from the operating room
e1 Surgeon arriving too late
e2 Anaesthetist arriving too late
e3 Double booking of surgeon

f Incident concerning materials/equipment
f1 Material has been double booked while only one or two devices are available in the OR
f2 In contravention of the OR schedule, material is being used by a third party
f3 Material is not in stock
f4 Material is in stock in unsterile state
f5 Incomplete set is sent to NedSter, but, on being returned to the sterile corridor, the set is not completed (the sterile corridor is the name used by the OR doctors and employees to refer to a corridor in the OR)
f6 Inadequate periodic check on sterility expiration date in the sterile corridor
f7 Check on materials before operation is inadequate in the sterile corridor
f8 During an operation, it turns out that there is something wrong with material

g Patient is deliberately treated with material which is inappropriate or non-standard for the operation concerned
g1 Surgeon deliberately violates sterility
g2 Inappropriate or non-standard material is used (e.g. wrong size)
g3 Material treated with disinfectants (Cidex)
g4 Patient's allergy is ignored

h Insufficient check on patient during operation route

i Operating room not properly prepared before the operation by staff of
i1 Previous shift
i2 Current shift

continued on next page
Structural causes

j Poor communication
j1 Before start of operation, surgeon changes operation as a result of which the operating room and/or the patient are/is not properly prepared
j2 Equivocal use of the terms 'urgent' and 'acute' in the OR
j3 Kind of operation is not clear on the white board as a result of which the operating room and/or the patient are/is not properly prepared
j4 Surgeon does not pass on message that he is engaged elsewhere
j5 Incidents arising from schedule alterations
j6 Unclear who surgeon is
j7 Responsibilities unclear
j8 Argument during the operation route
j9 Doctor unavailable

k Incidents concerning anaesthesia
k1 Anaesthetist has induced patient in the absence of surgeon
k2 Anaesthetist induces patient though the required data are not available
k3 Before start of operation, surgeon changes anaesthetic although patient has not been prepared for this
k4 Incidents with relating to the 'two bed policy' of anaesthetists

m Loss of operating room time
m1 Patient is too late or does not show up
m2 Programme is not scheduled effectively (e.g. too much time allocated for an operation)

p Other

The 345 incidents yielded 558 structural causes and are presented in the bar charts of figure 5.1 on the next page and figure 5.2 on the facing page. Among the 345 incidents, there are 3 Arbo incidents, yielding 4 structural causes. These 4 causes are included in the total of 558 causes found.

The 364 complaint cards about NedSter Over a period of 34 weeks, 364 complaint cards about NedSter were reported to the IRMS. In those cases in which instruments were missing in the net, in 3 out of 4 cases there was no indication on the packing that an instrument was missing (this constitutes a complaint); in the remaining cases the packing did indicate that an instrument was missing: this was no complaint, this was as it should
5.4 Results of the IRMS 155

Figure 5.1. Number of structural causes per main cluster (n = 558) as a result of the analysis of the first 345 incidents reported to the IRMS. The meaning of the clusters is given in table 5.4 (see pages 152–154).

Figure 5.2. Number of structural causes per subcluster (n = 558) as a result of the analysis of the first 345 incidents reported to the IRMS. The meaning of the subclusters is given in table 5.4 (see pages 152–154).
Table 5.5. Overview of the complaints about NedSter reported on the complaint cards, being part of the analysis of the first 345 incidents reported to the IRMS. For a comparison between the number of complaints about NedSter after the first analysis—after 345 incidents—and the second analysis—after 523 incidents—see figure 5.3 on the next page.

<table>
<thead>
<tr>
<th>Complaint reported on complaint card</th>
<th>Complaint coded in subcluster category</th>
<th>Number of complaint cards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dirty set or instrument</td>
<td>a1</td>
<td>46</td>
</tr>
<tr>
<td>Wet set or instrument</td>
<td>a2</td>
<td>12</td>
</tr>
<tr>
<td>Wrong protocol for packing set or instruments</td>
<td>a3</td>
<td>88</td>
</tr>
<tr>
<td>Absence of instruments in the net: not indicated on packing*</td>
<td>a4</td>
<td>148</td>
</tr>
<tr>
<td>Absence of instruments in the net: indicated on packing (No error)</td>
<td></td>
<td>(45)</td>
</tr>
<tr>
<td>Wrong name/wrong contents of set or wrong instrument</td>
<td>a5</td>
<td>70</td>
</tr>
</tbody>
</table>

be. Cf. the number of nets where the absence of instruments was not indicated though it should have been (148) with the number of nets where the absence of instruments was correctly indicated (45) in table 5.5.

For an overview of the results in a bar chart and a comparison with the complaint cards after the analysis of 523 incidents, see the frequency distribution in figure 5.3 on the facing page.

The reporters and their reporting behaviour  In total, 345 incidents were reported in 59 weeks which is an average of 6 incidents a week, see figure 5.4 on page 158.

The 345 incidents were reported by 26 doctors and 81 employees (so a total of 107 reporters, see figures 5.5 on page 158 and 5.7 on page 159) and this is more than 50% of the complete group of employees and doctors in the OR. The distributions of the doctors and employees who reported broken down into disciplines, are presented in figure 5.6 on page 159 and 5.8 on page 159 respectively. A number of incidents was reported by several persons. The doctors who reported produced 82 incident reports in all (mean = 3.2, S.D. = 3.5; see table J.1 on page 352) and the employees who reported produced 338 incident reports in all (mean = 4.2, S.D. = 6.0; see table J.1 on page 352).
Figure 5.3. The number of NedSter complaint cards per subcluster after the first analysis—after 345 incidents—and second analysis—after 523 incidents (n of complaint cards (first analysis) = 364, n of complaint cards (second analysis) = 334, t(period first analysis) = 34 weeks, t(period second analysis) = 34 weeks). The meanings of the subclusters can be found in table 5.5 on the preceding page and table 5.7 on page 165. The numbers per complaint card of the first analysis are given in table 5.5 on the preceding page, and of the second analysis are given in table 5.7 on page 165. The information about the correct indication on the packing in those cases in which instruments were missing in the net, which was also collected by means of the complaint cards (though it is not an error or complaint, see also table 5.5 on the preceding page and table 5.7 on page 165) was left out from the comparison.
Figure 5.4. Number of incident reports to the IRMS per week, belonging to the analysis of the first 345 incidents. The total number of incidents reported is 345, however, of 1 incident it is not known when it was reported (n = 344, t = 59 weeks, mean = 5.8, S.D. = 3.4).

Figure 5.5. Percentage of doctors who reported and who did not report incidents to the IRMS (n = 70: n of reporters = 26, n of non-reporters = 44).
5.4 Results of the IRMS

Figure 5.6. Doctors who reported incidents to the IRMS per discipline (n = 26).

Employees who reported: 58%

Employees who did not report: 42%

Figure 5.7. Percentage of employees who reported and who did not report incidents to the IRMS (n = 140: n of reporters = 81, n of non-reporters = 59).

Operating assistant: 64%

Anaesthesia assistant: 31%

Recovery nurse: 5%

Figure 5.8. Employees who reported incidents to the IRMS per discipline (n = 81). The contribution of the functions ‘preparation nurse’ and ‘secretary preparation’ to the whole is unknown.
Results after 523 reported incidents  This analysis was made by the IRMS committee with assistance from the department of Patient Affairs [144]. The sources for the analyses were the 178 incidents and the 334 complaint cards which were reported to the IRMS.

The 178 incidents reported  The structural causes that were found after analysing 178 incidents (incident numbers 326–504) are subdivided into 16 clusters and 64 sub-clusters, see table 5.6 (see pages 160–163).

Table 5.6. Overview of the different structural causes after the analysis of the last 178 incidents reported to the IRMS. In square brackets are the causes/clusters which were not found during the analysis, but are described here, all the same, because the purpose of this table is also to elucidate the meaning of (sub)clusters.

Structural causes

\underline{a} Incidents concerning NedSter

a1 Dirty sets or instruments
[a2 Wet sets]
a3 Sets not packed in accordance with protocol
a4 Failure to indicate absence of instruments on packing
a5 Wrong contents of set or wrong instrument
[a6 Weighing nets (deviation > tolerance)]
a7 Regulations about (emergency) sterilisation are not always complied with
a8 Instruments not checked properly

\underline{b} Blood-testing and -ordering procedure does not work (no blood, no cross-matched sample)

c Incidents concerning patients arriving from the ward

c1 Patient not prepared properly (e.g. set false teeth not removed)
c2 Incomplete patient file
c3 Pre-operative examination results and consultations missing
c4 Mixing up patient data (e.g. similar names, dates of birth)
c5 Laboratory results missing
c6 Pre-operative anaesthesia screening not performed properly
c7 Failure to deal adequately with available information
c8 Other

d Incidents concerning patients arriving from the preparation room
d1 Patient not prepared properly (e.g. false teeth not removed)

continued on next page
5.4 Results of the IRMS

continued from previous page

Structural causes

[d2 Incomplete patient file]
[d3 ECGs missing]
[d4 X-rays missing]
[d5 Mixing up patient data (e.g. similar names, dates of birth)]
[d6 Laboratory results missing]
[d7 Failure to deal adequately with available information

e Doctor absent from the operating room

[e1 Surgeon arriving too late]
[e2 Anaesthetist arriving too late]
[e3 Double booking of surgeon

f Incident concerning materials/equipment

[f1 Material has been double booked while only one or two devices are available in the OR
[f2 In contravention of the OR schedule, material is being used by a third party]
[f3 Material is not in stock]
[f4 Material is in stock in unsterile state]
[f5 Incomplete set is sent to NedSter, but, on being returned to the sterile corridor, the set is not completed]
[f6 Inadequate periodic check on sterility expiration date in the sterile corridor]
[f7 Check on materials before operation is inadequate in the sterile corridor]
[f8 During an operation, it turns out that there is something wrong with material

g Patient is deliberately treated with materials/equipment which are/is inappropriate or non-standard for the operation concerned

[g1 Surgeon deliberately violates sterility]
[g2 Inappropriate or non-standard material is used (e.g. wrong size)]
[g3 Material treated with disinfectants (Cidex)]
[g4 Patient’s allergy is ignored]

h Insufficient check on patient during operation route

i Staff did not prepare the operating room properly before the operation

[i1 Previous shift has not prepared the operating room properly]
[i2 Current shift has not prepared the operating room properly]

continued on next page
Structural causes

j Poor communication
j1 Before start of operation, surgeon changes operation as a result of which the operating room and/or the patient are/is not properly prepared
[j2 Equivocal use of the terms ‘urgent’ and ‘acute’ in the OR]
j3 Kind of operation is not clear on the white board as a result of which the operating room and/or the patient are/is not properly prepared
j4 Surgeon does not pass on message that he is engaged elsewhere
j5 Incidents arising from schedule alterations
j6 Unclear who surgeon is
j7 Responsibilities unclear
j8 Argument during the operation route
j9 Doctor unavailable

k Incidents concerning anaesthesia
k1 Anaesthetist has induced patient in the absence of surgeon
k2 Anaesthetist induces patient though the required data are not available
[k3 Before start of operation, surgeon changes anaesthetic although patient has not been prepared for this]
k4 Incidents relating to the ‘two bed policy’ of anaesthetists

l Incidents concerning the outpatients’ clinic: patients are given incompletemincorrect information by the outpatients’ clinic

n Incidents concerning on-call shift procedure
n1 Patient not announced in accordance with protocol
n2 Staff not called up in accordance with procedure

q Treatment by people lacking the required expertise or skills
q1 Anaesthesia assistant lacks the necessary expertise or skills
q2 Surgeon in training lacks the necessary expertise or skills
q3 Surgeon lacks the necessary expertise or skills
[q4 Anaesthetist lacks the necessary expertise or skills]
q5 Personnel of the preparation room lacks the necessary expertise or skills
q6 Other personnel lacks the necessary expertise or skills

continued on next page
5.4 Results of the IRMS

![Bar chart showing number of structural causes per main cluster (n = 284) as a result of the analysis of the last 178 incidents reported to the IRMS. The meaning of the clusters is given in table 5.6 (see pages 160–163).](image)

Figure 5.9. Number of structural causes per main cluster (n = 284) as a result of the analysis of the last 178 incidents reported to the IRMS. The meaning of the clusters is given in table 5.6 (see pages 160–163).

*continued from previous page*

<table>
<thead>
<tr>
<th>Structural causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>s Incidents concerning protocols/regulations</td>
</tr>
<tr>
<td>s1 Protocols/regulations are lacking</td>
</tr>
<tr>
<td>s2 Protocols/regulations are inadequate</td>
</tr>
<tr>
<td>s3 Protocols/regulations are not complied with</td>
</tr>
<tr>
<td>x Other</td>
</tr>
</tbody>
</table>

The 178 incidents comprise 284 structural causes and are presented in the bar charts of figure 5.9 and of figure 5.10 on the next page. Among the 178 incidents, there are 4 Arbo incidents, yielding 5 structural causes. These 5 causes are included in the total of 284 causes found. The distribution in figure 5.9 was compared with the distribution in figure 5.1 on page 155 after some data processing because the clusters—and subclusters—for both distributions are different; cf. table 5.6 (see pages 160–163) with table 5.4 (see pages 152–154). See section 5.5 for the comparison.

*The 334 complaint cards about NedSter*  As with the earlier analysis, over a period of 34 weeks, the complaint cards relating to the NedSter deliveries were recorded by the IRMS. A complaint card was filled in if it was detected that something was wrong
Figure 5.10. Number of structural causes per subcluster (n = 284) as a result of the analysis of the last 178 incidents reported to the IRMS. The meaning of the subclusters is given in table 5.6 (see pages 160–163).
Table 5.7. Overview of the complaints about NedSter which were reported on the complaint cards, as part of the analysis of the IRMS reports 326–504. A comparison between the number of complaints about NedSter after the first analysis—after 345 incidents—and second analysis—after 523 incidents—is found in figure 5.3 on page 157.

<table>
<thead>
<tr>
<th>Complaint reported on complaint card</th>
<th>Complaint coded in subcluster category</th>
<th>Number of complaint cards</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dirty set or instrument</td>
<td>a1</td>
<td>23</td>
</tr>
<tr>
<td>• Wet set or instrument</td>
<td>a2</td>
<td>2</td>
</tr>
<tr>
<td>• Wrong protocol for packing set</td>
<td>a3</td>
<td>4</td>
</tr>
<tr>
<td>or instruments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Absence of instruments in the net:</td>
<td>a4</td>
<td>208</td>
</tr>
<tr>
<td>not indicated on packing</td>
<td>(No error)</td>
<td>(3)</td>
</tr>
<tr>
<td>• Absence of instruments in the net:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>indicated on packing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Wrong name/wrong/defective contents of set or wrong/defective instrument</td>
<td>a5</td>
<td>97</td>
</tr>
</tbody>
</table>

with an instrument set. For an overview of the complaints reported, see table 5.7. See figure 5.3 on page 157 for a comparison between the number of complaint cards per complaint category for both the first—after 345 reported incidents—and the second analysis—after 523 incidents. Both a chi-square test and Fisher exact probability test were performed to test whether the distributions of cluster categories of the complaint cards were different. According to both the chi-square and the Fisher exact probability test, the distributions were convincingly different (p < 0.0001 in the case of chi-square and p = 9.897 × 10⁻²⁶ in the case of the Fisher exact probability test). The chi-square cell values show that it was mostly categories a3 and a4 that contributed to this difference.

5.5 Analysis conclusions and recommendations

In this section, a further analysis, with conclusions and recommendations, is made of the results of the IRMS. The conclusions drawn and the recommendations made are based on the analysis of the first 345 incidents and the last 178 incidents.¹⁰

¹⁰In contrast to the discussion of the results of the IRMS in section 5.4, the conclusions and recommendations concerning the analysis moment after 62 incidents (see section 5.4 and [140]) are not described separately. The analysis of the first 345 incidents includes these first 62 incidents, and the conclusions and recommendations presented are thus also based on these incidents (see also table 5.2 on page 150). The moment of analysis
In order to gain an insight into which of the clusters deserves extra attention, bar charts at cluster level (figure 5.1 on page 155 and figure 5.9 on page 163) and at sub-cluster level (figure 5.2 on page 155, figure 5.3 on page 157 and figure 5.10 on page 164) were compiled. In this section, an overview is given of the most important clusters and subclusters with their related main causes, and an initial attempt at possible solutions is made. All eventual solutions should result in improvement measures which will have to be evaluated after implementation. This evaluation may result from reports to the IRMS (e.g. from analyses of whether some (sub)clusters have disappeared after action has been taken) but information about the effect of the measures can also be gauged from periodical measurements in the OR. The comparability of the distributions of figures 5.1 on page 155 and 5.9 on page 163, and figures 5.2 on page 155 and 5.10 on page 164 were tested with chi-square tests. To make this possible, the clusters and subclusters which did not have the same contents or definitions in both distributions, were combined into one category 'Others', see table 5.8 on the facing page. The chosen test approach, the chi-square test at subcluster level—i.e. figure 5.2 on page 155 versus figure 5.10 on page 164—was not possible (52% of the cells had expected counts less than five) and the Fisher exact probability test was not possible—i.e. the computational complexity was too large for the present computer and software (SAS version 6.12). The chi-square test at cluster level—i.e. figure 5.1 on page 155 versus figure 5.9 on page 163—showed that the distributions were significantly different (p < 0.0001). The cell chi-square values show that the clusters g (Patient is deliberately treated with materials/equipment which are/is) inappropriate or non-standard for the operation concerned), i (Staff did not prepare the operating room properly before the operation) and Others had a cell chi-square value larger than 6¼ [129] and are therefore mainly responsible for the significance of the difference between the two distributions. The statistical analysis shows that the two frequency distributions for the first 345 incidents and the last 178 incidents are different. This could be explained by a reporting bias or by the fact that things have changed, especially for the clusters g, i and Others.

The values of the chi-square and Fisher exact probability test for the complaint card distributions (see figure 5.3 on page 157) also show that the distributions were different. This could also be because things had changed or because of reporting bias. If things had changed, they were both improvements and changes for the worse. There were fewer complaints about using the wrong protocol for packing set or instruments (subcluster a3 which went from 88 complaint cards to 4 complaint cards, see figure 5.3 on page 157),

after the first 62 incidents was important because the IRMS was altered after that moment, see section 5.2.

11 In order to distinguish this category from the previous categories 'Other', a new category 'Others' (notice the 's') was created.
Table 5.8. Data processing performed for the comparison of the IRMS results of the first 345 incidents and of the last 178 incidents. See figures 5.1 (p. 155), 5.2 (p. 155), 5.9 (p. 163) and 5.10 (p. 164), and tables 5.4 (pp. 152–154) and 5.6 (pp. 160–163)).

<table>
<thead>
<tr>
<th>(Sub)clusters which are</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The same</td>
<td>a, b, e, f, g, h, i, j, k, c1, c2, c5 (figure 5.2) = c4 (figure 5.10), c6 (figure 5.2) = c5 (figure 5.10), d1–d6</td>
</tr>
<tr>
<td>Different</td>
<td>Figure 5.1/5.2: c3, c4, c7, m, p; figure 5.9/5.10: c3, c6, c7, c8, d7, l, n, q, s, x</td>
</tr>
</tbody>
</table>

but there were more complaints about the absence of instruments in the net which was not indicated on the packing (subcluster a4 which increased from 148 complaint cards to 208 complaint cards, see figure 5.3 on page 157). In the following sections each problem category will be discussed separately and conclusions will be drawn about action to be taken.

**Cluster a. Incidents with regard to instrument sets delivered by NedSter** The analysis of the first 345 incidents and of the complaint cards about NedSter which the IRMS committee had collected, proves that NedSter is a structural cause: NedSter is not able in all cases to meet the quality desired by the OR. Because of this, it is not certain that the set delivered can be used during the operation.

Related main causes:

- Before the start of the operation it turns out that the set has been packed in a wet or dirty state, or has not been packed in accordance with the protocol.
- Before the start of the operation it turns out that the set is incomplete and this is not indicated on the outside of the packing.
- Before the start of the operation it turns out that a wrong instrument is in the set.
- Regulations about (emergency) sterilisation are not met.

After an analysis of the first 345 incidents and the first set of complaint cards, it was recommended that it was advisable to consult with NedSter about which targets for improvements should be set. These targets should be realistic with a view to finally attaining a quality that is acceptable for the OR. Moreover, the OR should continue to collect the complaint cards about NedSter for the purpose of permanent quality control.

The second set of complaint cards and the last 178 incident reports show that there is an indication that the number of sets delivered with dirty instruments (a1) is lower than in the first analysis.
There is also an indication that wet instrument sets (a2) hardly occurs any more. The wrong packing of instrument sets (a3) hardly occurs any more. So, it looks as if the measures that were taken may have been effective.

According to the complaint cards, the number of cases in which there was an absence of instruments in the net which was not indicated on the packing (a4), increased alarmingly (increase of 51%). Two measures can be taken:

- NedSter can see to it that the absence of instruments is always indicated on the (packing of the) set.

- NedSter needs to possess an adequate number of instruments to make the sets complete. In the case of a shortage, NedSter should make a request to the OR for more instruments.

After the analysis of the last 178 incident reports, there is an indication that the wrong composition of sets (a5) still has not improved. It frequently occurs that the wrong instruments have been included in a net or that instruments have been incorrectly assembled. The sets are also often wrongly labelled. The question arises whether the staff of NedSter has sufficient expertise about the designation of the instrumentarium and in handling instrumentarium. If this expertise does indeed turn out to be inadequate, NedSter staff need to be given the appropriate training.

**Cluster b. Incidents concerning the availability of blood** With regard to the blood-testing and -ordering procedure, 24 incidents were reported during the first 14 months of the IRMS’s existence. The blood-testing and -ordering procedure turns out to be not always very adequate. Because of this, it is not certain that the blood ordered is available before the operation.

Related main causes:

- It happens that no cross-matched sample is available at the lab so that blood cannot immediately be made available to the OR.

- If the patient is not present when blood samples are taken, then obviously no cross-matched blood sample is taken. If this failure to take cross-matched samples is not recorded, this fact will not be known, with (potentially) far-reaching consequences.

- The first operation starts at 8:15 a.m. and the blood is not delivered until 8:30 a.m.

The blood-testing and -ordering procedure needs to be changed. In order to bring about this change, a committee will have to be set up, composed of all persons involved in
testing and ordering blood. This committee should map out the whole blood-ordering procedure, and draw up a procedure for testing and ordering blood which should apply to all departments.

After the analysis of the last 178 incident reports, it appears that the availability of blood before an operation still left a lot to be desired (this was found 21 times). In spite of a careful start in making improvements, the initiatives taken so far have not resulted in a noticeable decrease in the number of reports. It is clear that the blood-ordering procedure is still unsatisfactory. What becomes clear from this analysis is that often things go wrong if patients are moved forward in the operation schedule. Another observation is that it sometimes takes the lab an extremely long time to deliver the blood products ordered. In drawing up a new blood-ordering procedure, care should be taken to ensure that blood is available for patients who are moved forward in the operation schedule, and for emergency cases.

**Cluster c. Incidents with regard to the transfer of patients arriving from the ward** After the analysis of the first 345 incidents, 82 structural incident causes were registered involving patients who had not been transferred properly by the department. Preparation of the patients in the departments is often incomplete, and results in a delay for the patient, in additional risks for the patient, and sometimes in dropping the patient from the operation schedule.

Related main causes:

- Patient has not been shaved, still has false teeth in, has been given wrong medication etc.

- Patient is carrying an incomplete patient file.

- Patient is carrying no ECG or X-ray.

- Patient is carrying another patient’s data.

- Patient has not had a proper pre-operative screening.

After the analysis of the first 345 incidents, it was recommended that a committee should draw up a checklist which departments can use to check whether the patient has been prepared properly, whether the right data are in the file, and whether all preconditions have been met (e.g. cross-matched blood sample and ECG).

The analysis of the last 178 incidents showed that in 22 cases patients still arrived in the OR having been prepared poorly. On arrival in the preparation room, it turned out
that patients often still wear dentures, have not been shaved, are still wearing jewellery, etc.

In 14 cases, the patient had been inadequately pre-operatively examined, and in 7 cases the pre-operative examination results did not accompany the patient.

In 15 cases a mix-up of patients’ data occurred.

In 10 cases, the available information was not dealt with properly. E.g., the OR schedule which is provided to the nursing wards, was not given proper attention. Also as a result of this, patients were not prepared properly. (E.g. patient had to be given spinal anaesthetic instead of local anaesthetic.)

In the case of an absence of clear rules or regulations, the nursing ward may fail to take action or to comply with regulations such as administering antibiotics.

During the nine months covered by the analysis of the last 178 incidents, an experiment was started with a checklist for a number of nursing wards, so the wards can check whether everything is present and all right before transferring the patient to the OR. The outcome of this experiment was not yet completely clear because it still did not result in a decrease in the number of reports (no statistical analysis used). In the preparation room, it seems sensible to record how effective the checklist is. This can be done simply by recording from which nursing wards the poorly prepared patients arrive. Action should be taken to encourage the wards to deal more effectively with the available information, and to be more active if the nursing wards detect cases of incompleteness. The fact that patients (still) are not being transferred to the OR in accordance with protocol, should be brought to the attention of the nursing wards.

*Cluster d. Incidents regarding patients arriving from the preparation room*  The analysis of the first 345 incidents revealed 15 structural causes which showed that the preparation team did not check the patient properly. This resulted in delay and additional risks for the patient, and sometimes the patient could not be operated on any more that same day.

Related main causes:

- Patient has not been shaved, still has false teeth in, has been given the wrong medication etc.

- Patient is carrying no ECG.

- Patient is carrying another patient’s data.

It was recommended after the analysis of the first 345 incidents that the patient should be more extensively checked in the preparation room to find out whether the preparation has been carried out correctly, whether the correct data are in the patient file and
whether all preconditions have been met (e.g. cross-matched blood sample and ECG). This extensive check should continue to be made until all departments have a specific checklist to ensure that all patients are transferred without a hitch in the OR. In addition to this extensive check, clear criteria should be established about which conditions a patient should meet if he is to be operated on in spite of inadequate preparation for the operation by the department.

The analysis of the last 178 incidents showed that patients were still being transferred to the operating room with a number of anomalies with regard to their preparation. Some of these should have been picked up by standard checks, others could have been prevented by incorporating it as part of the check in the preparation room, for instance by checking the name tag of the patient, shaving the part of the body which is to be operated on, and suchlike.

A few of the last 178 incident reports showed that there were some unfamiliar situations in which staff in the preparation room did not know what to do and consequently took no, or inadequate, action. It is important to train staff in coping with such situations.

**Cluster f. Incidents concerning materials/equipment** The analysis of the first 345 incidents showed that it was not always certain whether the necessary materials/equipment were/was available during the operation.

Related main causes:

- Materials/equipment are/is not in stock.
- Materials/equipment are/is in stock in unsterile state.
- Materials/equipment which have/has been returned in incomplete state by NedSter are/is not completed.
- It does not become clear until after the start of the operation whether materials/equipment are/is in stock.
- Periodic check on sterility expiration date is not done adequately.

After the analysis of the first 345 incidents, it was recommended that a (computer) system for materials/equipment in the OR should be designed, a system in which the non-sterile stock, the use of materials/equipment during operations, and the stock in the sterile corridor should be filed. It would also be possible to give NedSter the responsibility for re-ordering materials/equipment. NedSter is engaged in providing all individual nets with a
unique bar code. Theoretically, it would be simple to create a system with which to moni-
tor the location and the expiry date automatically. In the near future, problems relating
to the periodical checking of nets for expiry dates could be solved in this way.

After the analysis of the last 178 incidents, it was recommended that the risk of mate-
rials being out of stock (subcluster f3, 6 times) could be prevented in the future partly by
pointing out to everyone the existing protocols which have to be complied with after the
use of materials, and partly by the possible adaptation of these protocols if it becomes
clear they are not working in practice: materials not being available is also caused by the
carts not being filled up, etc. It would be wise to find out whether this may be caused by
negligence or work pressure.

Incident reports the cause of which turned out to be a defect were made 8 times.
They concerned defects both of apparatus and of instrumentarium. The reports about
operating room tables are probably attributable to wear, and the solution could be to
replace the operating room tables by new ones. The other reports do not point to a
specific problem.

In the case of the reports caused by defective instrumentarium, it appears that, in a
number of cases, the cause can be traced back to the CSD where instruments have been
wrongly assembled. A check should be made to find out whether staff at the CSD who
assemble the instruments in question have the necessary expertise and skills. If neces-
sary, extra training should be provided. It might also be considered whether it might be
possible to test the proper functioning of the instrumentarium before it is packed.

Several clusters combined From the analysis of several clusters on the basis of the first
345 incidents, the following conclusions were drawn and recommendations were made:

- In many incidents, a working culture\textsuperscript{12} in the OR surfaces in which the interests
  of the employees and doctors prevail over those of the patients. In addition, the
  atmosphere in the OR is sometimes strained. This also becomes evident from the
  terms in which some of the reporters expressed themselves on the reporting form.

Related main causes:

- Surgeon or anaesthetist arrives too late.
- Surgeon deliberately violates sterility.
- Argument during the operation between different disciplines.
- Surgeon answers the bleeper during the operation.

\textsuperscript{12}What is meant by ‘culture’ is the whole of the mentality, attitudes, and way of working of doctors and
employees, and the organisational set-up of the OR.
5.5 Analysis conclusions and recommendations

- An operation is performed with alternative materials because the right material is not in stock.
- Anaesthetist induces the patient in the absence of surgeon.
- Surgeon does not pass on the message that he is engaged elsewhere.
- Checks before and during the operation are not carried out.
- Anaesthetist induces patient though the required data are not available.

Culture changes are always a management matter in which the top management must be involved in order to decide which measures should be taken. In addition, the question of whether doctors and employees in the OR can be called to account directly about their behaviour and attitudes should be considered. In consultations with and between all parties in the OR, strenuous efforts should be made to foster a deeper understanding of each other’s position.

• There is no clear responsibility for a number of management aspects.

Related main causes:

- The preparation of the operating room after a shift.
- The replacement of defective sets or other materials.
- Changes in schedule are not correctly passed on to the relevant persons.

The existing protocols should be scrutinised critically and, if necessary, adapted, for instance by a committee.

• Other matters that became evident after the analysis of the first 345 incidents:

- During an operation, it turned out that material was defective. This occurred 26 times.
- Materials that were cleaned with disinfectants. This occurred 11 times.
- Before the start of the operation, surgeon decided to change the operation as a result of which the operating room and/or the patient were/was not properly prepared. This occurred 9 times.
- During the programme, it turned out that the schedule was too tight or too lax. This occurred 9 times.
- The kind of operation was not indicated correctly on the white board as a result of which the operating room and/or the patient were/was not prepared properly. This occurred 7 times.
Cluster g. Incidents because patients were not treated with the right material  During the nine months covering the analysis of the last 178 incidents, it happened 6 times (as against 53 times during the fourteen months covering the analysis of the first 345 incidents) that a patient was deliberately treated with materials/equipment which were/was inappropriate or non-standard for the operation concerned. The 4 times mentioned under g2—inappropriate or non-standard material used (e.g. wrong size)—were caused by instruments not being present when needed. The causes cannot be attributed to one specific issue, which makes it difficult to provide a solution. It should be pointed out to everyone involved in the treatment of instruments how important proper and prompt treatment of the instruments is. The analysis of the last 178 incidents show an improvement with regard to cluster g, i.e. significantly fewer cases in which patients were not treated with the right material.

Cluster i. Employees did not prepare the operating room properly before the operation  The analysis of the last 178 incidents shows an improvement. There were significantly fewer cases in which employees did not prepare the operating room properly before an operation.

Cluster j. Incidents as a result of poor communication  The analysis of the last 178 incidents shows that scheduling information which is incorrect or incomplete still continues to be passed on. The consequence of this is a loss of time and materials.

The management team of the OR have to convince doctors that it is in their own interest that the information passed on is as complete and correct as possible. Incomplete scheduling information should not be accepted.

Alterations in the operation schedules by surgeons or OR management are not always passed on to all staff involved. It is not clear who is responsible for passing on the changes and which procedure should be followed. A possible solution would be to appoint a person to whom all changes would have to be reported and who is responsible for informing all participants.

A serious point of concern is the fact that patients regularly witness disagreements and arguments in the operating room. This is not conducive to the patient’s peace of mind and is detrimental to the trust he has put in persons under whose care he is. It goes without saying that this sort of scene should be prevented at all costs.

Cluster k. Incidents concerning anaesthesia  The analysis of the last 178 incidents show that patients are still being induced while the surgeon is not present in the OR rooms. Because of this, the patient is anaesthetised for an unnecessarily long time. A protocol to
prevent this should be drawn up. If this protocol is already in place, it should be brought to the attention of the persons concerned and it should be complied with.

It turns out that anaesthetists still induce patients without all research results being known or, for instance, without blood products being in stock. It is possible that this is done to avoid losing time but it ought to be considered whether this is not a risk for the patient which, if possible, should be prevented.

Nevertheless, two incidents were reported which were caused by the 'two bed system' in combination with the handing over of operations to another anaesthetist. Because of this, it may occur that at certain times one anaesthetist is responsible for two operations simultaneously, and therefore is not always instantly available. This may have a negative effect on the quality of care and on the running of the operating schedule, and consideration should be given to ways of preventing this.

Cluster 1. Incidents concerning patient information This cluster relates only to the analysis of the last 178 incidents. The outpatients' clinics regularly provide wrong and incomplete information. The consequence is that patients report too late or have not been prepared properly for an operation which sometimes leads to the cancellation of the operation. It would be advisable to check whether the outpatients' clinics' information about patients is still up-to-date, and to think of ways of continuing the provision of up-to-date information to the outpatients' clinics.

Cluster 2. Incidents caused by actions of people lacking the required expertise or skills This cluster relates only to the analysis of the last 178 incidents. After studying these incidents, it appears that they all could have been prevented: the persons involved should have asked themselves whether they were allowed or able to perform the action concerned and what the possible consequences of their acts could have been. Therefore, it is important that these persons become aware of the limitations of their own expertise or skills. They should not hesitate, either, to refuse to cooperate if they are not competent to perform certain tasks and they should insist on additional training.

Cluster 3. Incidents concerning protocols This cluster relates only to the analysis of the last 178 incidents. It occurred on 33 occasions that doctors and staff of the OR did not comply with the existing protocols. A number of these can be blamed on ignorance and forgetfulness. It is of more serious concern that sometimes protocols are deliberately not complied with.

It is necessary to see to it that everyone is informed and is kept informed of the protocols. There also should be periodical checks whether the protocols are still up-
Table 5.9. Summary of the data—partly presented earlier—about doctors and employees who report and who do not report (total n of doctors = 70, total n of employees = 140, t = 14 months). A number of incident reports was submitted by several persons. See also appendix J.

<table>
<thead>
<tr>
<th></th>
<th>Doctors</th>
<th></th>
<th>Employees</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>26 (37%)</td>
<td>44 (63%)</td>
<td></td>
<td>81 (58%)</td>
</tr>
<tr>
<td>n of incident reports</td>
<td>82</td>
<td>-</td>
<td></td>
<td>338</td>
</tr>
<tr>
<td>Mean n of incident reports (S.D.)</td>
<td>3.2 (3.5)</td>
<td>-</td>
<td></td>
<td>4.2 (6.0)</td>
</tr>
</tbody>
</table>

to-date, and whether new protocols need to be drawn up; on 6 occasions an incident could have been prevented if a protocol had been in place. As far as flouting protocols is concerned, the OR management obviously ought to raise this issue with the persons concerned, and, if necessary, take action.

**Incidents from cluster x (Other)** This cluster relates only to the analysis of the last 178 incidents. It concerns 16 reports which did not fit into the other clusters. All but three of these reports are of a different nature; these three concern the loss of operating time because staff from other disciplines (e.g. the X-ray department) did not report on time in the operating room.

After 14 months, 107 employees and doctors had handed in reports. The number of incidents reported by one person varied widely. Compared with doctors, a higher proportion of employees handed in reports and employees reported more incidents per person than did doctors (see table 5.9). It may be conjectured that there was a substantial under-reporting of incidents because the number of incidents that was reported per person varied so widely (see also table J.1 on page 352), and 103 people (49%) made no reports at all.

After the analysis of the first 345 incidents, the conclusion was that the IRMS is a system that can be used for the purpose of detecting structural causes of incidents. Whether the kind of incidents which were found could be prevented in the future, depends on whether the management team is ready to act upon these findings. This applies not only to the situation within the OR department, but also to the board of directors and to other departments. For the purpose of establishing a general quality policy in the OR—a policy which a training hospital should have, for obvious reasons—a dialogue with the board of directors should be initiated. Ways of achieving better collaboration with other
Table 5.10. IRMS results and conclusions based on the number of incident reports and the incident analyses after the first 345 and the last 178 incident reports.

<table>
<thead>
<tr>
<th>Result</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRMS committee established no appreciable improvements except for a number of the NedSter complaints (no statistical analysis used)</td>
<td>Under-reporting deteriorates</td>
</tr>
<tr>
<td><strong>and</strong></td>
<td></td>
</tr>
<tr>
<td>Average n of incident reports/month decreased from 25 (first 345 incidents) to 20 (last 178 incidents)</td>
<td></td>
</tr>
<tr>
<td><strong>and</strong></td>
<td></td>
</tr>
<tr>
<td>Chi-square test shows that proportions of cluster distributions changed</td>
<td></td>
</tr>
<tr>
<td><strong>and</strong></td>
<td></td>
</tr>
<tr>
<td>Clusters g and i show an improvement, cluster ‘Others’ a deterioration (the cell chi-square values of these clusters were &gt; 6%)</td>
<td>IRMS apparently changed both reporting and professional behaviour of doctors and employees</td>
</tr>
</tbody>
</table>

The result of the sum total of these improvement measures should be a qualitatively improved OR, in which operating room time will be used more efficiently. This may be achieved by a reduction of the number of disruptions of an operating room schedule.

After the analysis of the last 178 incidents, the IRMS committee was not satisfied with what had been done to bring about improvements on the basis of the conclusions and recommendations of the first 345 incident reports. The IRMS committee did not perceive any appreciable improvements except for a number of the NedSter complaints (no statistical analysis used), so the hospital organisation apparently did not learn from the first 345 incidents. Two conclusions can be drawn on the basis of the number of incident reports and incident analyses after the first 345 incidents and the last 178 incidents, see table 5.10. A comparison of the number of reports showed a decline in the average number of incident reports per month from 25 during the first 345 incidents to 20 during the last 178 incidents. However, the reason for this decline was probably not the successful implementation of improvements but, more probably, the failure to introduce improvements had a negative effect on the willingness of reporters to report incidents. So, the conjectured problem of under-reporting (see page 176) seemed to deteriorate after the first 345 incidents. This under-reporting does not have to be a problem as far as draw-
ing conclusions about action to be taken is concerned, provided that the decline is equal across (sub)clusters. However, no data are available to test this, since changes between the two distributions could also be due to changes in the actual distribution of problems. What is clear is that the two distributions were significantly different (p < 0.0001). Clusters g (Patient is deliberately treated with materials(equipment) which are(inappropriate or non-standard for the operation concerned) and i (Staff did not prepare the operating room properly before the operation) showed an improvement, the newly formed cluster ‘Others’ (see footnote number 11 on page 166) showed a deterioration. It is therefore likely that the IRMS has changed both the reporting and professional behaviour of doctors and employees, although it is not possible from the data to indicate to what extent.

Because major improvements failed to materialise, the willingness to report of the reporters and the motivation of the IRMS committee members were bound to suffer. It is important for the management team of the OR to quickly produce tangible results, especially if the management team feels that the IRMS as a quality system should remain in place.
Risk management adjustments in the OR: trial by error?

6.1 Introduction

This chapter describes the subsequent developments (i.e. the successes and frustrations) with risk management in the OR. This chapter relates to the period which started after the analysis of the first 345 incidents and ended at the moment of the analysis of the last 178 incidents which were reported to the IRMS. In section 6.2, the initiative for the further development of the IRMS into a broader quality system was described. This resulted in a new protocol for the IRMS, which is described in section 6.3, and in the reporting of Arbo incidents (i.e. occupational health and safety incidents), which is described in section 6.4. The use of the new IRMS procedure is described in section 6.5. In section 6.5.1, the allocation of structural process failure to two critical points is described. In section 6.5.2, considerations about the desirability of or need for further research into the specific nature and dimension of problems are discussed. Section 6.5.3 describes experiences and frustrations with the design and implementation of process and system improvements. This chapter ends with section 6.6, a discussion, and section 6.7, which presents conclusions and recommendations.

6.2 Initiative towards the further development of the IRMS into a quality system

The researchers of this project conceived the plan to develop the IRMS into a broader quality system. Some of the reasons for this were:

- The hospital management insisted on the development and embedding of structural quality management activities within a number of function groups including the OR.

- After the analysis of 345 incidents, as mentioned in chapter 5, it turned out that nothing or little had been done with the results of the IRMS. From the point of view of quality management, this kind of important management information should on no account be ignored, and it is the responsibility of the management to take proper action.
6.3 New IRMS protocol

To initiate the evolution of the IRMS into a broader quality system, adaptations to the IRMS had to be made. The following two adaptations were suggested:

- The IRMS should focus on more than just patient incidents, but also on, for instance, Arbo incidents (i.e. occupational health and safety incidents) involving doctors and employees. Paying attention to certain aspects of the quality of the work, such as the safety of doctors and employees, may be expected to have a beneficial effect on the quality of service to the patient. Complications would also obviously qualify for being registered and analysed (see sections 3.3.2 and 3.4.8) but were (still) not included in the IRMS. Complications were included in the design of the CIRMS, see also section 3.4.8.

- The function of ‘improvement’ should be given a more prominent position in the IRMS protocol. This was done because hardly or no improvements had been realised although ‘proposing, initiating and securing improvements’ was part of the IRMS, see table 3.8 on page 78. In the more general quality system IRMS that is generated in this way, the IRMS committee is activated to, if necessary, conduct research into and to lend support to the design and implementation of process and system improvements. The new IRMS protocol is shown in figure 6.1 on the facing page. New concepts in the protocol, such as the term ‘critical point’, are discussed in section 6.5. Feedback is given at the beginning (sending an acknowledgement of receipt) and at the end of the protocol (giving feedback on analysis results and improvements). No other feedback points are included in the protocol but they may be included if this is going—or expected—to be a problem. For instance, after the ‘clustering of incidents to structural process and/or system failure’, these results could be given as feedback information to the doctors and employees.

After consultation with the management team of the OR and the IRMS committee, it was decided:

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1Because the learning process was not getting off the ground, this research clearly shows that, in order to learn from incidents, an organisation—as Koornneef [80] puts it—‘needs to organise the learning process and allocate learning functions’; see Koornneef’s recently published framework for organisational learning and his learning agent/agency. Koornneef defines an agency as follows: ‘an agency is a collection of people that makes decisions, delegates authority for action, and monitors membership, all on a continuing basis’. In this case, see also figure 6.1 on the next page, the IRMS committee fulfils the role of Koornneef’s learning agency.

2Critical points are used for the allocation of structural process failure in the process description of the OR. This is done in order to visualise the location of process failure and to support further focusing on what the problems are and where they are to be found.
6.3 New IRMS protocol

Figure 6.1. The new IRMS protocol.
A. To include Arbo incidents. By adapting the reporting form, these incidents can be reported by means of the same reporting form as the patient incidents. See section 6.4.

B. To alter the IRMS protocol. Although the IRMS was originally geared to generating, in consultation with the management, improvement proposals (see also table 3.8 on page 78), and to turn these proposals into improvement actions, all its efforts came to nothing (see also section 5.5).

In order to realise A and B, the IRMS committee should, in close consultation with the management team, be given additional duties and tasks.

In view of the above observations and considerations, the objectives for the expansion of the activities of the IRMS are:

a1. The inclusion of Arbo incidents with a view to the health and safety aspects of doctors and employees of the OR.

b1. The allocation of structural process failure to critical points.

b2. Further research, if necessary, into the precise nature and dimension of the problems.

b3. The design and implementation of process and system improvements with a view to removing structural failure factors from the system.

The items a1 and b1–b3 will be developed further in the next two sections. The inclusion of Arbo incidents in the IRMS is described in section 6.4. Section 6.5 describes the allocation of structural process failure to critical points, the possibility of further research into the problems, the design and implementation of improvements, and experiences and frustrations.

6.4 Expansion of the IRMS with occupational health and safety incidents

Occupational health and safety is called ‘Arbo’ in Dutch (‘ARBeidsOnstandigheden’) and this acronym is (also) used in this research. The reasons for including Arbo incidents were:

- The opportunity to register and analyse Arbo incidents within the IRMS.
- Initiate structural Arbo care\(^3\) in the function group.

\(^3\)There is structural Arbo care at hospital level, although the hospital employs only one Arbo coordinator for its 2,400 employees.
Some Arbo incidents were already being reported to the IRMS, see also section 5.4. Incidentally, it had already been possible in the original IRMS to report Arbo and management—i.e. the availability of staff and means—incidents to the IRMS, but this never got off the ground (see [140]).

Besides, as stated earlier, it may be assumed that a higher level of performance will also be achieved as a consequence of good Arbo care, since good Arbo care has a positive influence on the quality and hence (probably) also on the safety of services.

In order to process Arbo incidents, the IRMS did not have to change considerably. Only the incidents which could have undesirable effects on doctors and employees (the Arbo incidents) were added (for a definition see section 3.2). The reporting and analysis of Arbo incidents were simply fitted into the IRMS. In order to achieve this, there had to be:

- Consultations with the hospital’s Arbo coordinator⁴ and with the management team of the function group. The Arbo coordinator was added to the IRMS committee when Arbo incidents were at issue.

- Providing information to the sections in the function group. This was realised by organising information meetings for and providing written information to all employees, and by providing written information to all doctors.

- Adapting the reporting form. In the case of an Arbo incident, the focus is on the possible effects on doctors and employees.

The last item implies that ‘dangerous situation’ can also be reported, e.g. a socket that has come loose. According to the Health and Safety Act (in Dutch ‘Arbo-wet’ [163]), both incidents and dangerous situations should be reported. In the causation model (see figure 3.3 on page 54), a ‘dangerous situation’ falls under the category of ‘process deviation’ and is nearly always caused by a combination of technical, organisational and human failure, see also Van der Schaaf [154]. A distinction between accidents and near accidents is not made because this difference is irrelevant as both accidents and near accidents should be reported. ‘Welfare incidents'⁵,⁶ also fall under the definition of an Arbo incident and can therefore be reported. The IRMS as described in table 3.8 on page 78 remains unchanged and applies both to incidents and Arbo incidents.

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⁴To determine whether the Arbo coordinator agrees with the reporting of Arbo incidents to the IRMS committee. This was because e.g. pricking incidents are supposed to be reported to the Arbo coordinator.
⁶E.g. a public quarrel which took place.
In order to report, describe and register Arbo incidents, a number of actions and small adaptations to the IRMS were necessary. In consultation with the IRMS committee members, the manager of the function group OR and the Arbo coordinator, it was decided to adapt the reporting form so that it could be used to report Arbo incidents on. The adapted version of the reporting form can be found in appendix I.⁷

The reported Arbo incidents are placed at the Arbo service’s disposal,⁸ but the reporter can indicate on the reporting form that this can only happen on the proviso that the report is anonymized (see appendix I). In this way, the reporter can safely submit his report to the IRMS, in the knowledge that the IRMS will not pass on the report to the Arbo service until it has anonymized the report. This applies, for instance, to incidents involving welfare aspects like a public quarrel which took place. For incidents having to do with the safety aspect and the health aspect of Arbo care, it is often also in the interest of the reporter that these incidents are also made known to the Arbo coordinator. In the improvement path, after the analysis of the reported Arbo incidents, the Arbo coordinator can advise directly about possible process improvements in order to improve the quality of work. In this way, the Arbo coordinator gets a clearer insight into the state of affairs with regard to Arbo care in the OR, which enables him to carry out more effectively his coordinator’s task of directly advising the hospital management in his capacity of staff official.

The IRMS committee informs the doctors and employees of the OR of the option to report Arbo incidents. The Arbo coordinator is responsible for Arbo care and will, in the long term, also be responsible for this organisational aspect within the reporting system. ‘In the long term’, because given the under-reporting of Arbo incidents, like pricking incidents, it is, for the time being, satisfactory for the Arbo coordinator to be able to join the existing structure of the reporting system, since this enables him to get a clearer insight into Arbo risks and into effects for doctors and employees in the OR.⁹ An effective Arbo policy can only be created after establishing what and where the bottlenecks

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⁷The main change is the option on the form to indicate by ticking the box concerned that, in the case of an Arbo report, the report is allowed to be passed on to the Arbo coordinator, but only after the report has been anonymized. Moreover, an additional explanation is added that an Arbo incident is about the (possible) effects on the reporter himself and/or others, that the procedure which must be followed in case of a pricking incident is entered in the infection file, and that all reported incidents come within the area of responsibility of the IRMS.

⁸This is in contrast to patient incident reports, which were never made available to the FONA committee (see also section 5.2).

⁹The Arbo coordinator has very little insight into the structural Arbo risks in the OR. One of the sources of information available to the Arbo coordinator are Arbo incidents—like pricking incidents—but they are not always reported. So, any additional insights provided by the IRMS reports into the Arbo conditions and structural Arbo risks in the OR will be welcome.
are; this is done prospectively by job safety analysis, inspection and auditing, and retrospectively by incident analysis. This process of 'measuring leads to knowledge' can be achieved to an important extent by analysing Arbo incidents which have been reported to the IRMS. A proposal was put to the Arbo coordinator, pointing out that a number of the Arbo coordinator's duties could be delegated to the members of the IRMS committee, because staffing capacity had, in principle, been reserved for this purpose. This was entirely in conformity with the nature of the new IRMS, which is an initiative towards a much broader quality system.

To sum up, all preconditions for a successful introduction of reporting Arbo incidents were met:

- The IRMS members, the Arbo coordinator and the management team of the OR were enthusiastic. The IRMS committee even asked for information from the Arbo coordinator about Arbo care so that the committee could read up on Arbo care.

- The incident reporting form was adapted so that Arbo incidents could also be reported.

- The doctors and employees were informed in a letter by the Arbo coordinator. In addition, the employees were also informed by the Arbo coordinator during discussions about progress made.

At the moment this research ended, the IRMS was ready to process Arbo incidents reported. The results, i.e. the analysis of the incident numbers 505 and upwards, therefore fall outside the scope of this research. However, it was noticed by the Arbo coordinator that interest in Arbo matters increased from the moment the IRMS began to turn its attention to Arbo, so this increase in attention given to Arbo incidents has not been in vain.

6.5 Using the new IRMS protocol

This section describes the alterations made to the IRMS protocol which resulted in the new IRMS protocol. The allocation of structural process failure to critical points, is described in subsection 6.5.1. In subsection 6.5.2, the investigation of the precise nature and the dimension of problems will be described. This section ends with 6.5.3, in which

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10 The 504 incident reports of the first, second and third incident analysis taken together correspond to the analysis of 523 incidents because some incident reports consist of more than one incident, see table 5.2 on page 150.

11 There was not enough time to make another analysis, which was because of the researcher's temporary contract.
Figure 6.2. Reducing structural failure factors in the OR to two critical points, I and II. This is presented in the process model of the OR at the second highest aggregation level.

the design and implementation of process and system improvements are described, as well as the experiences and frustrations with risk management in the OR.

6.5.1 Allocation of structural process failure to critical points

After the analysis of the first 345 incidents which were reported to the IRMS, it turned out that a large part of the clusters of structural causes mentioned in table 5.4 (see pages 152–154) could be allocated to two points—which will be called critical points—in the process model of the OR, see figure 6.2, table 6.1 on the facing page and figure 3.8 on page 68. In other words, this means that a large part of the structural process failure in the OR is reduced to two critical points—i.e. places in the process description which structural failure has been reduced or allocated to—represented as I and II in the process model at the second highest aggregation level of the OR (see figure 6.2):

I. The patient's arrival in the OR. The preparation of patients arriving from other departments may have been inadequate.

II. The start of an operation in the operating room. Not all preconditions for starting an operation have been met, e.g. a patient may be anaesthetised before the surgeon is present in the OR.

In retrospect, the allocation of structural process failure to these two points is not surprising because these are two important hand-over points—one point concerns the transfer of the patient from another department (the arrival point of the patient in the OR) and the other point concerns the handing over of the patient to the operating room (the starting point of the actual operation).

With regard to both critical points, roughly the same preconditions for the operation of the processes within the boundaries set by the standards apply. These preconditions for I and II are:
Table 6.1. The two OR critical points and the accompanying clusters. For each critical point, the management can select one or more clusters for an improvement path and, if necessary, initiate follow-up research. The clusters mentioned, are the clusters found after the analysis of 345 incidents, see table 5.4 (see pages 152–154). All clusters mentioned refer—for the greater part—to the critical point concerned.

<table>
<thead>
<tr>
<th>Critical point and accompanying cluster(s)</th>
<th>Cluster selected by management?</th>
<th>Follow-up research necessary to determine the nature and dimension of the cluster?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical point I</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Incidents concerning (the preparation of) patients arriving from the ward</td>
<td>Yes</td>
<td>Yes. The nature is clear: department(s) do not transfer their patients in accordance with the standards. The details are unclear and must be investigated in order to establish more precisely which department(s) does/(do) not transfer patients properly, so a selection can be made of the departments to focus on</td>
</tr>
<tr>
<td><strong>Critical point II</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Incidents concerning NedSter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Blood-testing and -ordering procedure (no blood, no cross-matched sample)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>d. Incidents concerning patients arriving from the preparation room</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Doctor absent from the operating room</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Incident concerning materials/equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Staff did not prepare the operating room properly before the operation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>k. Incidents concerning anaesthesia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Patient and organisation must meet all conditions making it possible to operate the patient according to the standards. These conditions have been set out by the doctors in the OR and by the hospital organisation, and constitute the agreed minimum requirements for performing an operation correctly in accordance with the standards.

Or, in other words, to critical point I (see figure 6.2 on page 186) applies that the patient must be completely prepared by the department in accordance with the standards. The following preconditions, for instance, must be met: the presence of an anaesthesia list which must, if necessary, be filled in completely, the surgeon’s medical record of the patient, the patient’s medical record used by the fellow doctor in attendance or the findings by the doctor(s) in attendance, as well as, if necessary, authorisation, the ECG (if required according to the criteria), laboratory results, X-rays, punch card. Checking the patient for name, kind of operation, file, wristband, operating coat, patient’s fasting status, presence of dentures, glasses and contact lenses, jewellery etc. Adding or completing missing items, or as yet making up for a deficiency, e.g. putting on an operating hat, indicating on the anaesthesia list whether there are any crowns (and false teeth etc. as differentiation from prothesis) present.

To critical point II (see figure 6.2 on page 186) applies in concrete terms that all preconditions must have been met to make it possible to start the operation in accordance with the standards. The following preconditions, for instance, must be met: the presence and completeness of the correct nets, prostheses, consumables (e.g. ordered blood, tubes, anaesthetics, painkillers, gauzes) and equipment (e.g. masks), data (completeness: checking name, operation, any special circumstances like iodine allergy), the presence and completeness of the anaesthesia and operating cart, checking equipment (every morning: respirator, saturation meter, sphygmomanometer, ECG, capnograph, Ambu-bag etc.), the presence of doctors (surgeon(s), anaesthetist), employees (operating assistants, anaesthesia assistant, if necessary, perfusion technologist, X-ray technician etc.).

The OR management selected cluster c under critical point I and cluster b under critical point II for the improvement path, see table 6.1 on the preceding page.\textsuperscript{12} For both clusters, the question whether follow-up research was necessary presented itself, see the next section.

\textsuperscript{12}The OR management made its decisions autonomously, so the reasons for these decisions are not known. The management probably based its decisions also on the feasibility of a certain solution to a given problem.
6.5.2 Considerations about (possible) further research into the precise nature and dimension of problems

After analysing 345 incidents, it turned out that a large part of the clusters found was related to critical point II, see also section 5.4, figure 6.2 on page 186 and table 6.1 on page 187. In retrospect, this was not surprising because critical point II concerns the final transfer of the patient to the actual anaesthesia and operating processes. Follow-up research to narrow down the problem more precisely before starting with the actual problem solving is not always necessary because e.g.:

- The problem and/or solution are/is clear. See e.g. the blood-ordering procedure in table 6.1 on page 187. Keeping count of how often the blood ordered arrives too late and of the possible reasons for this will not do, because from the point view of the OR only a part of the blood-ordering procedure is ‘visible’. For the purpose of improving the blood-ordering procedure, the whole procedure chain should be reviewed.

- The problem is well-known. For instance, it is common knowledge among the doctors, employees and management of the OR that operations start too late because surgeons are too late, see also cluster e in table 6.1 on page 187 and e.g. table 5.4 (see pages 152–154).

A decision as to whether follow-up research is necessary or not is quite simple. If it is known what the problem is, no follow-up research is necessary and it is possible to act on the basis of what is already known. If not, follow-up research is necessary.

In the case of incidents with regard to the preparation of patients arriving from the department (see table 6.1 on page 187), follow-up research can (easily) be conducted by asking the preparation nurses to record which mistakes are made and how often they are made by which department. However, the management team of the OR did not select this option.  

6.5.3 Design and implementation of process and system improvements to remove structural failure

The design and implementation of process and system improvements for the purpose of removing structural failure factors from the system is a task which the management can transfer to the IRMS committee. For this it is imperative that the management knows

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13 For reasons not known to the researcher, see also footnote 12 on the facing page. However, the manager of the OR made a checklist and started a pilot project with two function groups, see also further down in section 6.5.3.
exactly what it wants and how it needs to set about achieving this, partly via delegation to
the IRMS committee. The IRMS had already been designed for this in principle. However,
as mentioned earlier, in practice nothing came of this because the IRMS committee
did not have the authority to carry out these tasks successfully. The plan was for the gen-
eration and implementation of improvements to be performed by the IRMS committee
members under the supervision of the management. In practice, this was done through
the manager of the OR as far as improvements in the preparation of the patient was con-
cerned. The improvements in the blood-ordering procedure were brought about by the
head of the anaesthesia section and an anaesthetist who were both members of the manage-
ment team of the function group OR. These two improvement paths are important
because:

- From the point of view of the OR, preparation incidents are not incidents but pro-
  cess deviations or errors which have been committed by the preceding department
  in the process and which are recognised and corrected by the OR \(^{14}\) by means of
  entry control. The causes lie outside the OR.

- From the point of view of the OR, \(^{15}\) incidents regarding the blood-ordering pro-
  cedure are real incidents. The causes lie partly inside and partly outside the OR.

- In this way, the following aims were achieved at one and the same time:
  - An improvement path for the prevention of process deviations for both criti-
    cal points I and II was followed.
  - In the case of the inadequate preparation of patients, process deviations were
    tracked down which lie primarily within the scope of quality management
    and less within the scope of risk management, \(^{16}\) see also figure 3.3 on page 54.
  - In the case of incidents regarding the unreliable blood-ordering procedure,
    incidents are tracked down which lie primarily within the scope of risk man-
    agement.

It was decided to let the improvement paths operate as autonomously as possible,
and to offer support only in case these processes stalled, and then only in consultation
with the manager of the OR. This resulted in the following situations and actions in the
OR:

\(^{14}\) Depending on the stance one adopts, the same reports may be interpreted as process deviations or inci-
dents, see the boxed text ‘Further considerations about critical point I: process deviations vs. incidents’ on the
next page.

\(^{15}\) (At least) with regard to that part of the procedure that the OR is responsible for.

\(^{16}\) In section 6.7 the conclusion is drawn that the distinction between risk management and quality manage-
ment is not important.
Further considerations about critical point I: process deviations vs. incidents

Another point of consideration is that, in the case of critical point I, the majority of the reports are about process deviations and not about incidents,\(^a\) i.e. from the OR point of view, insufficiently prepared patients are process deviations which can result in incidents further on in the OR chain. In principle, the OR organisation is equipped to recognise and deal with these process deviations by means of entry control. The preparation nurse and the secretariat just do their jobs if they succeed as yet in adequately preparing patients who arrived in the OR inadequately prepared. However, these process deviations are incidents from the point of view of the function group which transfers the patient. From the perspective of these function groups, safety mechanisms to correct these process deviations are missing or may not be up to the mark. Follow-up research may be necessary to find out, for instance, what these process deviations and/or transfer incidents are exactly,\(^b\) how often they occur and which function groups are involved. Without the additional information from the follow-up research, it may be impossible to take specific action to reduce the number of transfer incidents. In this way, the IRMS is not only occupied with incidents but also with process deviations which are obstacles to efficient management. This follow-up research may be conducted by the IRMS committee and the doctors and employees themselves, and they can use statistical tools and methods (see e.g. [17]). The initiative for this follow-up research as well as the responsibility for its supervision may be taken jointly by the management and the IRMS committee. The management decides on the basis of the structural failure factors found what the priorities are and in which cases follow-up research is necessary in order to be able to take more specific action. The management team can, for instance, delegate the job of conducting the follow-up research to the IRMS committee. It is imperative for this that the management knows exactly what it wants and how it needs to set about achieving this, partly via delegation to the IRMS committee.

\(^{a}\)See for concepts and accompanying framework, sections 3.3.1 and 3.3.2, figure 3.2 on page 50 and figure 3.3 on page 54.

\(^{b}\)E.g., something wrong with patient's medical record: what information is missing?
• In the case of the two improvement paths mentioned before, no use was made of the available staffing capacity of the IRMS committee.

• In the case of the improvement path aimed at a better preparation of the patient (so that the patient is transferred to the OR, with complete patient files and prepared in accordance with the regulations), the manager of the OR drew up a checklist and started a pilot project in two function groups. The two function groups responded differently to this checklist which was offered to them, and which was drawn up as a result of the process deviations indicated by the preparation nurses of the OR. One of the departments was enthusiastic and was willing to cooperate with the pilot project without being given any further explanation. The other department was extremely surprised to find themselves involved in incidents which the OR had collected about them; consequently, this department had the feeling that it was being watched and monitored, and needed additional explanation and reassurances. After being given a detailed explanation, this department also showed itself willing to cooperate with the pilot. It was decided to wait for the results of the pilot project and to allow this improvement process to go ahead autonomously and without interference, because it appeared to be going as planned.

• With regard to the improvement path of the blood-ordering procedure, the head of the anaesthesia section and an anaesthetist, both members of the management team of the OR, conferred with the manager of the blood laboratory. They agreed to build in a number of checks for the OR in order to enable it to monitor the process better. In the morning, the laboratory presents a list to the OR of patients for whom blood has been ordered, patients for whom a cross-matched sample has been determined, and patients for whom blood is being prepared. These checks took place at the laboratory and in the OR, but they did not structurally solve the problem of the unreliability of the blood-ordering procedure. Because there seemed to be a slumbering conflict between the anaesthesia section and the blood laboratory, and the improvement path was in danger of stalling at this point, it was decided (in consultation with the manager of the OR), partly for reasons of organisational politics, to start charting the blood-ordering procedure, and to leave the blood laboratory alone for the time being. Of the four parties involved in ordering blood (see figure 6.3 on page 194), it was therefore decided not to interview the blood laboratory until the manager of the OR had paid a visit to the laboratory. The other three parties, viz. the OR, the partnerships/outpatients’ clinics and the

17This is a matter of suboptimisation. It is well-known that errors outside the communication route OR-blood laboratory are responsible for the unreliability of the blood-ordering procedure.
nursing wards, were interviewed to chart the current procedure and the structural weaknesses in it. The charting of the blood-ordering procedure started by assessing the disciplines/partnerships/outpatients' clinics which order blood (regularly) before an operation. These are the secretariats of the following outpatients' clinics: orthopaedics, surgery, plastic surgery, heart surgery, gynaecology and urology. A number of interviews was held, on the basis of which the conclusion could be drawn that the blood-ordering procedure was particularly unreliable in the case of:

- Last-minute changes in the operating room scheduling.
- Operations which are scheduled to take place at short notice (shorter than or equal to one week).

In the case of some partnerships, the latter phenomenon occurs (very) frequently. The assessment was not finished because the staffing capacity required was not available in the OR, and the priority of this was not recognised sufficiently by either the management of the OR or by the hospital management. The hospital organisation lacks the staff and awareness to perform a full assessment with a view to improving the blood-ordering procedure. A reason for this can be found in the aftereffects of the reorganisation, as a result of which the organisation is both unable and unwilling to reserve manpower for this kind of projects. Because this is a case of procedure failure which goes beyond function group boundaries, the function groups involved should solve the problem by concerted effort, or the initiative should be taken by the hospital management. It remains unclear who is responsible and has the authority to reserve staffing capacity and to tackle the problem. But even if it is clear who is responsible and has the authority, both hospital management and function group management lack the staff required to take the necessary steps.

The two improvement paths, to ensure a better preparation of the patient and to establish a reliable blood-ordering procedure, were still up and running when this research in the OR finished, but they did not seem to be very successful. The blood-ordering procedure has not been put in writing, which is a problem because the procedure is unreliable. The management started this improvement path more on the basis of intuition, focusing on where the problem in their view was mainly situated, rather than on the basis of a systematic analysis in which the problem has been mapped out so that it can be solved structurally and completely. The aim should be an objective and reliable blood-ordering procedure, and the management should recognise the priority of a reliable blood-ordering procedure. To bring this about, the whole blood-ordering procedure should be critically reviewed and mapped out.
Staffing and availability problems in connection with the IRMS committee members. A staffing problem which occurred in this period was that the IRMS committee consisted of only two instead of the agreed three members, and also that the members were not available at the same time, so that they had to carry out their work separately. This problem was initially caused by understaffing in the anaesthesia section and the even more limited availability of operating assistants, as a result of which it proved to be impossible to roster these two staff members off-duty simultaneously. The position of the third staff member on the committee was (still) vacant. In order to break the deadlock with regard to the staffing problem and the availability of the IRMS members, and also in order not to frustrate any further the initiative, creativity, commitment and enthusiasm manifested by the two IRMS committee members, a request was made to produce an agenda for a meeting between the members of the IRMS committee and the OR manager, a meeting at which one of the two heads of Patient Affairs would act as an intermediary. The head of Patient Affairs could also lend support in implementing the solutions arrived at. The position of this head of Patient Affairs in this matter was difficult and rather delicate. The head of Patient Affairs has no formal authority over the OR, but it was possible to get this authority (temporarily) from the medical director. At the time, it was precisely this authority which had (still) not been established. This indicated clearly that the status quo in the hospital was—consciously or unconsciously (this is not clear but probably unconsciously)—opposed to change. The fact was, however, that the medical director’s point of view was that the IRMS should be preserved for the hospital at all costs. Should there be any staffing problems, these would have to be solved.

In general, the results of the IRMS hardly led to any improvements, because at the time the hospital and the OR were in the process of reorganising, during which process:
• The OR management attached a low priority to the improvements.

• It was not clear who was responsible for initiating and implementing improvements. The duties and responsibilities of the function groups had not been formally laid down. At that time, these duties and responsibilities were still undefined and were left to the various spheres of influence within the organisation.

6.6 Discussion

Initiative for the subsequent development of the IRMS into a more general quality system. The adaptations made to the IRMS, in the context of making a start with the development of a more general quality system, had resulted in a better IRMS because Arbo incidents could now be reported to the IRMS and analysed, and the IRMS protocol had been revamped. The degree of success of the initiative towards the development of the IRMS into a more general quality system depends on the success of the reporting and analysis of Arbo incidents and on the degree of success of the implementation of improvements in the OR. This falls outside the scope of this research because this research ended the moment the IRMS was ready for the reporting of Arbo incidents and the moment the new IRMS protocol was finished, although—as stated earlier on page 185—the Arbo coordinator noticed that interest in Arbo matters increased from the moment the IRMS began to turn its attention to Arbo. Further development of the IRMS into a more general quality system is feasible, for instance in accordance with the model presented in section 2.5, but a lot of work still remains to be done. If the reporting and analysis of Arbo incidents turn out to be a success, the question of whether to start tackling other kinds of process deviations like complications might be considered.

New IRMS protocol The actual use in practice of the new IRMS protocol falls partly outside the scope of this research because this research ended when the new IRMS protocol was finished and was only partly in use. Of the most important changes in relation to the earlier protocol, only the phase of the design and implementation of improvements was not finished when this research ended. The allocation of structural process failure to critical points went quite well. The opportunity to conduct follow-up research was not seized by the OR management, see also further down in this section.

Allocation of structural process failure to critical points The level of mapping which was used in figure 6.2 on page 186 allowed only a very limited number of points to allocate the failure factors to. The failure factors allocated to the critical points relate to
preconditions which were not met but which are essential to a controlled carrying out of processes, and most of these failure factors involve communication, cooperation and coordination, and planning problems between groups, for instance, between the preparation and the anaesthesia-operating part, between the OR and NedSter, between the OR and nursing departments.

The opportunity to conduct follow-up research into the precise nature and dimension of problems Before going ahead with the design and implementation of process and system improvements in order to remove structural failure in the OR, it would make sense to conduct research into the precise nature and dimension (of the causes) of structural failure. The management decides whether follow-up research is necessary to determine the problem more precisely, before moving on to the problem solving phase. This follow-up research may not always be necessary. As stated above, this opportunity to conduct follow-up research was not taken advantage of by the OR management. This was the right thing to do in the case of the blood-ordering procedure because here the solution was already clear: to make the procedure more reliable, the whole procedure should be redesigned.\(^{18}\) In the case of the inadequate preparation of patients arriving from other departments, it would have been better if follow-up research had taken place in order to determine exactly which departments did not prepare their patients in accordance with the standards. This follow-up research could easily have been conducted by recording which mistakes are made, how often they are made and by which department. In this way, follow-up research can reduce the number of departments that have to be approached for the purpose of solving the problem of the transfer of inadequately prepared patients.

6.7 Conclusions and recommendations

Based on the experiences with realising improvements in reducing patient risks, this section presents conclusions which can be drawn and which result in recommendations for preventing further future frustrations.

In spite of what was said in the preceding sections, the risk management project shows that the distinction between risk management and quality management is in prac-

\(^{18}\)And to do this, further research must be conducted, see section 6.5.3. Just to be perfectly clear, follow-up research is conducted in order to get a clear picture of the case (e.g. procedure must be redesigned). If the picture case is clear, further research may be conducted in order to improve things (e.g. to determine how the procedure must be redesigned). Or to put it differently, the purpose of follow-up research is to determine where the solution is to be applied (e.g. redesigning procedure, which department(s)); when this is clear no follow-up research is needed. Further research is used to determine what the solution is: this is always necessary.
tice not important. Quality management methods are used for the benefit of risk management, for instance: entry control to intercept process deviations which may develop into incidents in the OR, FMEA to assess patient risks and CTA—which is based on FTA—to analyze incidents.

Because nothing came of reducing patient risks, the hospital and OR management should make clear who is responsible for the design and implementation of process and system improvements. The two improvement paths—one relating to an incident which is more within the scope of risk management, the other relating to a process deviation which is more within the scope of quality management—which are described in this chapter both show this lack of clarity with regard to responsibility.

The function group or hospital management should make staff available to process the information about the development of incidents into process and system improvements in order to reduce the risks for patients. There should be a guarantee that an improvement path does actually result in improvements. Important preconditions for this are that:

- The management endorses the improvement path and intends to implement improvements.
- It is absolutely clear who is responsible, and that clear goals have been set.

In order to deal with the structural incident causes, more staff should be made available by the OR management. However, the organisation was unable and reluctant to reserve staff for bringing about improvements. This may have been caused by the after-effects of the reorganisation (see section 1.5.2) and is a case of procedure failure\(^\text{19}\) which should be solved by the OR management, or, failing this, by the hospital management. It must be clear that the OR management is primarily responsible for solving this problem and should reserve staffing capacity for this purpose. Otherwise, it is the responsibility of the OR management to take up this matter with the hospital management. Therefore, in this specific case (understaffing), it becomes the responsibility of the hospital and OR management to solve the problem.

Once the problem of responsibility has been solved, lack of staff at both the OR and the hospital level may be the next problem. In theory, the incorporation of risk management into the quality management structure of both the department and the hospital might be a solution. However structural quality management did not exist at that moment either at departmental or at hospital level. So, because it was not possible to use quality management staff, it was up to the OR management and, if necessary, the

\(^{19}\)The organisation, in this case mainly the OR and hospital management, does not regulate the solving of problems within and between departments; there is no procedure for this.
hospital management, to generate or reserve sufficient staffing capacity for this purpose. An option might be to use the staff of the IRMS. The OR management should see to it that the IRMS committee consists of the agreed number of three members instead of the actual two. Because few reports are submitted by the recovery section of the OR, it might be a good idea to recruit the third committee member from this section of the OR as this might boost the reporting behaviour of the recovery employees. In addition, the OR management should also make it possible again for the IRMS members to meet simultaneously. However, neither the hospital nor the OR management took any action to tackle or solve the staffing problem with the IRMS committee in the OR. This may be solved, for instance, by planning the IRMS committee meetings after working hours and paying for overtime (providing, of course, the IRMS committee agrees to this).

The conclusion from all this has to be that the management of the OR function group, whether deliberately or not, did not (even partly) delegate the improvement path to the members of the IRMS committee or to others like doctors and employees. By not bringing the IRMS committee into action (section 6.5.3), the improvement path is probably less efficient and effective than it possibly could have been. 'Less efficient', because the IRMS committee has, in principle, the staffing capacity for this purpose but this staffing capacity is not being utilised by the management team. Instead, more expensive staffing capacity is used in the form of the manager of the OR, an anaesthetist and the head of the anaesthesia section. 'Less effective', because the efforts to tackle and/or solve the problem are characterised by an intuitive approach and constitute only an intermittent activity (among many other management activities), instead of being based on a more structural and project like approach, preferably after a systematic assessment of the problem. In this way the advantages which IRMS committee members have—they are closer to the problem and to the party responsible for the problem than the management, and (therefore) are capable of greater insight into the problem—gets lost. This is why the informal feedback\(^\text{20}\) is not very satisfactory. An advantage which members of the OR management do have compared with the IRMS committee members, is that they have greater authority and enjoy wider powers than the committee members, and that the current culture within the hospital is not used to IRMS committee members performing their roles of assessors of causes and of problem solvers. The authority which the IRMS committee possesses probably varies from one function group to another, which can affect the chances of success of the improvement path that has been initiated. A way out of these problems might be a hybrid variant, in which the management team initiates the improvement path and then manages the IRMS committee members during the course.

\(^{20}\)The IRMS committee members are asked informally by their colleagues about any progress on the improvement path with regard to the incidents they have reported.
of the improvement path. If, for instance, it is anticipated that the presence of a member of the management team when introducing a committee member to a department is necessary, then this should be arranged. However, if the presence of a committee member and/or a member of OR management team is found to be too polarising—resulting in an impasse—one of the heads of the department of Patient Affairs, for instance, may be called in to assist in breaking the impasse.21 Both the IRMS committee member and the management team member belong to the OR and represent the party responsible for the problem, but the head of the department of Patient Affairs is independent and can therefore act as an intermediary. Because of a lack of management capacity and in order to maximise the chance of successful implementation of improvements, it would be advisable to delegate as much as possible. This (delegating as much as possible) would be part of a learning process for the management, the IRMS committee, and the doctors and employees in the OR.

After the incident data have been collected and analysed, the problem is how to generate and how to implement improvements. Both the hospital and the OR organisation are not geared to implementing improvements. This should be changed; the new IRMS protocol may be a step in the right direction, but it is no guarantee for improvements, so the OR management should attach higher priority to the improvements.

With regard to the two improvement paths described—the preparation of patients arriving from the ward and the blood-ordering procedure—the conclusion may be drawn that in both cases, the OR management acted too intuitively and did not look beyond the system boundary of the OR. The management should look into the whole chain of processes both inside and outside the OR—the whole procedure chain—in order to prevent suboptimisation. Where and when necessary, processes will need to be redesigned.

The management of both the OR and the hospital did not shoulder their responsibility. The management wished to make a start with structural quality management—and risk management—in the OR but did not take the necessary action: they did not provide unqualified top-down support. The management should not ignore crucial management information about patient risks but should take measures to ensure that this information receives due attention. The medical director's point of view about the IRMS was that the IRMS should be preserved and maintained for the hospital at all costs (see section 6.5.3). But it makes no sense just to collect and analyse incidents without acting on the results. Although the board of directors knew that nothing was being done with the results of the IRMS, they did not take any action to change this. At best, the board of directors

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21 This role of the head of the department of Patient Affairs is comparable to that of the supra function group central quality system (see section 2.5.4 and figure 2.2 on page 36) which hierarchically stands above the function groups and whose role is to act as an intermediary.
may be considered to have been too passive. Another example would be that the OR management team do not view procedure failure which crosses the system boundaries as their problem. However, if the OR management team do not view this as their problem, the OR is still faced with the problem and cannot just back off from it: if only for the sake of the OR patients, it ought to take decisive action. The conclusion may be drawn that both the OR management and the hospital management manifested a lack of inspiration, vision and initiative with regard to the question of how to find a solution for the risks found.

As mentioned above, the management should make more and better use of the IRMS committee or of other doctors and employees when conducting follow-up research and designing and implementing improvements. It should be emphasised that in this way the employees are deprived of a certain measure of job enrichment with all the discouraging consequences this entails: initiative, creativity, commitment and enthusiasm are thwarted, though these qualities are highly desirable, and should self-evidently be encouraged and fostered by the organisation, under the supervision, of course, of inspired and inspiring management.
Risk management in the Haemodialysis department

7.1 Introduction

This chapter describes the risk management research in the Haemodialysis department of the Catharina Hospital which is a monodisciplinary department in contrast to the multidisciplinary Operating Room (OR). Table 7.1 provides a brief overview of the methods used in the OR and Haemodialysis department, and of what these methods assess. For further overviews and comparisons between the methods used in the OR and Haemodialysis department, and the results of these methods in the OR and/or Haemodialysis department, see e.g. also table 1.1 on page 22, table 7.4 on page 237 and table 8.1 on page 256. The differences between the risk management project in the Haemodialysis department and in the OR are described below in this section.

The goals of the Haemodialysis project were:

• To obtain greater insight into the nature and causes of incidents in the Haemodialysis department.

• To establish to what extent the risk management methods and tools of the OR could be applied to another department, in this case the Haemodialysis department.

• To include complications in the risk assessment.

Table 7.1. A brief overview of the methods used in the OR and Haemodialysis department, and of what these methods assess.

<table>
<thead>
<tr>
<th>Method</th>
<th>Location</th>
<th>Assessment of</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIIs</td>
<td>OR</td>
<td>Incidents, causes, recovery factors</td>
</tr>
<tr>
<td></td>
<td>Haemodialysis</td>
<td>Incidents, causes, recovery factors, complications</td>
</tr>
<tr>
<td>FMEA</td>
<td>OR</td>
<td>Failure modes, physical (and psychological) effects, causes</td>
</tr>
<tr>
<td></td>
<td>Haemodialysis</td>
<td>Failure modes, physical effects, causes</td>
</tr>
<tr>
<td>IRMS</td>
<td>OR</td>
<td>(Arbo) incidents, causes, complaints</td>
</tr>
<tr>
<td></td>
<td>Haemodialysis</td>
<td>—not implemented—</td>
</tr>
</tbody>
</table>
The objectives of this research with regard to the registration and analysis of complications, were to assess whether complications occurred and, if they did, to determine what the nature of these complications was. This objective was subordinated to the assessment and analysis of incidents: if—during a CII—sufficient interview time was left after one or more incidents had been discussed, the interviewee was asked to subsequently discuss a complication. The ultimate goal was to develop and implement a management system which registers and analyses both incidents and complications.

The research related to all patients for whom the Haemodialysis department was responsible. In addition to passive and active haemodialysis, the Haemodialysis department also carries out peritoneal dialysis.

From the point of view of quality control, the minimum requirement for complication control is the registration of which complications occur and what the frequency of their occurrence is. Because complications and incidents cannot always clearly be distinguished from each other, and because complications can result from incidents (and in that case are preventable), the registration and analysis of complications must be carried out side by side with the registration and analysis of incidents. A development model for incidents and complications, and a set-up for complication registration and complication analysis, are described in chapter 3.

The primary research goal was the assessment of incidents, of the structural causes which resulted in the development of incidents and, if present, of the recovery factors which limited or prevented the (possible) effects on the patient.

The secondary research goal was the assessment of complications for (possible) effects on the patient and for possible causes.

The risk management project in the Haemodialysis department started after the last data analysis of the IRMS in the OR (see also section 1.6.2 for a chronological overview of the project). Compared with the risk management project in the OR differences are:

- Process description:

  - The process description of the Haemodialysis department was more detailed than the process description of the OR. This was because the process description of the peritoneal dialysis (PD) was already to a large extent finished, see section 7.2.2. A more detailed process description had the advantage of making possible a qualitatively better FMEA. A new method of describing the process was devised and used for the primary process of the haemodialysis, see the charts hemo01–hemo06 on the CD-ROM (see appendix B).
• CIIs:

- The distinction between accidents and near accidents—which was made during the FMEA and the CIIs in the OR—was no longer made because it turned out that the effects on patients—over time, and physically—are not always clear. The catch-all term ‘incident’ was used instead (see also section 3.2).

- Because classifying causes in accordance with the ECM was too laborious and only useful in the case of comparing methods (see e.g. section 4.5), the causes found by using the CIIs were, in contrast to the CII causes of the OR, not classified.

- In contrast to the CIIs held in the OR, all the CII causes were now used. A distinction between actual causes and possible causes was not made.

- The CIIs in the Haemodialysis department were used to gain greater insight into the nature of complications. If the interviewee knew of any complication and sufficient time was left during the interview, one or more complications were discussed.

• CTA:

- In contrast to the causal trees created as a result of the CIIs in the OR, one-on-one relations\(^1\) were allowed for the sake of clarity. This means that one (overall) description can be broken down into a sequence of shorter descriptions.

• FMEA:

- In contrast to the FMEA meetings in the OR, the complete model of the Haemodialysis department was used and validated during the FMEA meetings.

- In contrast to the FMEA meetings in the OR in which doctors, nurses and paramedics participated, the FMEA participants in the Haemodialysis meetings were (by agreement with the management team of the Haemodialysis department) all nurses.

- Because classifying causes in accordance with the ECM was too laborious and only useful when comparing methods (see section 5.3), the causes found by using FMEA in the Haemodialysis department were not classified.

\(^1\)See also footnote 8 on page 145.
The FMEA made in the OR also assessed the psychological effects on patients and the effects on doctors and employees (see also section 4.5). The FMEA in the Haemodialysis department was restricted to the physical effects on patients.²³

The process of classifying the values for seriousness, frequency and the extent to which corrections are possible was carried out differently in the Haemodialysis department as compared with the OR. Cf. appendix C which represents the procedure followed in the OR, with appendix D which represents the procedure followed in the Haemodialysis department. To prevent too much argument about assigning the values for seriousness, frequency and the extent to which corrections are possible, and promote a smooth assignment of these values, the number of values for seriousness, frequency and the extent to which corrections are possible were reduced. This was no problem because these values were only used for the calculation of the RPN which in its turn was only used to establish priorities as to which risks must be dealt with first.

• IRMS (or CIRMS):

  It was not possible to implement an IRMS (or CIRMS) in the Haemodialysis department because of a lack of time.

The patient risks in the Haemodialysis department were assessed by CIIs and an FMEA. During the FMEA meetings, a model which described the processes in the Haemodialysis department was used. The results of the research can be divided into two categories: experiences gained in working with the methods used—the methodological results—and the risks that were found by the use of the different methods—the intrinsic results. Both the methodological results and the risks found will be discussed for each of the three methods, with the emphasis on the risks found. In sections 7.2–7.4, the methods that were used are described, and the results of these methods and the resulting conclusions and recommendations are presented. This chapter ends with section 7.5 which presents the overall conclusions and recommendations.

² The highest priority was assigned to physical effects on patients so the focus of the FMEA was on the assessment of failure modes resulting in physical effects on patients, and not on the assessment of, for instance, any psychological effects on patients.

³ In the case of the FMEA made in the OR, a sifting of the FMEA results took place after the FMEA was made: the failure modes resulting in psychological effects on patients and effects on employees and doctors were removed, see section 4.5. So, the FMEA made in the OR assessed too broadly, and this was avoided in the case of the FMEA in the Haemodialysis department by explicitly focusing on physical effects on patients.
7.2 Process model

7.2.1 Description of the Haemodialysis processes

In addition to passive and active haemodialysis, the Haemodialysis department also carries out peritoneal dialysis (PD). In the Catharina Hospital, PD is understood to mean:

- CAPD (Continuous Ambulant Peritoneal Dialysis).
- APD (Automatic Peritoneal Dialysis).

The population of long-term haemodialysis patients consists of 5 active and 65 passive patients. The population of long-term PD patients consists of 15 CAPD and 15 APD patients (1998). All in all, the department carried out 9,000 haemodialyses a year (1998). In the ICU, the Haemodialysis department carried out 685 treatments (1998).

The process model was created by using interviews with a haemodialysis nurse and a PD nurse. The process description technique used was based on system theory—the system approach by In 't Veld—in which a system consists of one or more processes. For more information about system theory and process descriptions, see section 3.4.2 and In 't Veld [166]. In order to control these processes, measuring and control loops are put in place. The processes within the systems of haemodialysis and PD are described: this description is generated by recording the processes the patient passes through during his stay within both systems. These systems do not stop at the physical department border of the Haemodialysis department but they also include, for instance, the processes which take place in the ICU department.

As mentioned in section 7.1, a new method—i.e. different from the method used in the OR—of describing the process was devised and used for the primary process of the Haemodialysis department, see the charts hemo01–hemo06 on the CD-ROM (see appendix B). For each of the five primary haemodialysis processes (see chart hemo01 on the CD-ROM), a more detailed description was produced (see the charts hemo02–hemo06 on the CD-ROM). In these descriptions, the focus is on the subprocesses the nurse takes part in within the context of monitoring and checking the patient and the dialysis machine.

7.2.2 Results, conclusions and recommendations

In this subsection, the description of the processes of the Haemodialysis is described. The workload and lead time of the method are discussed, and with respect to the content (i.e. the risks found), the results and conclusions and recommendations will be presented.
Chapter 7. Risk management in the Haemodialysis department

**Workload** The creation of a process description carries a heavy workload. The process description was created partly by a PD nurse and partly by the researcher on the basis of interviews with two nurses, a haemodialysis and a PD nurse. After each interview, the data were processed and incorporated into the model. This was a laborious and time-consuming process: the total workload was more than four weeks. However, it is a one-off investment with only updating costs as the processes change—so it is worthwhile doing in the longer run.

**Lead time** The lead time was many times larger than the workload because sometimes there were intervals of weeks between successive interviews. This was caused by the heavy workload in the case of the employees and by disruptive factors like holidays.

**Process model** The process model consists of a description of the system Haemodialysis which breaks down into acute, chronic and peritoneal dialysis (PD), and is to be found on the CD-ROM, see also appendix B.

<table>
<thead>
<tr>
<th>Summary of the data and data processing: Haemodialysis process model</th>
</tr>
</thead>
<tbody>
<tr>
<td>The n of charts is 31 (including 1 legend and 1 overview chart). The n of problems found = 19.</td>
</tr>
</tbody>
</table>

The validation of the process model took place over a number of interviews with a haemodialysis and PD nurse, and during the FMEA meetings.

The processes of the PD had already been mapped to a large extent by a PD nurse. The method used by the PD nurse to describe the PD was based on the method that was used to describe the processes in the OR. The process description method used in the OR was based on the method described by In 't Veld. The PD nurse was taught the OR process description method by a member of the Human Resources Department who had been involved in the OR project. The PD nurse adjusted the method so it became more suited for describing the PD. According to In 't Veld, this kind of adjustments, if necessary, are permissible. The fact that the PD part of the Haemodialysis had already been mapped, indicates that the method is suitable for mapping the Haemodialysis processes. At the same time it indicates that the reliability of the method is satisfactory: different persons—i.e. the PD nurse, a member of the Human Resources Department, and the researcher—used the method in the same way.

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In contrast to the process description used for the OR, adjustments were made by the nurse, for instance, by using boxes drawn with a dotted line for processes which are outside the system boundary (e.g. a process controlled by other departments such as blood sampling, which is controlled by the blood lab, see chart pd03—file *Pd03.cht*—on the CD-ROM) or by using circles with text inside and/or symbols as reference to a process description (see e.g. the charts pd02—file *Pd02.cht*—and pd03—file *Pd03.cht*—on the CD-ROM).
During the creation of the process model, a number of problems within the Haemodialysis came to light. These problems are presented in appendix F and were raised during the FMEA meetings. The process model of the Haemodialysis was used in the course of the FMEA in order to track failure modes in the processes in the Haemodialysis department in a systematic way.

Conclusions The conclusion may be drawn that the adjusted process description method by In 't Veld can be used for the purpose of describing the processes in a department and of using this description to assess possible risks, in this case physical effects on the patient. The method's suitability has to do with:

- The measure of transferability\(^5\) of the method. This enhances the reliability of the method, and makes the method suitable for use in and between different departments, hospital organisations and people.
- The use of the method and the problems the method revealed as input for a risk assessment method like an FMEA.
- The fact that the method represents the processes in their natural sequences.
- The fact that the process description has different aggregation levels as a result of which it can function, for instance, as a framework to which procedures and protocols can be attached.
- The fact that the method uses measuring and control loops with standards. This forces people to focus on processes and process control that correspond to generally accepted quality principles.

The method resulted in an unambiguous description of the processes in the Haemodialysis department.

Recommendation The process description of the Haemodialysis department could be used as (part of) a process description in a quality handbook.

7.3 CIIs

7.3.1 Approach

The patient risks were assessed using two methods: the CIIs and the FMEA. In this section the CII method is described, in the next section the FMEA. Both methods were

\(^5\)The method's measure of transferability between the researcher and the employees and doctors—e.g. the PD nurse and the member of the Human Resources Department mentioned above.
used again to determine to what extent the risk management methods and tools used in
the OR could be transferred to another department, see section 7.1, and to compare the
results. As will be concluded in section 7.5, the recommendations which can be made as
a result of the FMEA are a complement to the recommendations which can be made as
result of the CIIs. This means that the FMEA complements the CIIs well.

All in all, 25 CIIs were held. In the Haemodialysis department, at least one person
per section was interviewed. The main purpose of the CIIs is to gain an insight into the
causes of incidents with (possible) undesirable physical effects on the patient. If there was
time left and the interviewee knew of a complication, one or more complications were
discussed. This was done to gain an insight also into the nature of complications.

Before the interview, the interviewee received a letter in which the setup and purpose
of the interview were explained.

Because it was an open interview, an interview plan was used to standardise the in-
terview as much as possible.

After one or more incidents had been discussed and if there was any time left, the
interviewee was asked to describe a complication. The interviewer put a list in front of the
interviewee with all possible factors which might have contributed to the development of
a complication. The list contained sixteen factors—the same sixteen factors presented in
figure 3.4 on page 56—and was part of the interview plan that was used during the CIIs.

After each interview, the interviewer wrote a report and created a causal tree of the
incident, see also section 3.4.5.

The interviewee was given feedback on the results after they had been worked out in
detail: the interviewer discussed the results with the interviewee. Possible changes were
made, the results were, if necessary, discussed once again with the interviewee and also,
if necessary, changed.

For more information about the CIIs, see section 3.4.4.

7.3.2 Results, conclusions and recommendations

In this subsection, the results of the CIIs are discussed, and the resulting conclusions
and recommendations. Of the methodological results, the workload and lead time are
discussed. Of the intrinsic results (i.e. the risks actually found), the structural causes, the
recovery factors for incidents, and the complications found are discussed.

Workload The workload of, in total, 25 interviews, was heavy. An interview on average
lasted about an hour, in the course of which at least one incident was discussed and
often—if there was any time left and if the interviewee knew of one or more compli-
cations—also one or more complications. The interview was then worked out in detail,
and, depending on the number of incidents, one or more causal trees were drawn: one causal tree for each incident. Subsequently, the worked out results were discussed with the interviewee after which possible changes could be made.

**Lead time** The lead time was long because for each of the 25 interviews, an individual appointment with the interviewee had to be made. The same applied to the feedback process. In a few cases it was necessary to make a third appointment.

**Structural causes, recovery factors and complications** Because the CIIIs are confidential, the structural incident causes found can only be described in general terms. The effects of the incident on the patient cannot be described because of the confidential nature of the interviews. Because of the confidentiality of the interviews, the recovery factors found are also described in general terms in order to prevent as much as possible any traceable link with persons and incidents. Of the complications discussed, the effects on the patient and the (possible) causes—or the aspects which are important for an explanation of the development of the complications—will be described. See table G.4 on pages 320–332 in appendix G.

<table>
<thead>
<tr>
<th>Summary of the data and data processing: Haemodialysis CIIIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>The original n of interviews = 25. The n of interviews used for analysis = 24 which means in this case that the number of incidents discussed and analysed = 33 (some interviews yielded more than one incident). The following figures relate to this number of interviews (24) and incidents (33). The n of causes = 180. These 180 causes include all causes, i.e. both the actual causes and the possible causes. The n of structural causes found = 28. The n of recovery factors = 17 of which 13 were successful (of these 13 were 6 directly successful and 7 indirectly, see also table G.3 on page 318). The total n of complications which were discussed was 23, 15 of which were preventable. See also table 7.4 on page 237.</td>
</tr>
</tbody>
</table>

During the 25 interviews, a total of 33 incidents and 23 complications were discussed. An overview of the number of incidents and complications per interview is presented in table G.1 on page 314.

The distribution of the 25 CIIIs over the different functions within the Haemodialysis department and the number of interviews held per function are described in table 7.2 on the following page. Two internists, both also attached to the Haemodialysis department (one of them specialised in haemodialysis, the other one in PD), were not included in the research: both perform on-call shifts for the Haemodialysis department. Of the 25 CIIIs

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6The two internists are ICU doctors and look after dialysis patients at the ICU.
Table 7.2. The distribution of the CIIs per function within the Haemodialysis department.

<table>
<thead>
<tr>
<th>Function</th>
<th>Total n working in function</th>
<th>FTEs</th>
<th>n interviewed</th>
<th>n of usable interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor in training</td>
<td>1</td>
<td>−</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Haemodialysis nurse</td>
<td>35</td>
<td>28.3</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Nephrologist</td>
<td>2</td>
<td>−</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>PD nurse</td>
<td>6</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Secretary</td>
<td>2</td>
<td>0.9</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Nursing manager</td>
<td>1</td>
<td>0.8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>47</strong></td>
<td><strong>32</strong></td>
<td><strong>25</strong></td>
<td><strong>24</strong></td>
</tr>
</tbody>
</table>

that were held, a total of 24 turned out to be usable; one interview was unusable because no incidents and no complications were discussed.

A FONA report was drawn up of 4 of the 33 incidents, see table G.1 on page 314.

The structural incident causes found, the recovery factors which occurred during the incidents, and the complications will be discussed below.

**Structural causes** A total of 28 structural causes was found; these are presented in table G.2 in on pages 315–317. After examining the results, the causes were classified in four failure categories, see table 7.3 on the facing page: failure category A was further subdivided into function categories.

The clustering process in order to arrive at these failure categories was performed in a way similar to the method adopted in the OR with regard to the IRMS, but the results were different, cf. the four failure categories with the structural causes in table 5.4 (see pages 152–154) and table 5.6 (see pages 160–163). The failure categories can be reduced to Van der Schaaf’s ECM [154] (see also appendix E), e.g. design error (category C) corresponds to technical failure (especially TE), although an unequivocal projection of the failure categories onto the ECM categories is not possible because the failure categories are not entirely mutually exclusive—just like the ECM categories themselves. For instance, the scheduling of operations is not always reliable and this regularly results in the postponement of operations (cf. structural cause number 28 in table G.2, see pages 315–317); this was assigned to the failure category D (organisational failure) but could possibly also be assigned to failure category B (absence of or inadequate protocol and/or procedure).

The structural causes found were aggregated because of the confidential nature of the
Table 7.3. The failure categories into which the structural causes found by means of the CIIs in the Haemodialysis department were classified.

<table>
<thead>
<tr>
<th>Failure category</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Lack of knowledge and/or experience.</td>
</tr>
<tr>
<td>I. Specialist.</td>
</tr>
<tr>
<td>II. Nurse:</td>
</tr>
<tr>
<td>a. Haemodialysis.</td>
</tr>
<tr>
<td>b. PD.</td>
</tr>
<tr>
<td>III. Doctor in training:</td>
</tr>
<tr>
<td>a. Internal Diseases.</td>
</tr>
<tr>
<td>b. Surgery.</td>
</tr>
<tr>
<td>c. Other.</td>
</tr>
<tr>
<td>B. Absence of or inadequate protocol and/or procedure.</td>
</tr>
<tr>
<td>C. Design error.</td>
</tr>
<tr>
<td>D. Organisational failure.</td>
</tr>
</tbody>
</table>

CIIs. This means, on the one hand, that a certain measure of specificity and detail gets lost which is not such a bad thing, because it relates to structural failure. On the other hand, this also means that conclusions and (general) recommendations can be drawn directly from these causes. The structural causes and the conclusions and recommendations are discussed by using the four failure categories mentioned before.

A. Lack of knowledge and/or experience:

II. Nurse:

a. Haemodialysis:

- The (material) knowledge which some haemodialysis nurses have of subclavian catheters is inadequate.
- Some haemodialysis nurses have insufficient knowledge of and experience of the CAVHD (Continuous Arterial Venous HaemoDialysis).
- The knowledge of and experience of catheter care is inadequate.
- Some nurses have insufficient experiential/working knowledge to enable them to work with the new dialysis machine.

b. PD:

- Insufficient knowledge with regard to catheter care.
III. Doctor in training:

a. Internal Diseases:
   - Too inexperienced in using the different dialysis techniques.
   - Inadequate nephrological knowledge.
   - Inadequate on-the-job training and lack of information, and therefore not (or insufficiently) conversant with organisational protocols and procedures.

b. Surgery:
   - Inadequate nephrological knowledge.
   - Inadequately conversant with constructing a CAPD catheter.

c. Other:
   - Insufficient nephrological knowledge (Accident and Emergency (A & E) Department).

*Recommendations* as a result of the structural causes found during the CIIs, failure category ‘Lack of knowledge and/or experience’:

- The absence of sufficient medical and nursing knowledge and skills with regard to concrete matters, could be put right by specific education and training programmes focusing on the above-mentioned.

- The implementation of new equipment should be improved, with regard to both the instructions about using the equipment, and to the hands-on training in using equipment, and to the availability of assistance in the form of an expert who can help in the case of problems.

- As for people being insufficiently conversant with organisational protocols and procedures, the organisation must ensure a maximum uniformity and effectiveness of protocols and procedures, paying special attention to simplicity, logic and robustness.

It would be advisable to have the housemanships/internships of successive doctors in training overlap to a certain extent. In this way the outgoing doctor in training could train his successor and point out pitfalls.

In a ‘living’ document a record should be kept of matters—not only those of an organisational nature but also those of a medical nature—which go wrong and

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7Protocols relate to how something is regulated within a department, while procedures describe matters extending beyond the department. See also section 2.5.2.
which the doctor in training and the organisation consider important enough to be prevented in the future. This document should also contain matters which are considered important—both by the doctor in training and the doctor in training’s (immediate) environment—to pass on to future crops of doctors in training. This should be done for the sole purpose of preventing future failure and incidents. The organisation and new doctors in training could avail themselves of the knowledge accumulated in this document.

B. Absence of or inadequate protocol and/or procedure.\(^8\)

- Novice doctors in training are inadequately trained and informed. Doctors in training are not or made insufficiently conversant with organisational protocols and procedures.

- The introduction of a new type of dialysis machine could have been better. No expert was present in the department during its introduction. In the case of nurses, their experiential/working knowledge was inadequate.

- Protocol/procedure about doctors doing their rounds was ineffective. It turns out that it is possible to overlook patients and the hand-over or transfer of patients is not effective.

- The status, working and updating of the admissions board are unclear. There is no protocol for this.

- Arrangements which have been made with patients are passed on incompletely.

- Arrangements between the Haemodialysis department and other departments are not complied with.

- Setting up a haemodialysis machine is performed by too many different people.

- The monitoring of the patient is performed by too many, different members of staff (one or more haemodialysis nurses, and one or more ICU nurses).

- There is no protocol for the transfer of acute patients who are unknown to the department.

- There is no protocol for a euthanasia wish expressed by a patient.

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\(^8\)These shortcomings were not mapped onto the process description because at the time there was no need for them. Mapping the shortcomings and the concomitant solutions onto the process description is not easy but it should be possible. (These solutions, e.g. an additional protocol which was absent, must then be clearly represented as ‘Soll’ elements: see page 92 for the ‘Ist’ and ‘Soll’ concepts.)
• The blood-ordering procedure is unreliable.

• There is no protocol for starting up the R.O. (Reversed Osmosis) machine.

• There is no effective protocol for the haemodialysis of patients whose operation has been postponed.

• Transfers (of data) are not carried out effectively.

• Unclear and incomplete CAVHD protocol.

• The protocol for the scheduling of patients for the PD training is unclear.

Recommendations as a result of the structural causes found during the CIIIs, failure category ‘Absence of or inadequate protocol and/or procedure’:

• See also the recommendations mentioned before under point A. Protocols and procedures should be devised and drawn up to make doctors in training conversant with the operating procedures within the hospital. The hospital and the departments should see to it that protocols and procedures are clear, logical and effective.

• A protocol should be drawn up for the introduction of new equipment to ensure that access to expertise during the introduction period has been adequately regulated.

• A protocol/procedure should be drawn up for the following:

  – The use and maintenance of the admissions board.

  – (The communication of) arrangements which have been made with the patient.

  – Arrangements which have been made with other departments and the way in which these arrangements have been recorded and passed on within the department.

  – The setting up of a haemodialysis machine by more than one member of staff.

  – The transfer of acute patients who are unknown to the department.

  – A euthanasia wish expressed by patients.

  – Starting up the R.O. machine.

  – The haemodialysis of patients whose operation has been postponed.
The following protocols/procedures should be made more effective:

- The complete procedure about doctors doing their rounds, ensuring that care is taken that no patients are overlooked and that arrangements made are recorded in such a way that a correct transfer is possible. Orders issued by doctors doing their rounds should also be clearer.
- The ordering and delivery of blood and blood products.
- The communication of data.
- The CAVHD protocol. The protocol is unclear and incomplete.
- The scheduling of patients for the PD training. This is unclear.

Monitoring the patient should be optimised as much as possible. If this monitoring is performed by too many members of staff and/or departments, this may adversely affect the quality of the care provided.

C. Design error:

- The dialysis machine of the type Integra jumps inadvertently into the general safety state when a particular button is pressed unintentionally or (apparently) too hard.

- The differences in outward appearance between the artificial kidney which is standardly used and the non-standard artificial kidneys are, in the case of some artificial kidneys, virtually indistinguishable.

Recommendations as a result of the structural causes found during the CII's, failure category ‘Design error’:

- The button in question by means of which the Integra machine can accidentally be turned off, should be shielded physically so that the machine can no longer be turned off inadvertently. This may be accomplished by, for instance, fitting an easily removed or easily lifted off cap onto the machine. The manufacturer and/or the supplier also need to be informed. Perhaps they know of a way to remed the problem, for instance by adapting the software so that extra confirmation is required before the machine turns itself off. In any case, in the near future this sort of flaw needs to be taken into account when designing a new version or type of the machine.

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9 The general safety state the machine jumps into cannot easily be reversed. The machine has to be replaced by another one, a process which takes 30 min.; the technical department has to come and collect the machine in order to get it ready for use again.
• The non-standard artificial kidneys which outwardly resemble the standard artificial kidney too much, should be made to look different as much as possible so that errors will be avoided. This may be accomplished, for instance, by attaching a number of brightly coloured stickers or a strikingly conspicuous, unique tape to non-standard artificial kidneys. The manufacturer and/or the supplier (and/or the hospital pharmacy) should also be informed. They may be able to do something definitive about the problem in the future, for instance by providing the artificial kidney with strongly distinctive features, such as a conspicuous (non-standard) packing, or an unconventional shape and/or size and/or colour. The study group Artificial Kidneys should look into this problem.

D. Organisational failure:

• The treatment of dialysis patients at the ICU is not always optimal because dialysis nurses have to be called up from their homes.

• On Friday afternoons the level of staffing within the hospital is inadequate. This results in an increase of risks for patients.

• The hospital has inadequate staffing levels because of (too) high a rate of sickness absence and because there is a shortage of nurses.

• The scheduling of operations is not always reliable. Patients’ operations are regularly postponed.

Recommendations as a result of the structural causes found during the CIIs, failure category ‘Organisational failure’:

• It might be worth considering to hand over the CVVH (Continuous Venous Venous Haemofiltration) treatment at the ICU completely to the ICU. In this way, the undesirable delays in the treatment of dialysis patients at the ICU, may be prevented. Another solution may be to let dialysis nurses do attendance shifts at night and at weekends.

• The hospital has to recognise that staffing levels on Fridays afternoon are inadequate and should ensure that sufficient manpower is available.

• The hospital has to recognise the shortage of staff, look into the causes of this and take measures to make up for the shortage.

• The scheduling of the operating programme should be made more reliable.
Recovery factors  During the CIIIs, a number of recovery factors were found which (could have) positively affected the effects of an incident. For the 33 incidents which were discussed during the CIIIs, a total of 17 recovery factors were found. Of these 17 recovery factors, 13 were successful: 6 recovery factors had directly led to complete recovery and 7 had led indirectly to recovery. Three recovery factors did not lead to recovery, 1 recovery factor was of a general nature. The 17 recovery factors relate to 14 different incidents; this means that a recovery factor occurs in less than half of the incidents and that in 12% of the incidents (4 of the 33) recovery is direct and successful. The recovery factors were anonymized because of the confidential nature of the CIIIs. The recovery factors found are presented in table G.3 on pages 318–320 in appendix G.

The list of recovery factors shows that:

- Recovery factors can prevent incidents or limit their effects. On the one hand, the confirmation that accidental recovery factors can prevent incidents or limit the effects of incidents, is worrying. Just as with the occurrence of incidents, it indicates that processes are not well controlled. On the other hand, accidental recovery is often useful and potentially present. Recovery factors occur particularly in the case of protocol/procedure failure and in the case of a lack of knowledge, the two largest failure categories in case of structural incident causes (see earlier in this section and appendix G). Both protocol/procedure failure and a lack of knowledge can be put right. In 11 cases, recovery factors relate to ‘protocol/procedure failure’, and in 4 cases to a ‘lack of knowledge’ in the case of doctors in training.

- Recovery factors are so often absent that it is worrying. Recovery factors do not occur in the case of each incident, only in just under half the number of incidents. This in contrast to the CIIIs of the OR where in the case of each incident at least 1 recovery factor was established.¹⁰

- In 3 cases recovery factors were not successful. In 1 case because the recovery factor was a hunch which was not explicitly put forward, in 2 other cases because the recovery factors came too late.

Recovery factors 4 (doctors in training important source of recovery and failure factors) (see table G.3 on pages 318–320), 9 (plasma substitute is uniform and interchangeable between patients) and 15 (patient not covered with blankets, in contravention of protocol) are not goal-oriented recovery actions. Recovery factors 9 and 15 are an (accidental) fact and an event which contributed to an incident working out for the best,

¹⁰A reason for this might be that the number of degrees of freedom in the case of the OR processes is much larger than in the case of the Haemodialysis processes, resulting in many more possible recovery opportunities in the case of the OR processes.
respectively. Recovery factor 4 is of a general nature. On the one hand doctors in training who are starting out on their housemanships, can be a risk factor, on the other hand the role of the doctor in training is important as a recovery factor for the system Haemodialysis. It may be expected that, as the doctors in training become more experienced, they will be a more effective recovery factor.

Three recovery factors relate to the ICU, in the case of 2 of which the ICU detected an irregularity and took specific action.

Recommendations as a result of the recovery factors found during the CIIIs:

- Doctors in training (A & E, department 6 East\textsuperscript{11} etc.) have too little nephrological knowledge (inexperienced in the various dialysis techniques, not conversant with (different) catheters etc.). This needs to be improved.

- Protocols and procedures must be complied with better. ‘Failure of a protocol/procedure’ means that a protocol or procedure is not complied with, that it is incomplete or that it is lacking. In the concrete:\textsuperscript{12}
  
  - The procedure for the dialysis at the ICU of OR patients whose operation has been postponed, is not effective and should be improved.
  
  - The setting up of dialysis machines should be improved in accordance with protocol.
  
  - Dialysis nurses must always set up their dialysis machine themselves.
  
  - Completely handing over the CVVH at the ICU to the ICU should be considered. Administering, as well as carrying the responsibilities for and qualifications for, a dialysis treatment of ICU patients at the moment are shared by two departments and by at least one nurse of each department. This results in undesirable delays in the treatment of patients, for instance, because it takes (too) long before a haemodialysis nurse arrives at the ICU if the haemodialysis nurse has to be called up from on-call shift, and because OR patients whose operation has been postponed, are often overlooked and are consequently dialysed much later than planned. In the case of dialysis treatments at the ICU, recovery factors are not optimally used because the ICU nurse is not responsible for the treatment. The organisation passes up opportunities for a (more) direct solution to problems by the ICU nurses. At the moment the problems are being solved (much) later by the dialysis nurse.

\textsuperscript{11}Department 6 East is the Haemodialysis department.

\textsuperscript{12}Locating these recovery factors in the process description was not performed because at the time there was no need for it. However, it will be no easy task to locate them clearly in the process model, e.g. because the process model did not describe all protocols and procedures (in detail).
- A protocol needs to be drawn up for the transfer of acute unknown patients.
- Transfer procedures of ICU patients should be observed more carefully.
- A protocol for turning on the R.O. machine needs to be drawn up. Perhaps it may be possible to install a time switch for the on and off button.\(^{13}\)
- Protocols for setting up dialysis machines should be observed better: reading the day list,\(^{14}\) checking for the correct artificial kidney, checking a machine set up (partly) by colleagues. Perhaps checklists will have to be used which are afterwards ticked off and signed by the nurses.
- The outward difference between different artificial kidneys should be more conspicuous. This could be done by adding distinctive features, for instance, by storing the different artificial kidneys in different locations, by the use of strikingly visible stickers etc. The manufacturer and supplier (and the hospital pharmacy) should also be approached about this. Perhaps they could make the design and packing of the artificial kidneys differ as much as possible in shape, colour etc. This issue might be looked into by the Artificial Kidneys study group.
- There should be a protocol for the operation and updating of the admissions board.
- There should be a proper protocol for OR patients whose operation has been postponed.
- Doctors in training need to be made more conversant with and trained with regard to organisational protocols and procedures. Perhaps it might be a good idea to draw up a ‘living’ document of important protocols and procedures, and to distribute it to starting doctors in training. Furthermore, novice doctors in training could perhaps be trained by their immediate predecessors.
- The protocol for doctors doing their rounds is ineffective. Patients and their treatments may be overlooked. Appointments need to be recorded clearly so as to minimise the risks of overlooking patients and of failing to transfer data.
- The transfer protocols (among other things: between (acting) heads, between staff on early acute shift and on late acute shift, transfer by reading the patient file, oral communication of special circumstances) should be observed more

\(^{13}\)This problem has been solved in the meantime because the R.O. machine has been replaced.

\(^{14}\)A day list (in Dutch ‘daglijst’) is a list used to monitor, for instance, a patient’s blood pressure, but also to register the administration of medication in case of an emergency. The term ‘day list’ is used interchangeably with the term ‘day report’ (in Dutch ‘dagstaat’).
carefully. Perhaps it might be worthwhile to devise checklists and to have these signed by the persons in question.

- Surgeons in training and operating assistants are insufficiently conversant with regard to the fitting of a PD catheter. This needs to be improved.

- Both PD and haemodialysis nurses are insufficiently conversant with the protocol for catheter care. This will have to be improved, e.g. by the controlled periodic revision and testing of all protocols for all nurses of the Haemodialysis department.

- Protocols and procedures which are not up to the mark need to be adapted and improved continuously. This must be regulated clearly: who is responsible and carries authority for this?

- Patients should stick to the protocols. Perhaps it might be considered to go periodically over the protocols which are relevant for the patient. If the patient turns out to have been inadequately informed, it may be possible to act on this. If the protocol is not clear, it will need to be improved.

- The Catharina Hospital has inadequate staffing levels because of (too) high a rate of sickness absence and because there is a shortage of nurses.

- Operations are often postponed and this causes planning/scheduling problems. It would be advisable to keep the postponements of operations down to a minimum. The operating programme needs to be made more reliable.

• People's awareness should be raised of the role played by recovery factors and of their own contribution to the origin and the degree of success of recovery factors. An example would be recovery factor 8 (see also table G.3 on pages 318–320): nurse A may pass on information to a colleague (nurse B) which nurse A had (by chance) overheard the day before. Naturally, this information should have gone directly, via the regular channels, to nurse B the day before.

Complications Two aspects of the complications discussed are reported here: the effects on the patient, and the factors which are important — according to the interviewee — for the development of the complication.

All in all, the interviewees had described 23 complications. The distribution of the complications discussed per interviewee is to be found in table G.1 on page 314.

The complications discussed during the CIIIs are presented in table G.4 on pages 320–332. This table provides a brief description of the effects on the patient of each complication. In addition, the (possible) causes of the development of a complication or those
aspects which the interviewee thinks are important for an explanation of the development of a complication, are represented.

Complications which are the effect of an incident or complications which contain elements of an incident, are preventable because incidents are preventable. In all, 15 of the 23 complications discussed contain elements of an incident. This means that nearly two thirds of the 23 complications are in principle (partly) preventable. Table G.4 (see pages 320–332) indicates whether a complication contains elements of an incident, i.e. whether it stems from an incident. In that case, one or more (possible) causes are known and the complication could be, or could have been, prevented.

The difference between an incident and a complication is difficult to define (see chapter 3). During the interviews, 5 complications were put forward by interviewees which were actually incidents because their causes were known. In this research, these complications are treated as incidents.

So, a number of incidents were initially presented as complications but are incidents because their causes are known. This emphasises the importance of having a sound definition of the concepts ‘incident’ and ‘complication’; because the data analysis is different, incidents and complications should be registered differently. In the case of complications, the possible causes need to be established. In the case of incidents, these are known. There is a need to look more deeply into complications to check whether they are, after all, incidents.

Below, a list of the complications discussed which are (potentially) preventable, is presented. The list describes the effects—the top events i.e. the complications—on the patient and, if discussed, the possible causes:

- The (too) short life span of a shunt. The most important probable causes are:
  - Problems with the needle in accessing the shunt.
  - Patient’s blood has too high haemoglobin level and/or excessive coagulation time.
  - Too long and/or too much squeezing.
  - Too much fluid withdrawn during dialysis.

- The clogging up of a shunt. Possible causes:
  - Temporarily too low diastolic pressure, e.g. during the operation. What is the cause of this low diastolic pressure?
  - Compress applied around a shunt for too long or too tightly. What would be ‘too long’ or ‘too tight’ in this case?
• Poor accessing of shunt by the nurse. For the patient, this may result in bruises and a loss of the shunt. The ‘poor accessing of shunt’ may have to do with the nurse’s accessing technique, but it may also be that the shunt is defective. The latter possibility may be pointed out by a nurse and then the doctor can order to have an examination performed. If it takes too long before a follow-up examination is requested and performed, it may result in percutaneous angioplasty being no longer possible and to the shunt needing to be replaced. Periodical checks of the accessing technique used and of the shunt are necessary (see also the recommendations).

• Withdrawing too much fluid from the patient. This is:
  – Bad for heart and blood vessels in general and for the shunt in particular. It can shorten the life span of the shunt.
  – Bad for the general well-being of the patient; the patient may get convulsions.

• Problems with subclavian catheter. Catheter has no or inadequate flow capacity, and this results in inflammations.

• In the case of inserting a subclavian catheter, the following complications are possible:
  – Haemothorax. Possible causes:
    * Patient moved when subclavian catheter is inserted.
    * Surgeon pricks through the blood vessel because he does not, or cannot feel properly, whether the needle is actually within the blood vessel.
    * Position of the blood vessel is abnormal because of the patient’s abnormal anatomy.
    * The condition of the vessel is bad.
    * Inadequate oral communication of special circumstances.
    * Careless reading of the patient file.\textsuperscript{15}
  – Pneumothorax.

• Needle slides out of the patient’s blood vessel. Possible causes:
  – Patient is fidgety.
  – Patient is engaged in an activity (e.g. making sandwiches).
  – Warmth, so that the plaster comes off.

\textsuperscript{15}A patient file consists of a nursing file and a medical file. Depending on the context, patient file means the nursing file, the medical file, or both.
- Hairy arm, so that the plaster does not stick well. A solution might be to shave the arm. However, in the circumstances, this is not possible or the patient does not want to have this done:
  * For cosmetic reasons: the shunt becomes more conspicuous.
  * Because the shunt may become damaged while patient is being shaved. Small wounds may result.

- Peritonitis after changing the extension line of the catheter or because of actions which the patient has performed at home as part of his PD. Possible causes:
  - Infection of the peritoneum with Staphylococcus aureus.
  - Infection of the peritoneum with bacteria found in the mouth and bronchial tubes.
  - Inflammation of the catheter entrance or catheter tunnel.
  - Infection of the peritoneum with E. coli.

- Infection of the catheter entrance because of a failure to remove the plaster on the catheter entrance before taking a shower.

- Internal haemorrhages caused by repositioning a catheter. However, the patient had been admitted to hospital for two days for the purpose of repositioning the catheter and was probably not dialysed during that time; evidently, the hospital does not have the staffing capacity to perform this repositioning on the same day and perform the necessary dialyses.

A number of preventable complications are not specifically mentioned because, for instance, the possible causes were unconnected with the hospital, as in the case of complication number 2 in table G.4 on page 320, or because the complication discussed dated back 22 years and was no longer relevant, see complication number 3 in table G.4 on page 320. The complications for which no plausible reasons could be found during the research and which therefore remain for the time being unpreventable,\(^{16}\) are not specifically mentioned here, either, but are presented in table G.4 on pages 320–332. An example of a complication belonging to this category is a lowering of the blood pressure during the dialysis.

**Recommendations** as a result of the during the CIIs discussed (potentially) preventable complications:

\(^{16}\)Hopefully, this will be a temporary problem which the CIRMS—or, more specifically, that part of the CIRMS which Koornneef [80] calls a learning system—can tackle.
• The life span of a shunt needs to be prolonged as much as possible. Perhaps a study group should be set up to look into this and provide information to haemodialysis nurses, haemodialysis patients, and other persons concerned both within and outside the hospital.

• Withdrawing too much fluid from the patient during the haemodialysis should be avoided. Perhaps there should be an examination for every patient of how much fluid over which period of time could be withdrawn. It would perhaps be advisable to set up a study group to look into the variables (e.g. seasonal influences) which apply to the withdrawal of fluid from a patient over a set period of time and to the (technical) possibilities for withdrawing this fluid from a patient over a set period of time (e.g. the functional features of new dialysis machines).

• Setting up a study group to look into the possible causes of the short life span of the subclavian catheters. At the same time, the construction of the catheter by the surgeon and the option of an alternative like a Tesio catheter should also be examined.

• Look into ways of preventing the needle from sliding out of the vessel. Perhaps a study group can be set up to look into this.

• A protocol needs to be drawn up for the periodic check of the nurse’s accessing technique of a shunt. If necessary, the technique the nurse uses should be improved. This issue should be tackled in an open, relaxed and mature way. After all, for the patient a shunt is very important (it is literally a life artery), but once in a while, something goes wrong with accessing a shunt. Therefore, accessing a shunt must be performed properly because this is essential for the success of a course of treatment. A number of (general) points can be made to ensure that the evaluation and (potential) improvement of accessing skills can be performed smoothly and properly:
  - Making mistakes is part of a learning process.
  - Feedback is often hard to accept but should still be viewed as constructive.
  - Accessing skills need to be discussed, in order to prevent the poor accessing of shunts from becoming a structural problem.
  - ‘Explaining away’ errors or mistakes by attributing these to a defective shunt should (as much as possible) be prevented.
  - There should be a focus on the continuous improvement of the accessing skills and techniques.
A self-evaluation of skills is possibly a solution to ensure that the accessing skills of every dialysis nurse are up to the mark. Perhaps left-handed dialysis nurses may be able to access certain types of 'strange' shunts more easily.

- A protocol should be drawn up for periodic checks of the quality of a shunt. If necessary, (preventive) percutaneous angioplasty of the shunt may be performed.

- Oral communication should be improved.

- The patient file should be read more carefully.

- The periodical testing of PD patients on their knowledge of and skills in PD protocols e.g. the PD actions the patients have to perform at home. If necessary, the protocols should be adapted, e.g. be made clearer.

- The hospital should ensure there is sufficient staffing capacity and should not keep patients waiting longer than necessary before admitting them: if it is established in the morning that a certain type of surgical intervention is necessary, for instance, the repositioning of a catheter, then in principle this intervention should be performed on the same day. If this is not possible, a controlled course of care provision should be organised, in the course of which the patient is dialysed at set times.

### 7.4 FMEA

#### 7.4.1 Approach

The FMEA participants were selected by the nursing manager of the Haemodialysis department—after consultation with the management. The FMEA group consisted of three haemodialysis nurses (including the Haemodialysis nursing manager) and a PD nurse. The researcher acted as coach. Every FMEA participant received in advance an explanatory letter setting out the method and the purpose of the meeting, and a participants’ manual (see appendix C).

Four meetings were held and they all went smoothly. The process descriptions which were used during the FMEA meetings, were, at the same time, (further) validated during the meetings. See section 7.1 for a list of differences with the FMEA in the OR.

In the case of the extent to which a certain cause could be corrected, the FMEA mainly looked at its visibility, i.e. whether a cause could be identified immediately, or whether it was dormant and had a small chance of being identified.

The FMEA focused only on the physical effects on patients.

For more information about the FMEA, see section 3.4.3.
7.4.2 Results, conclusions and recommendations

In this section, the results of the FMEA will be discussed. Of the methodological results, the workload and lead time will be discussed. Of the results with respect to the content, the results and conclusions and recommendations will be discussed.

Workload The workload of the FMEA was relatively small compared with that of the CIIs and the process description. In the course of four meetings, all (primary) processes of the systems haemodialysis and PD were covered and the failure modes with their concomitant causes and effects were discussed. The average time of a meeting was about 2½ hrs. In the case of an FMEA, elaborating the results in detail did not, relatively speaking, involve much work.

Lead time The lead time was relatively small. The four meetings were planned in fairly rapid succession.17

Failure modes During four FMEA meetings, in total 29 possible failure modes of processes inside the Haemodialysis department and PD were generated on the basis of the process model which had been created. The FMEA team restricted itself to the possible physical effects on the patient and ignored the psychological effects—without wishing to detract in any way from the seriousness of these. This was not always easy because the psychological effects of a failure mode can be worse than its physical effects. Psychological effects can also result in physical effects, as, for instance, in the case of a patient who has to wait for an hour, who in consequence becomes stressed and whose blood pressure goes up. The results of the FMEA are presented in table H.1 (see pages 334–345) in appendix H.

<table>
<thead>
<tr>
<th>Summary of the data and data processing: Haemodialysis FMEA</th>
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<tbody>
<tr>
<td>The n of failure modes = 29. The n of causes = 73. See also table 7.4 on page 237.</td>
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</table>

The failure modes which were found using the FMEA are to be found in table H.1 (see pages 334–345), together with the accompanying effects and causes, and with the measures generated by the FMEA group and—if determined—guarantees that the measures would be implemented:

- A suboptimal dialysis result by selecting the wrong artificial kidney. This is caused by not looking at the patient's day list or because the artificial kidneys are not or hardly distinguishable from each other.

17In the period from 7–29 April 1998.
• Due to a lack of resources, the number of (spare) dialysis machines is inadequate, and so patients have to wait, dialysis treatments last longer than expected and patients experience physical discomfort in consequence.

• Insufficient blood supply because of a bad shunt or a catheter not working properly. As a result, the dialysis is either ineffective, or the dialysis becomes impossible and a new entrance needs to be made. In this case, the patient will possibly have to wait even longer for the construction of a new entrance (shunt).

• The incorrect insertion of the needle, the needle sticking through the blood vessel, and the obstruction of the shunt can all lead to a high venous pressure. The result may be that the process needs to be repeated, the patient has to wait longer and therefore the treatment takes longer, the patient may get extravasations of blood, and the shunt can (temporarily) not be used optimally.

• A failure to mention in the day report that the artificial kidney is becoming clean may result in the patient’s loss of blood going unnoticed for a long time. This may result in anaemia, in being given a blood transfusion and in the addition of epo. This is because dialysis nurses underestimate the importance of making a note about the artificial kidney becoming clean.

• If the doctor arrives too late for a consultation or does not do his rounds in accordance with the planning schedule, then it is possible that the patient is left with unanswered questions, that the dialysis treatment is not adjusted, and that the results are not scrutinised and/or are not communicated to the patient. All this is caused by bad planning and/or organisation: the number of doctors available is too low.

• On Saturday mornings, one doctor does his rounds and another is on call. On Saturday afternoons, no doctor does his rounds. The Saturday is regarded as part of the ‘weekend’, and the result is a shift of standards: care aspects which are considered to be important on weekdays, are apparently not important during the weekend. The patient may be left with unanswered questions, the dialysis treatment cannot be adjusted (should this be necessary), results (if any) are not scrutinised and/or communicated to the patient, and if the patient is out of luck—i.e. he also needs dialysis on a Saturday—then there is a chance that the patient may go a whole week without seeing a doctor.

• Because the examination room is often occupied (the examination room is also used for PD), the patient often has to wait and is often dragged around in search of
an examination room. In the worst case, the examination is made in the (screened off) dialysis chair, because there is not enough room in the Dialysis department.

- Because urologists and cardiologists underestimate the importance of the examination, a patient has to wait too long for the urologic and cardiologic examination results, and there will be a delay in the patient’s being put on the transplant waiting list.

- The nursing file is not read carefully by the nurses. This may be a matter of oversight on behalf of the nurses or perhaps the nurses underestimate the importance of working carefully. The consequence for the patient is that a proper evaluation is not made or there is a failure to make an appointment.

- Because the importance of proper reporting is underestimated in the Dialysis department and there is a perception among the nurses that the data which need to be reported will be known anyway, the treatment is reported incompletely by the nurses. In consequence, the patient continues to be bothered by complaints longer than strictly necessary.

- Because of the absence of a clear distinction between what is temporary and what is permanent, temporary components become permanent. This results in a ‘self-mutating’ policy in which temporary actions become permanent policy. The consequences may be that the patient will continue to be bothered by complaints much longer, and that the patient may be ‘overtreated’, which may be rather inconvenient and stressful.

- Policy changes are not recorded in the computer system because of incorrect reports by the nurse, or because of the incorrect (or no) input (into the computer system) by the nurse. As a result, the patient cannot get his medication for a couple of weeks.

- Because of bad communication in the Dialysis department, the message that the patient will need another appointment time is not passed on. As a result, an examination has to be postponed because the dialysis brooks no delay and therefore takes priority.

- Uncertainty about the job and the job description of the social counsellor results in irregular, incomplete or no reporting. As a result, patients receive inadequate social support.
• The frequency of delivery of artificial kidneys and blood lines is too low, as a result of which the dialysis starts at a later point of time and lasts longer than expected. For reasons unknown, the sterile supply room will not cooperate.

• Goods are delivered too late by the transport service as a result of which the dialysis starts at a later point of time and lasts longer than expected. The delivery frequency of Medimath\textsuperscript{\textcopyright 18} is too low.

• A doctor in training is not conversant with the form ‘waiting room’ (or the relevant organisational procedure) and does not fill in the form. The consequence is that the patient is informed too late about the treatment plan, and may be given the wrong treatment plan.

• Patient may be bothered longer than necessary by his complaints because there is an incomplete (or no) communication of the information which was collected during the first and the second dialysis and the pre-dialysis stage. This happens because there are no regulations about the communication of information in the protocol in question.

• Patient may be bothered longer than necessary by his complaints because nurses hardly, if at all, use the information checklist. This is because of the nurses’ insufficient awareness of the importance of using a checklist.

• Patient does not dare to phone to call the doctor in attendance, or it is not clear who is the doctors in attendance. The patient does not get in direct touch with the doctor and is instead put through to the doctor in training who is insufficiently conversant with the dialysis or to a dialysis nurse who is not allowed to make a diagnosis. As a result, the patient has to wait longer and gets the feeling that he is being driven from pillar to post.

• The dialysis nurse connects and disconnects ICU patient, and the ICU nurse supervises the subsequent treatment and calls in the dialysis nurse in the case of problems. However, the ICU nurse does not perform his monitoring duties properly, as a result of which the dialysis process is disrupted too often. This may result in the interruption of the continuous dialysis treatment, it may result in unnecessary loss of blood, and the entrance to the bloodstream may get blocked. All this may be caused because the ICU nurse is insufficiently conversant with the CVVH

\textsuperscript{\textcopyright 18}Medimath is the automatic supply system of the Catharina Hospital named after the cabinet in which certain materials (medicines, sterile goods etc.) are stored.
treatment, because he omits changing the fluid bags, or because of an error in operating the machine (although the operating instructions are indicated in big, bold letters on the very machine).

- CCU (Coronary Care Unit) nurse performs his monitoring duties of a CAVHD treatment unsatisfactorily. This may result in the continuous dialysis treatment being interrupted, it may cause unnecessary loss of blood, and the entrance to the bloodstream may get blocked. This is because of being insufficiently conversant with the treatment, and because the treatment does not occur frequently enough to ensure a good level of quality.

- A patient cannot change until later and/or has to change with different fluid/concentration because the supplies of fluid in the PD chamber in 9 East\textsuperscript{19} are inadequate: the PD nurse should check supplies and, if necessary, order additional supplies when a large number of patients is being admitted. This is because the frequency of delivery by Medimath is too low, and because the sterile supply room will not cooperate.

- Because the PD nurse does not know the date of the CAPD catheter implantation, the catheter may possibly be constructed in the wrong place because the catheter has not been clearly marked off, or it may be that the patient needs again to be fitted with a new catheter. The failure to mark off the catheter may be because the date of the implantation has not been passed on to the PD nurse by the doctor in training, or because the nurse of 9 East did not get in touch with the PD nurse. The need to fit a patient with a new catheter may be due to the fact that the catheter was constructed in the wrong place.

- A patient may get peritonitis because he is given no prophylactic antibiotics. This is because the doctor in training has failed to instruct the nurse of 9 East, or because the nurses of either 9 East or the Haemodialysis department have failed to contact the doctor in training (checklist).

- MDO\textsuperscript{20} (Multidisciplinary Consultation) may be postponed and questions raised by the patient are not discussed if the data of the patient in question are not available or incomplete, and/or if the doctor in attendance and/or the care nurse are not present. This is because of poor planning or because there has been a change in the planning which was subsequently not passed to another discipline/department.

\textsuperscript{19}Department 9 East is the Internal Diseases nursing department.
\textsuperscript{20}In Dutch 'MultiDisciplinair Overleg'.
• The medical policy for the patient is started only after a delay because the patient has to wait a long time in the Haemodialysis department before the doctor's arrival. This is because the doctor in training has too much work to do, or because the patient does not stick to the appointment: the patient has to take the initiative to make an appointment.

• A patient may have a problem in regard to his changing time (CAPD), because he has to wait for too long in the Haemodialysis department for the doctor's arrival. This may be because the doctor and/or the patient do not make sufficient allowances for the patient's changing times of fluid bags.

• (According to the PD unit) there is inadequate staffing capacity to train several patients simultaneously. This results in a waiting list, and the patient must temporarily change over to haemodialysis because the PD treatment cannot start yet; first the catheter has to be inserted. This is caused by insufficient insight into the possibilities and limitations of the availability of training staff, which is twice 8 hrs. a day. No research has been conducted into this.

Recommendations The recommendations result directly from these failure modes and causes, and were mostly formulated by the FMEA group itself: see for this the column 'Measures' in table H.1 (see pages 334–345). The column 'Guarantee' in the same table is partly processed in here.

Recommendations as a result of the failure modes and causes found during the FMEA:

• To prevent a wrong artificial kidney from being used, the day list of the patient always needs to be checked carefully in advance. In addition, the artificial kidneys should be made to look as distinct as possible. This may be achieved, for instance, by letting the packing, the legend, the shape and the colour of the artificial kidney stand out as much as possible. When storing the artificial kidneys, a distinction can also be made, for instance by storing the non-standard artificial kidneys in another place in order to minimise as much as possible chances of making an error or mistake.

• The number of (spare) dialysis machines is inadequate. There should be more dialysis machines.

• The surgeon or the person who examines the patient needs to intervene sooner if the blood supply is inadequate because of a bad shunt or malfunctioning catheter.
• It should be pointed out to the nurses once again that, if the artificial kidney is becoming clean, this needs to be recorded in the day report.

• Doctors arriving too late for a consultation or their failure to do their rounds in accordance with the planning schedule, should be discussed in quality consultations. Whenever this occurs, nurses should point this out to doctors. If necessary, planning and organisation need to be adjusted and the number of doctors be increased.

• On Saturday mornings, not all doctors do their rounds, and no doctor does his rounds on Saturday afternoons: care aspects which are considered to be important on weekdays, are, apparently, not regarded as important during the weekend. Doctors should be consulted about doing rounds on Saturdays.

• The examination room is often occupied because there is a lack of room in the Haemodialysis department. This should be taken into account when drawing up any future plans for extending the hospital.

• A patient's being put on the transplant waiting list is delayed because urological and cardiological research results are too slow in becoming available. The nephrologists should make clear the importance of expediting examinations to urologists and cardiologists, so that the patient can be put on the transplant waiting list sooner.

• Careless reading of the nursing file by nurses results in failure to make an evaluation or make an appointment. This needs to be pointed out (again) to the nurses.

• Patient is bothered longer by symptoms because the treatment is reported incompletely by nurses. This needs to be pointed out (again) to the nurses.

• Because of 'self-mutating' policy in which temporary actions degenerate into permanent policy, the patient is bothered longer by symptoms and may be 'overtreated', which is inconvenient. This needs to be pointed out (again) to the nurses.

• Policy changes are not recorded in the computer system, as a result of which the patient does not get his medication for a few weeks. This subject should be raised at the periodic discussions of progress.

• Failure to pass on that the patient must be assigned another appointment time, resulting in the cancellation of an examination because the dialysis takes priority. Discussions should be held about ways of improving methods of passing on information.
• Irregular and/or incomplete or no reporting by the social counsellor about the dialysis patients results in inadequate social support. There is no readily available solution to this problem; this part of the social counsellor’s job has been taken on by nurses.

• The frequency of delivery of artificial kidneys and blood lines is too low, resulting in the dialysis starting too late and lasting longer. The frequency of delivery of artificial kidneys and blood lines needs to be increased to three times a week.

• Supplies are delivered too late by the transport service, as a result of which the dialysis starts later and lasts longer. The frequency of delivery by Medimath needs to be increased to three times a week.

• A doctor in training is not told about the ‘waiting room’ form (i.e. the organisational procedure) and does not fill in the form. The form should be included in the file of the doctor in training.

• A patient may be bothered by complaints, longer than necessary, because there is incomplete or no communication of the information which has been collected during the first and second dialysis and at the pre-dialysis stage. The information protocol needs to be adjusted because there are no regulations about the communication of information in the protocol. Clearer and more specific instruction should be given to the waiting room nurse.

• A patient can walk around, bothered by complaints, longer than necessary because the nurses hardly, if at all, use the information checklist. The usefulness of the checklist should be brought up for discussion. A possible solution may be the adjustment of the checklist.

• A patient does not get in direct touch with the doctor and is instead put through to the doctor in training who is insufficiently conversant with dialysis or to a dialysis nurse who is not allowed to make a diagnosis. The patient has to wait longer and gets the idea that he is being sent from pillar to post. It should always be clear who is the doctor in attendance, or care should be taken to ensure it is under all circumstances possible to get in touch with the doctor in attendance, for instance by the automatic redirection of a telephone number. It is the doctors’ duty to increase their accessibility and remove any inhibitions their patients may have about contacting them.

• Dialysis nurse connects and disconnects ICU patient and the ICU nurse monitors the subsequent treatment and calls in the dialysis nurse in the case of problems.
However, the ICU nurse does not perform his monitoring duties properly, as a result of which the dialysis process is disrupted too often. This may result in the interruption of the continuous dialysis treatment, it may result in unnecessary loss of blood, and the entrance to the bloodstream may get blocked. The solution is the transfer of the CVVH treatment to the ICU. Another solution would be to let the dialysis nurse work attendance shifts at night and at the weekend.

• CCU nurse performs his monitoring duties of a CAVHD treatment inadequately. This may result in the interruption of the continuous dialysis treatment, in unnecessary loss of blood, and in the blocking up of the entrance to the bloodstream. The CCU nurses should receive periodical and/or additional training with regard to the CAVHD treatment.

• A patient cannot change until later and/or has to change with different fluid/concentration because supplies of fluids in the PD chamber in 9 East are inadequate. The frequency of delivery by Medimath should be increased to three times a week and, at times when many patients are being admitted, additional supplies should be laid in.

• Because the PD nurse does not know the date of the CAPD catheter implantation, the catheter may possibly be constructed in the wrong place because the catheter has not been clearly marked off, or it may be that the patient needs again to be fitted with a new catheter. A brief induction course should be given to doctors in training, and specific arrangements should be made with 9 East/Short Stay about when to call in the PD nurse. It may also be arranged that the surgeon marks off the catheter. All this should be submitted for discussion to the PD unit.

• A patient may get peritonitis because he is given no prophylactic antibiotics. Effective instructions should be given to new doctors in training, and this needs to be included in the file for the doctor in training. The nurses of 9 East or the Haemodialysis department (also) have to make arrangement about the prophylactic antibiotics or follow the checklist. This should also be discussed in the PD unit.

• MDO may have to be postponed and questions raised by the patient may not be discussed if the patient's data in question are not available or incomplete, and/or if the doctor in attendance and/or the care coordinator nurse are not present. This can be prevented if the planning is done centrally by the secretary instead of by each care nurse individually. This recommendation has been realised in the meantime.
7.5 Conclusions and recommendations

- The medical policy for the patient is initiated only after a delay because the patient has to wait a long time in the Haemodialysis department for the doctor’s arrival. This should be a matter for discussion in the quality consultations.

- A patient may have a problem in regard to his changing time (CAPD), because he has to wait for too long in the Haemodialysis department for the doctor’s arrival. This issue should be raised in the quality consultations.

- (According to the PD unit) there is inadequate staffing capacity to train several patients simultaneously. This results in a waiting list, and the patient must temporarily change over to haemodialysis because the PD treatment cannot start yet; first the catheter has to be inserted. An investigation into this problem at managerial level should be conducted. It could also be discussed with other dialysis centres in order to generate a fruitful exchange of ideas.

In the course of its meetings, the FMEA team generated three failure modes which are not related to (possible) undesirable physical effects on the patient and which therefore fall outside the scope of this research. It would nevertheless be advisable to look into these failure modes and try to prevent them (the three failure modes are presented at the end of table H.1, see pages 334–345).

7.5 Conclusions and recommendations

This section starts with a discussion in section 7.5.1 of the question whether it is necessary to perform both CIIs and FMEA. Section 7.5.2 discusses conclusions and recommendations for directly improving patient safety in the Haemodialysis department, and section 7.5.3 discusses conclusions and recommendations with a view to improving risk management in the Haemodialysis department.

7.5.1 CIIs or FMEA or both?

The conclusions which can be drawn from the CIIs and FMEA are complementary and therefore both (CIIs and FMEA) should be performed. The CII and the FMEA, as retrospective and prospective methods respectively, are complementary methods. A comparison of the causes generated by the two methods is not possible without classifying the causes—this was done in the OR, see chapter 4, with all concomitant problems this involved (see also chapter 5)—and it is much easier, and maybe better, to look at the final results produced by the two methods: the recommendations which can be made as a result of using both methods. Of the 29 recommendations resulting from the FMEA, only
4 recommendations—which is 14%—appear to correspond with the recommendations made on the basis of the results of the analysis of the incidents discussed during the CIIs (see also chapter 8). These 4 recommendations relate to the following risks:

- The differences in outward appearance between the standard and non-standard artificial kidneys are, in the case of some artificial kidneys, too small (this risk occurs in both the FMEA recommendation and the recommendations as a result of the CII causes and recovery factors found).

- The communication of information is ineffective (this risk occurs in both the FMEA recommendation and the recommendation as a result of the CII recovery factors found).

- Doctors in training are not sufficiently conversant with organisational protocols and procedures (this risk occurs in both the FMEA recommendation and the recommendations as a result of the CII causes and recovery factors found).

- Suboptimal CVVH at the ICU: this is because, at the moment, the Haemodialysis department and the ICU are jointly responsible and qualified for the dialysis treatment of ICU patients, and in actual practice they jointly administer the treatment (this risk occurs in both the FMEA recommendation and the recommendations as a result of the CII causes and recovery factors found).

The conclusion which can be drawn from the research in the Haemodialysis department is that the CIIs and FMEA largely complement each other, and they should therefore both be performed, provided time and resources allow this. Should this not be possible, a choice will have to be made. If a process description which can be used by an FMEA is already available, then an FMEA should be made because its workload and lead time are relatively small compared with the CIIs, although the number of problems and recommendations generated by CIIs is much larger. If there is no process description, there is not much to choose between an FMEA or CIIs, as far as workload and lead time are concerned. However, viewed over (a longer period) of time, the combination of FMEA and process model scores better since in the case of changes to the system, the process model can be adjusted and a future FMEA would then only need to be held for the changed processes.

A summary review of the results of the methods used in the Haemodialysis department is presented in table 7.4 on the next page.

Of the 28 structural factors found with the CIIs, the vast majority falls in the failure categories ‘absence of or inadequate protocol and/or procedure’ (16 times) and ‘lack of knowledge and/or experience’ (8 times), see also table 7.3 on page 211 and table G.2 (see
### 7.5 Conclusions and recommendations

Table 7.4. A summary review of the Haemodialysis results regarding the process model, the CIIIs and the FMEA.

<table>
<thead>
<tr>
<th></th>
<th>CIIIs</th>
<th>FMEA</th>
<th>Process model</th>
</tr>
</thead>
<tbody>
<tr>
<td>n of incidents</td>
<td>33</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>n of causes</td>
<td>180</td>
<td>73</td>
<td>–</td>
</tr>
<tr>
<td>n of structural causes</td>
<td>28</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>n of recovery factors</td>
<td>17</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>n of complications</td>
<td>23</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Percentage of complications at least preventable</td>
<td>65</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>n of failure modes</td>
<td>–</td>
<td>29</td>
<td>–</td>
</tr>
<tr>
<td>Mean n of causes per incident/failure mode</td>
<td>5.45</td>
<td>2.52</td>
<td>–</td>
</tr>
</tbody>
</table>

n of recommendations as a result of the:

- Causes                      | 25    | 29   | –             |
- Recovery factors             | 22    | –    | –             |
- Complications                | 10    | –    | –             |

Size model: n of charts        | –     | –    | 31\(^a\)     |

n of problems                  | –     | –    | 19            |

\(^a\)Including one legend and one overview chart.
pages 315–317). The vast majority of the recovery factors found during the CIIs recover or intend to recover this protocol/procedure failure (11 times) and lack of knowledge (4 times), see table G.3 on page 318–320. The majority of complications are preventable, see table 7.4 on the preceding page (and table G.4 on page 320–332).

7.5.2 Conclusions and recommendations regarding improvements

This section will present a number of observations and will discuss a number of conclusions and recommendations with a view to directly improving patient safety in the Haemodialysis department; all this as a result of the overall picture that emerges after studying the results of the process description, the CIIs and the FMEA:

- The role played by the doctor in training in the successful outcome of the dialysis is very important. He is present all day, he is an important source of recovery factors, and is also an important factor in rectifying errors that may have crept in. However, every four months there will be another doctor in training. Although the doctor in training is an important source of recovery factors, the doctor in training is at the same time an important risk factor, particularly in the initial stages of the period of four months that a doctor in training is present in the Haemodialysis department. This is somewhat paradoxical. In any case, as suggested before, failure and recovery factors of incidents and complications can be collected and presented to novice nephrology doctors in training.

- Transfer moments are failure-sensitive. It is therefore recommended always to check the state of the system (patient, equipment, medicine etc.) after the transfer.

- There is a feeling that there should be a more prompt reaction in the form of a follow-up examination when nurses indicate that a shunt is bad. If the reaction is too slow, the condition of the shunt may have deteriorated so much that percutaneous angioplasty is no longer possible and the shunt needs to be replaced. This fits in with the above recommendation for periodical check of the shunts.

- The hospital should increase the level of staffing outside office hours so that a larger number of specialists and doctors in training will be in attendance.

- The frequency with which the dialysis nurses perform CAVHD is too low as a result of which experiential knowledge is inadequate: a certain level of practice and skills is not established, let alone maintained. A clearer protocol and additional training are required to raise and keep the knowledge and skills up to the mark.
7.5 Conclusions and recommendations

- Nephrologists should be more persistent in their dealings with Surgery with regard to the construction of a CAPD catheter. Surgeons should coach their doctors in training better, and should draw up better guidelines.

- Inadequate consultation between the specialist who initiates the policy and the nurse who carries out the policy.

- The importance of working in accordance with protocol is emphasised once more by the 'anecdotal' incident of someone who habitually does not build up his machine in accordance with protocol, but already 'cleverly' changes certain settings when building up the machine, so that these changes no longer need to be made when actually connecting the patient and using the machine. When this same person is handed a machine which has been built up strictly in accordance with protocol by a colleague, he will forget to change the relevant settings. This example shows that it is absolutely essential always to work in accordance with protocol. This applies to all doctors and other staff.

- The unreliability of the blood and blood product ordering procedure is a problem the hospital should tackle. The results of the risk management project in the OR corroborate this conclusion.

- A large part of the recovery factors are not accidentally but structurally present and are built into the system, for instance, manually restoring blood to the patient in the case of a failure of the dialysis machine.

- The ICU in particular is a source of recovery factors, especially with regard to the dialysis treatments provided there. This would once more seem to justify the above recommendation to transfer the CVVH treatments to the ICU.

7.5.3 Conclusions and recommendations regarding risk management

This section will present a number of observations and discuss a number of conclusions and recommendations with a view to improving risk management in the Haemodialysis department; all this as a result of the overall picture that emerges from studying the results of the process description, the CIIs and the FMEA:

- The conclusion seems justified that the three risk management methods used in the OR—the process description method based on In 't Veld, the FMEA, and the CII in combination with the CTA—can also be used in the Haemodialysis department.
In order to increase and/or maintain the level of awareness and to expand experiential knowledge, it would be advisable to bring up for discussion a few incidents from which lessons can be drawn during the periodic discussions of progress (for instance once every four weeks). This can be done by the reporter of the incident, provided this does not clash with the 'culture' and work climate. A risk management protocol may be drawn up for this.

It would be advisable to anonymize the descriptions of the CIIs by removing all the names and job descriptions, and to present them to all employees, doctors in training and specialists associated with the Haemodialysis department for the specific purpose of learning from them.

Qualitative causal trees may be used to register and describe complications.

The FONA procedure is not effective and presents a false sense of security to the outside world. Of the total of 32 incidents discussed in the course of the CIIs, only 4 FONA reports were drawn up. The results of the risk management project in the OR support this conclusion.

The number of structural causes that were found during the CIIs was 28 based on 33 incidents; in the OR, 20 structural causes based on 17 incidents were found during the CIIs. The number of recovery factors which were found during the CIIs in the Haemodialysis department was lower than during the CIIs in the OR. The CIIs in the Haemodialysis department provided 17 recovery factors based on 33 incidents, 13 of which were successful, the CIIs in the OR provided 22 recovery factors based on 17 incidents, 14 of which were successful (see also table 8.1 on page 256). The larger number of structural causes per CII in the OR may be accounted for by the fact that the OR comprises a larger number of different processes and is more complex than the Haemodialysis department, resulting in more, and more diverse incidents. Thus, when a small sample of these incidents is discussed by CIIs, this leads to less overlap in the structural causes found, and therefore to a higher average of structural causes per incident. The larger number of recovery factors per CII in the OR may be accounted for in the same way. Because the OR is a larger and more complex system than the Haemodialysis, more, and more successful (accidental) recovery may be possible because of the greater degree of freedom (to control processes) offered by a larger and more complex system. Also the fact that a larger and more complex system may be more difficult to control—thus providing more opportunities for ad hoc recovery actions—may have been a contributing factor in this.
7.5 Conclusions and recommendations

- The data show that the FMEA complement the CIIIs well. Of the 29 recommendations on the basis of the FMEA results, 4 recommendations appear to correspond with the recommendations which were made on the basis of the CII incident analysis results. An explanation of why there was no greater overlap other than that the FMEA and CIIIs apparently assessed different patient risks or that both the FMEA and CIIIs apparently assessed only a relatively small part of all patient risks, cannot be given. See also section 7.5.1. A comparison of this with the OR results is discussed in chapter 8.

- The workload and the lead time for the application of all three methods is considerable. As mentioned in the introduction, the lead time of the project (excluding the reporting [153]) was 11 months. The work load and the lead time of the FMEA are, in principle, the smallest and briefest. However, in order to be able to use the FMEA, a process model is necessary, and creating such a process model is laborious and time-consuming. The use of a less elaborate and therefore less laborious process model is no option. See also the considerations mentioned in section 7.5.1.

- It remains difficult to get a true picture of the actual numbers of incidents that occur. The fact remains that it is much better to report and analyse incidents than to do nothing about them or to deny their existence. The reporting of incidents should be encouraged by the management because incidents contain valuable information for the management, and this information is wasted if incidents are not registered and analysed. So, a permanent incident registration system should be set up. The voluntary incident reporting system that was set up in the function group OR in 1995, may serve as an example. The big advantage is that such a management system is able to show clearly what the structural causes of incidents are. This would make it possible to take measures to prevent incidents from occurring in future. After the incident reporting system has been implemented, it can be enlarged with other kinds of process deviations such as complications and Arbo incidents (e.g. pricking incidents, people straining themselves when lifting heavy objects etc.). Because a complication may be the result of an incident and may not manifest itself until after some time, a complication registration needs always to be accompanied by an incident registration. The (possible) causes of complications are often known—and thus (potentially) preventable—especially in the case of complications which may have been caused by human intervention. An example would be complications which are inherent in the course of a certain disorder (in other words, which originate from the patient himself); compare these with complications which are caused by medical and nursing policy, and by medical and
nursing actions. An example of the latter would be the complication of a shunt becoming blocked up after the shunt was (probably) tied up too tightly. ‘Tying up a shunt too tightly’ is obviously a human act and therefore modifiable. Blood clotting, on the other hand, is patient-related and virtually impossible to modify. A complicating factor is the presence of a cause-effect relationship between the ‘condition of the patient’ and the ‘medical and nursing policy’. What is meant by this is that the condition of the patient is affected by the policy pursued and vice versa. See for this also chapter 3. In addition, complication registration should always be extended beyond the system boundaries (in other words, extend beyond the hospital department): because of a relatively long ‘incubation period’, a certain complication may manifest itself not in the place within the system in which it originated, but at a later time and in another place within the system (e.g. infections). Because of this, relevant causal factors of complications should be recorded from the moment the patient enters the hospital (system). As already mentioned in section 7.1, it was not possible to implement an IRMS in the Haemodialysis department because not enough time was left for this: the risk management research had to be finished because of the expiry of the researcher’s temporary contract with the hospital. However, if there had been more time, a CIRMS would have been implemented instead of an IRMS.

- In the case of incidents the name(s) of the person(s) who from a causal point of view is/are involved in the incident, should be recorded. However, this should be done with the greatest care and tact because it may adversely affect people’s readiness to report incidents. The focus should at all moments be on the continuous improvement of the skills and knowledge of doctors and employees, and protocols and procedures needed to steer this in the right direction should be drawn up. For instance, if a doctor’s or employee’s actions cause an incident (or complication), the name of the person who caused it should be put on record. In the description of a Complication and Incident Reporting and Management System (CIRMS), the recording of complications (by name) has already been provided for; this should also apply to the recording of incidents. Should the incident occur again, as a result of the actions of the doctor or employee, then this fact may, in a positive spirit, be evaluated, for instance, by looking for ways of improving skills or increasing knowledge or expertise.

- Before and during the risk management project, employees and doctors in the Haemodialysis department were already consciously engaged in the (continuous) improvement of the quality of patient care. This is completely in keeping with the
7.5 Conclusions and recommendations

spirit of these times and the nature of the (care) processes within the Haemodialysis department which to a great extent can be described and managed in 'industrial terms'. The latter aspect is a big advantage if the aim is quality management which is (still) being approached from an industrial production perspective. The risk management project has resulted in employees and doctors becoming more conversant with risk and quality management. This can, in our view, only have led to an (even) greater involvement in and commitment to the quality of care. So, this is also possibly a small but important step towards continuous quality management, for instance, a Complication and Incident Reporting and Management System (CIRMS) which records complications and incidents permanently, and tries, by means of specifically targeted analysis, to prevent as much as possible the development of incidents and complications. The risk management project has hopefully facilitated the introduction of such a reporting system by changing the (safety) culture for the better. The development and implementation of a management system for recording and analysing all incidents and (a part of the) complications can therefore be recommended highly. Incident and complication recording is necessary as a part of quality management and for the purpose of achieving process control.

- To gain a deeper insight into the development and therefore also into the prevention of complications, targeted research is necessary. This means that the recording of the nature and frequency of occurrence of complications needs to be unequivocal. In the case of the recording of complications, many more variables are taken into account than in the recording of incidents, because with complications, the causes are not known and the analysis needs therefore to be in greater depth, and more comprehensive than with incidents. A few points worthy of consideration in this context are:

  - In order to be able to recognise institute-dependent causes of complications, it would be preferable if various dialysis centres were to take part in the recording.

  - The recording and analysis of incidents also need to take place because incidents can cause complications.

  - The examination and recording of incidents take place mainly at management level. The examination and registration of complications take place mainly at management level, but above all also in medical terms: the investigation into the origin and development of complications has both managerial and medical epidemiological aspects. A model for the origin and development of
incidents and complications is presented in chapter 3 which is, among other things, based on this research.

- It would be advisable to have, for instance, more epidemiological research into the development of complications carried out by doctors in training. An example of such a complication is complication number 8 in table G.4 on pages 320–332: a shunt becoming blocked which results in physical effects on the patient. On the one hand, this is, in part, an incident, for instance, the element of the (too) tight compress around a shunt. On the other hand, it is also, in part, a complication: which causes and mechanisms are of relevance, and how can these be prevented? Here, the importance of an exclusion definition becomes evident: it does not matter what it is called—incident or complication—as long as it is recognised, recorded and analysed. The above-mentioned collaboration in this area with other haemodialysis centres is also necessary in order to be able to distinguish and determine the institute-dependent factors.

The management team of the Haemodialysis department has to eliminate the shortcomings and failings which have been set out above, and to effectuate and expedite the development and implementation of a permanent CIRMS. This management system can serve as a starting-point for the further development of a quality system. Risk management as part of quality management is a cyclical process and a never-ending aspect of management, like marketing.

**Necessary future risk management steps** It is up to the Haemodialysis department management—and the hospital management—to commit itself to the continuation of the risk management policy that has set in motion, e.g. the development and implementation of a permanent CIRMS. However, judging by the experiences in the OR (see chapters 4, 5 and 6), it is essential for successful risk management to have a risk management structure in place—both at departmental level and hospital level—which uses the assessed risks to generate and implement improvements. Unqualified top-down management support is absolutely necessary. The parallels with quality management—e.g. the above-mentioned management structure at different organisational levels (see chapter 2), the generation and implementation of improvements, the top-down management support—are evident. The management team, both at hospital level and at departmental level, should take the lead in this.
Part III

Conclusions and recommendations
Conclusions and recommendations

Executive summary

In this research a variety of methods—in combination with some tools and models—were used, ranging from retrospective (CHIs) via 'real time' (IRMS) to prospective (FMEA), to assess patient risks. Because the assessment of patient risks was done successfully both in a complex, multidisciplinary function group (OR) and in an 'industrial', a monodisciplinary department (Haemodialysis department), it may be concluded that the methods, tools and models used may also work in other hospital departments. However, in order to process the assessed risks into improvements, a learning agency (i.e. someone who learns on behalf of the organisation) [80] is necessary to ensure that learning experiences become embedded in the organisation. A framework consisting of these methods, tools and models in combination with a learning agent may provide the board of directors of a hospital with a policy instrument for risk management which can be enforced on hospital departments. Necessary conditions for effective risk management are that the hospital organisation is willing to learn, that the organisation is prepared to embark on risk management—for instance by appointing a safety board—and that explicit provisions in budgets and in the allocation of staff time are made in order to organise and configure a learning agency. A brief proposition for the composition of such a safety board is shown in the figure below.

\textsuperscript{a}See also page 30.

\begin{center}
\begin{tikzpicture}

\node (board) {Member of board of directors};
\node[below of=board, node distance=2cm] (agency) {Learning agency};
\node[below of=agency] (pharmacy) {Pharmacy: safety};
\node[below of=pharmacy] (engineering) {Engineering: safety};
\node[below of=engineering] (care) {Care: safety};
\node[below of=care] (nursing) {Nursing};
\node[below of=nursing] (medical) {Medical};
\node[below of=medical] (disciplines) {Disciplines (Surgery, Dermatology etc.)};

\draw[->] (board) -- (agency);
\draw[->] (agency) -- (pharmacy);
\draw[->] (pharmacy) -- (engineering);
\draw[->] (engineering) -- (care);
\draw[->] (care) -- (nursing);
\draw[->] (nursing) -- (medical);
\draw[->] (medical) -- (disciplines);
\end{tikzpicture}
\end{center}

8.1 Introduction

The aim of this risk management research was to improve patient safety. As stated in chapter 1, the reduction of patient risks can be divided into two parts: the assessment of risks and the organisational learning from risks. The focus of this research was on the as-
essment of risks; Koornneef's recent thesis [80] focuses on organised and organisational learning from incidents.

This chapter contains generally applicable conclusions and recommendations. The following questions will be answered:

- Which lessons can be learned from this research with regard to the risk management methods used and the risks found? This question will be answered in section 8.2 with regard to the risk management methods used, and in section 8.3—by way of illustration of the kind of output produced by a risk management system—with regard to the risks found.

- If the research could be repeated all over again, which issues would be reconsidered? Reflections about certain issues are discussed in section 8.4.

- Which recommendations can be made for further research? And what should be done in the near future? These questions will be answered in section 8.5.

### 8.2 Risk management methods used

This research used a number of methods to assess and analyse failure modes, incidents and complications: Critical Incident Interviews (CIIs) in combination with Causal Tree Analysis (CTA), Failure Mode and Effects Analysis (FMEA) in combination with process descriptions, and incident reporting via an IRMS. The Eindhoven Classification Model (ECM) was also used for the CIIs, the FMEA and the Incident Reporting and Management System (IRMS). The question what could be learned from the methods used resulted in a number of conclusions and recommendations which will be discussed in this section. A general conclusion is that the methods and techniques used in this research for the assessment and analysis of incidents—and to a lesser degree, of complications and health and safety incidents—can probably also be used for diagnostic failure, environmental incidents, waste or process deviations with other effects. This is because the main distinction between these deviations is the difference in their effects.

Although the ECM was chosen as a classification model for the classification of incident causes (section 3.4.6), the recognisability and translation of classifications into measures to be taken (see table 3.7 on page 76 and on page 77) proved to be difficult. After the first analysis of the IRMS results, the classification of incident causes was terminated because the time needed per analysis turned out to be too long (too laborious), see also table 3.7 on page 76 and on page 77 where the time per analysis was underestimated, and section 5.2. In the end the classification of causes was only used for the
comparison of the results of the CIIs and the FMEA,¹ see section 4.5.

The reliability of the classification of incident causes in accordance with the Eindhoven Classification Model of system failure (ECM) is low. The reliability problem was partly obviated by having the causes classified by a group of people over a short period of time. Training is not a solution because the problem is the general vagueness of the ECM.

**Recommendation 1.** Should the ECM be used again in the future for the comparison of different risk management methods, research should be conducted into the reliability of the classification process of classifying incident causes in accordance with the ECM, and into ways of increasing this reliability.

Fortunately risk management does not require a classification model for causes, see the risk management project in the Haemodialysis department in chapter 7.

This research shows that Causal Tree Analysis (CTA) is useful as a method for analysing patient incidents. A drawback is that the quality of the causal tree is personal and therefore considerably subjective. The reliability of the CTA method should be improved. Another drawback is that, if the CTA method is used in a more routine way for analysing large number of incidents, the method proves to be too laborious.

**Recommendation 2.** Research should be carried out to determine the reliability of CTA and into ways of increasing this.

The above leads to the following conclusion:

**Conclusion A.** The reliability of the combined use of CTA and ECM is low.² The use of both CTA and ECM is laborious, the combination of the two methods proves to be too laborious for routine use. The ECM is not necessary for risk management and can be omitted.

However, the combination of CTA and ECM provided clear lessons for improvement (see section 8.3), and for insights into the use of CTA and ECM which turned out to be very instructive.

The CIIs and FMEA are both laborious—in spite of the omission of the classification of the causes found in accordance with the ECM in the Haemodialysis department. If a process description has already been created, the job of making the FMEA itself is not a laborious one (see e.g. section 7.5.1, page 236). Creating a process description takes time and effort, but it is an essential part of a risk management system.

¹After the use of the classification of causes in accordance with the ECM in this research [140, 151], the ECM has also been used for research purposes in health care by e.g. [134, 161].
²See section 5.2, e.g. on page 145.
Recommendation 3. A process description is an essential part of a risk management system, and, if it is absent, time and effort must be found to create a process description.

The assessment and analysis of incidents in the case of a voluntary IRMS is also time-consuming—in spite of the omission, after some time, of the classification of the causes found in accordance with the ECM. In general, this research shows that implementing, using and maintaining a risk management method is very laborious, and should not be underestimated, see also Koornneef [80] and Van der Schaaf [154]. However, it does provide clear lessons for concrete improvements (see section 8.3), and also insights into and improvements for performing better risk management in the future (this section), and is therefore arguably cost-effective. This results in the following more general conclusion and recommendation.

Conclusion B. Risk management is time-consuming but it is essential.

Recommendation 4. Further research should be carried out into examining whether there are ways of improving the efficiency of risk management.

Risk management needs to be more efficient in order to make it possible for, for instance, a risk manager—see section 8.4—to carry out risk management in several function groups simultaneously.

The experiences gained with the FMEA in the OR were that not all possible failure modes were generated. This was because of the limited time per meeting, the limited number of meetings, and the incomplete use of the process model as a guideline to ensure no process was overlooked (see section 4.3.2). Because of the limited time available, it was not possible either to use the six Ms as safeguards that no causes were overlooked. All this results in the following conclusion and recommendation.

Conclusion C. The management should take risk management techniques more seriously and make more resources available.

Recommendation 5. The hospital should make explicit provision for risk management in budgets and in the allocation of staff time.

The CIIs and FMEA are both valid and assess process failure which may result in patient risks. But how about the causes found by the CIIs and FMEA: is there an overlap in the causes found? This question was not answered by directly comparing the causes found by the two methods because the two methods only assessed a part of all (possible) patient risks, which means that comparing them directly is not very useful. So, in the
OR the causes found by the FMEA and CIIs were classified and these classified causes were compared, so that the *kind* of causes found by the methods could be compared. The chi-square tests in section 4.5 convincingly demonstrate that the distributions of the classified FMEA and CIIs causes do not result from the same basic distribution. However, it was noticed in section 4.5 that the classified causes of both methods result in the same three ECM classification categories—OP, OM and HR5 (see appendix E for an explanation)—in which the greater part of the causes were classified. In the Haemodialysis department, the question of whether there was an overlap in the causes found by the FMEA and CIIs, was answered by comparing the recommendations resulting from the FMEA and CIIs in order to determine how many of them overlap. The conclusion arrived at in section 7.5.1 was that there was a 14% overlap in the recommendations found and that the CIIs and FMEA complement each other. So, on the basis of the above and also in view of the fact that both an FMEA and CIIs can only assess a part of the set of all patient risks in a complex (sub)system (such as a hospital department), the following conclusions may be drawn.

**Conclusion D.** An FMEA as a prospective risk assessment method for patient risks does not find the same (categories of) causes as do the retrospective CIIs.

**Conclusion E.** Because an FMEA and CIIs only assess a small part of the set of all patient risks in a complex (sub)system (such as a hospital department), a large overlap is not likely, and both an FMEA and CIIs can be carried out because they complement each other’s risk assessments.

If sufficient resources and time are available, both an FMEA and CIIs should be performed. If a choice has to be made between an FMEA and CIIs, and a process description of the (sub)system is available, an FMEA should be made because its workload and lead time are relatively small compared with the workload and lead time of CIIs. If no process description is available, no preference for either an FMEA or CIIs can be established on the basis of workload and lead time, but an FMEA might be a sensible idea because this necessitates the creation of a process description which can subsequently be used for other quality management activities. Viewed over time, the combination of FMEA and process models scores better since, in the case of changes to the system at a later date, the process model may be adjusted and a future FMEA will in principle only need to be made for the changed processes.

**Conclusion F.** If a choice has to be made between an FMEA and CIIs, an FMEA is preferable to CIIs.
Chapter 8. Conclusions and recommendations

The above leads to the conclusion that neither the CIIs nor the FMEA by themselves are adequate for the purpose of assessing all (possible) structural incident causes, and that probably even the combined use of these methods will not assess all (possible) structural incident causes, either. So, this poses the question of how to assess all (possible) incident causes. Or, phrased differently and more pragmatically, what is the most reliable method for estimating patient injury? This issue was already discussed in chapter 1: Wilson et al. [181] plead for a retrospective review of medical records as the most reliable method, but O’Neil et al. [114] compared physician reporting with medical record review and found that reporting uncovered as many incidents as did record review, and that reported incidents are more likely to be preventable. Reporting was used in the OR by the IRMS. However, the distribution of reporters and non-reporters (see figure 5.5 on page 158 and figure 5.7 on page 159 based on the first 345 incidents reported), and, in the case of the reporters, the substantial differences in the number of incidents they report (also based on the first 345 incidents reported) feed the suspicion that the IRMS still suffers from the problem of under-reporting. The suspicion of under-reporting is reinforced by the fact that the reporting of incidents to the FONA committee primarily involved medication errors and falling incidents mostly reported by nurses [29], see also e.g. [141]; medication errors and falling incidents are not or hardly ever found by using the risk management methods used in this research, including the IRMS. The question is why these falling and medication incidents which were not mentioned during the FMEA and CIIs, were reported to the FONA committee. This may be because a number of the falling and medication incidents had so few consequences for the patient that the reporter to the FONA committee may have felt that nobody could be compromised by reporting them. They may, however, have considered this kind of incidents to be not important enough to mention them during the FMEA and CIIs. In the case of reporting falling and medication incidents to the IRMS which operates independently of the FONA system, the fact that the falling and medication incidents were reported exclusively to the FONA committee was perhaps because it is a custom which has developed over time. This leads to the conclusion that the FONA reports complement the reports to the IRMS, the incidents discussed during the CIIs and the failure modes discussed

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3I.e. for the number of incident reports per reporter, the standard deviations were greater than the means, see table J.1 on page 352.

4See also the end of section 5.5 and, in particular, table 5.10 on page 177 for the conclusion about the deterioration of under-reporting based on the incident analysis after the first 345 and last 178 incidents reported.

5NB: the FONA system itself is subject to under-reporting, see sections 4.4.2 and 4.4.3, which the FONA committee itself is aware of [49].

6Kooreneef [80] writes in this context: 'The compulsory form to report patient-related incidents is hardly used by members of the medical staff: it is too time-consuming and its usefulness is doubted; conversely, the nursing staff uses this form regularly, mainly to report fall incidents and medication errors.'
during the FMEA.

Because the number of incidents collected by the risk management methods used in both the OR and the Haemodialysis department is many times larger than the number of incidents reported to the FONA committee and also displays much greater diversity, it is safe to say that the risk management methods used are a necessary complement to FONA reports for the purpose of informing the management about risks in the organisation which the management would otherwise be unaware of.

The contribution of the FONA and the earlier discussion about the reporting of falling incidents and medication errors to the FONA, have to be put into perspective because in 1995, the total number of FONA reports from the OR was 29, 2 of which were medication errors and none were falling incidents [49], and also because the conclusion (based on the CII results) may be that the vast majority of the incidents were not reported to the FONA committee. It is unlikely that the addition of the FONA reporting system to the methods used will result in an assessment of the complete range of possible structural incident causes.

**Conclusion G.** FONA reports by themselves are inadequate as a source of management information with regard to patient risks, but they can complement an IRMS.

**Recommendation 6.** Make the FONA report an integral part of the reporting of incidents to the IRMS or CIRMS.\(^7\)\(^8\)

The issue of under-reporting to the IRMS cannot easily be obviated by making incident reporting compulsory like the FONA reporting, but substantial improvements will have to come from a greater involvement of doctors and employees, for instance by more frequent and better feedback meetings.

To maintain the level of willingness to report, feedback should be given to the doctors and employees about the measures that are taken to reduce risks, also with a view to maintaining people’s awareness of risks and incidents. Periodical discussions of incidents to enlarge the system-experience knowledge of doctors and employees, may also be held during the feedback stage, see also section 8.4. The following conclusion—which is also a recommendation—can be drawn.

**Conclusion H.** In the case of the voluntary incident reporting to the IRMS, adequate feedback should be given to the reporters to maintain the level of willingness to

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\(^7\) Koornneef [80] integrated the FONA report into his SINS (Systematic Incident Notification System) to minimise the workload for a reporter (‘one-stop policy’: to prevent the same data from being submitted twice for different notification purposes).

\(^8\) See also the remark about the solution to the blaming bias of the FONA system as a prerequisite on page 124.
report, in order to minimise under-reporting and to enlarge the system-experience knowledge.

In summary, the fact that there are virtually no falling and medication incidents and the fact that the distribution of reporters and non-reporters (large group of non-reporters) in combination with the distribution of reports per reporter (for which the standard deviations are greater than the means) prove that there is more or less under-reporting in the case of voluntary incident reporting, i.e. the IRMS in the OR, and that there are blind spots with regard to the scope of the FMEA and CII methods, leading to the following conclusion and recommendation.

Conclusion I. The methods used in this research’s risk management framework did not assess the whole range of all possible patient incidents and thus do not assess all patient risks.

Recommendation 7. Research should be conducted into testing or designing new risk assessment methods for the purpose of assessing a larger part of the set of patient risks. These methods can then be incorporated into the risk management framework.

Possible candidates for this might be prospective analysis methods such as HazOp [26, 39] and Design FMEA [146].

Recovery factors which can be assessed by e.g. CIIIs and incident reports, should be recorded and analysed. Awareness of recovery factors and their application are discussed by Gaba et al. [55] who write about ‘breaking the chain of accident evolution’. Gaba et al. [55] discuss ‘loose coupling’: ‘systems in which the causal network is more flexibly linked, or linked in a much slower temporal fashion’. What happens in one part of the system does not directly affect other parts as is the case with ‘tight coupling’. Gaba et al. [55] write about loose coupling: ‘A mainstay of anesthetic practice involves attempts to loosen couplings, by keeping homeostatic mechanisms intact when possible (awake intubation, regional anaesthesia); providing temporal buffers (titration of drugs, and use of

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9 The reporting of medication and falling incidents is mentioned in literature, see e.g. [5, 40, 88, 92, 104, 119, 120, 139, 167].

10 An FMEA can be used in two different ways. The first is assessing failure modes and determining the effects and causes of an existing system, called ‘Process Potential FMEA’ in which risks (caused by (lack of) process control are identified [146]. This was the case in the function group OR and in the Haemodialysis department. The second way is assessing failure modes and possible effects and causes for a system which still does not exist, called ‘Design FMEA’ [146], see also e.g. [50].

11 For more information about loose and tight coupling, see [117].
drugs with short onset times and rapid termination of effect); and providing safety margins using appropriate pre-treatments (pre-oxygenation, atropine in children, etc.). Further means of loosening coupling should be identified and promoted. Gaba et al. [55] also advise to ‘improve the detection of simple incidents’, to ‘improve the anaesthesiologist’s ability to construct and utilize useful mental maps of anesthetics in progress’ (for the development of anesthesia simulators to assist in training and education, see also Nyssen [112]), to ‘enhance recovery by detailing backup equipment appropriate for various types of surgery’, and to ‘catalog and disseminate effective protocols for handling of rapidly propagating incidents’. This leads to the following recommendation.

Recommendation 8. Explicit research into the phenomenon of recovery should be encouraged.

It is interesting to note that in November 1999, the EUT started a research project focused on recovery factors, see e.g. [73, 74, 155]. Van der Schaaf and Kanse [155] formulate ‘the following tentative implications for designing a socio-technical system:

- Consider recovery promotion as an alternative to failure prevention, especially when certain errors or failures are predictably unavoidable.

- Do not simply design out failure factors without considering the possible reduction of recovery factors: raising the level of automation in process control, or installing too many decision support tools for your operators may leave them helpless under certain situations.

- Support all recovery phases (detection (observability), localisation, correction (reversibility)) primarily by means of an optimal man-machine interface.

- Invest in deep process knowledge of operators: reasoning beyond procedures appears to be essential for many recovery actions. Also, consider error management training [51]: learning to learn from errors is perfectly in line with the concept of recovery promotion.’

A summary review of the OR and Haemodialysis results of the methods used in both the OR and Haemodialysis department is presented in table 8.1 on the following page.
Table 8.1. A summary review of the OR and Haemodialysis results with regard to the process model, the CIIs and the FMEA.

<table>
<thead>
<tr>
<th></th>
<th>OR CII</th>
<th>OR FMEA</th>
<th>OR Process model</th>
<th>Haemodialysis CII</th>
<th>Haemodialysis FMEA</th>
<th>Haemodialysis Process model</th>
</tr>
</thead>
<tbody>
<tr>
<td>n of incidents</td>
<td>17</td>
<td>-</td>
<td>-</td>
<td>33</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>n of complications</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>23</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>n of failure modes</td>
<td>-</td>
<td>66&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-</td>
<td>-</td>
<td>29</td>
<td>-</td>
</tr>
<tr>
<td>Size model: n of charts</td>
<td>-</td>
<td>-</td>
<td>9&lt;sup&gt;b&lt;/sup&gt;</td>
<td>-</td>
<td>-</td>
<td>31&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mean n of causes per incident/failure mode</td>
<td>5.76</td>
<td>9.65&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-</td>
<td>5.45</td>
<td>2.52</td>
<td>-</td>
</tr>
<tr>
<td>Mean n of recovery factors per incident</td>
<td>1.29</td>
<td>-</td>
<td>-</td>
<td>0.52</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Percentage of complications at least preventable</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>65</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>n of risks/problems</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>19</td>
</tr>
</tbody>
</table>

<sup>a</sup>After the removal of the failure modes which led to psychological effects on patients, and effects on employees and doctors (see section 4.5). Without this removal, the n of failure modes found by the FMEA is 85, and the mean n of causes per failure mode 11.73.

<sup>b</sup>Including one legend and one overview chart.
What is noticeable is that the Haemodialysis process model consists of a number of charts more than three times the number of charts of the OR process model. The number of failure modes found with the FMEA, on the other hand, is less than half the number of failure modes which was found with the FMEA in the OR. The same goes for the mean number of causes per failure mode for the Haemodialysis FMEA which is less than one third of the mean number of causes per failure mode for the FMEA in the OR, see table 8.1 on the preceding page. The same goes for the difference in the mean number of recovery factors per incident. A possible explanation for this may be that the Haemodialysis process is, relatively speaking, standardised and controlled in a more industrial-production-way, and has fewer degrees of freedom—the process is smaller and less complex—than the OR process. This facilitates the (easier) creation of a more detailed process model, it results in fewer failure modes and fewer opportunities for recovery. See also section 7.5.3. Also the fact that the Haemodialysis process was created later (e.g. the FMEA in the OR took place in 1995, the one in the Haemodialysis department in 1998) and the fact that the Haemodialysis department was (perhaps as a consequence), to the researcher’s mind, further advanced in quality thinking\(^{12}\) than the OR, are relevant in this context.

At the beginning of this research, the assumption was that a large number of incidents would have to be collected in order to be able to learn from them via profiles of classified causes.\(^{13}\) However, this view changed and in the course of the risk management project in the OR, the following conclusion gradually emerged.

**Conclusion J.** A single incident may be enough to expose structural failure factors.

This conclusion was applied after changes to the original IRMS during the analysis of 523 incidents. It turned out to be possible to establish—even in the case of a single incident—whether certain elements in the cause-effect path have structural elements and are therefore likely to happen again in the future resulting in the same—or different—kind of incident. See, for instance, the blood-ordering procedure mentioned in table 6.1 on page 187. This conclusion is supported by Koornneef [80] who writes: ‘If the learning system is well organised, any organisation should be able to draw worthwhile continuous lessons from its small-scale incidents, however few they are’.

In the IRMS (see table 3.8 on page 78), one activity is trend analysis, which should check over time whether certain (sub)clusters become larger or smaller, particularly the

\(^{12}\)Quality management for its part is probably relatively easier in the Haemodialysis department than in the OR because of the above-mentioned greater standardisation and controllability of the Haemodialysis processes.

\(^{13}\)Koornneef [80] writes about this: ‘Learning about systemic causal factors just from large data sets, i.e. many cases, is a dead end street in accident analysis’.
(sub)clusters against which measures have been taken (see under activity 4 on page 79). There is a problem—a bias—when trend analysis is performed in this way, viz. the above-mentioned (possibility of) under-reporting of incidents to the IRMS. A solution to this probably does not exist except for trying to keep the under-reporting to a minimum. It is not a serious problem, either, if under-reporting remains at a constant level and does not change across scenarios. In that case it only makes the system less sensitive. Trends will only appear over a longer time. Trend analysis in this way should be performed because there is no better alternative. This also applies to the Complication and Incident Reporting and Management System (CIRMS) discussed in section 3.4.8. In this research, trend analysis was performed in the case of the IRMS clusters and complaint cards in the OR, comparing the IRMS clusters and complaint cards after the second analysis with the IRMS clusters and complaint cards after the third analysis, see especially section 5.5.

To explain the development of incidents and complications, two models are presented in section 3.3: a general model to account for the development of process deviations, and a model to account for the development of incidents and complications. As already mentioned in section 3.3.2, the causation model presented in figure 3.3 on page 54 is not completely watertight because in reality it is not always possible to separate and freeze cause and effect very neatly in a cause-and-effect chain—e.g. an effect can also be a cause—and the boundary between process deviation and failure, in so far as it is a cause, is not always clear. This inevitable domino effect can only be approached via careful recording and analysis. The definitions of incident and complication (see section 3.2) can be confusing: once the cause of a complication is known, the complication by definition becomes an incident.

**Recommendation 9.** Research could be carried out in order to get better working definitions for the concepts of incident and complication which does justice to the fact that both result in undesirable effects on patients and that complications need a different kind of analysis than incidents because, in the case of complications, causes may be (more) hidden.

This research produced a usable framework for risk management in hospitals by using the above-mentioned risk management methods (see section 3.4). These risk management methods were all successfully used to assess patient risks in the OR and in the Haemodialysis department. Only the CIRMS, planned for implementation in the Haemodialysis department, was not actually used owing to a lack of time. The risk management methods yielded information about patient risks—such as structural causes, suggestions for improvement—which could be used by the management. The question whether this information was adequate could not be answered because in the OR, the management
8.2 Risk management methods used

The team did not (or hardly) act on the information—see further on in section 8.4—and the improvement path in the Haemodialysis department was outside the time span of this research (the project in the Haemodialysis department finished the moment the risk assessment was completed). The risk management framework could possibly be improved with the earlier mentioned prospective methods such as Design FMEA and HazOp.

Using a risk management method like FMEA or CIIs is a good preparation for the implementation of a continuously present risk management method like an IRMS. The approach pursued in this research made a good start with risk management. The question which risk analysis method is the most suitable method in a specific situation cannot easily be answered. If considerations of time and money are ignored, the situation which needs to be analysed determines which method should be used. For example, in the case of patients who arrive improperly prepared in the OR, a number of FMEA meetings with all relevant parties may be a good method to assess the possible causes (i.e. to establish why different wards prepare patients improperly or inadequately) and to discuss possible solutions. Another example may be the situation in which a serious incident takes place in the Haemodialysis department. In this case, a CII or a number of CIIs in combination with CTA may be the best way to analyse this specific incident. In this way the specific incident can be thoroughly examined by interviewing all persons concerned, and the structural cause(s) can also be established. If it is a matter, for example, of monitoring the failure and incident situation in a particular department, an IRMS may be the best method. Or if it is a question of making a start with risk management in a particular department, an FMEA may be the right option, see also considerations about the available resources mentioned before in this chapter.

Interest in patient safety in health care—at least in the Netherlands—has been scattered and haphazard over the last few years, and consequently developments are slow and remain ‘work in progress’. There have been some new developments since the risk management project in the OR took place, mainly in the UK and US, and probably as a result of the above-mentioned report ‘To Err Is Human: Building a Safer Health System’ [78]. The Institute of Medicine (IOM, see also www.iom.edu), for instance, has set up a committee on data standards for patient safety. Among the safety and quality improvement systems and tools the IOM is considering, is HACCP (Hazard Analysis and Critical Control Points)—a systematic approach to the identification, evaluation and control of food safety hazards. A modified version of FMEA called HFMEA (Healthcare Failure Mode and Effects Analysis) is also a novelty.

The implication of this research is that the methods and models used and discussed in this thesis may also be used in other sectors outside the medical domain such as production environments (industry) or aviation (transportation) with an emphasis on e.g.
product quality or safety.

In the next section, some key lessons which can be learned from the risks found with the risk management methods will be discussed.

8.3 Risks observed

The risks found in this research are those which were revealed by data collected up to a given point of time (April 1998). Strictly speaking, they are specific to the Catharina Hospital. The issues mentioned in this section seem to recur often and are only a sample of the output of a risk management system; they do not present a complete picture of what is wrong (see criticism about the under-reporting of the IRMS). However, from the risks found with the FMEAs, CIIs, and IRMS—and to a lesser degree the process models—which are discussed in chapters 4–7, a number of conclusions can be drawn and recommendations can be made.

Conclusion K. All incidents and, at least, some complications are preventable and manageable.

This conclusion seems trivial—certainly because incidents were defined as having known causes, see section 3.2—but it is important to realise that incidents can be prevented, and that, at least, some complications are preventable. The research in the Haemodialysis department found that at least 65% of the complications discussed during the CIIs were preventable. This means that incidents, and to a lesser degree complications, can be managed. What is important in this context is the problem of definition, see the discussion in chapter 3. The difference between incidents and complications was defined in terms of whether the causes are known (in the case of incidents) or not (in the case of complications). Because both incidents and complications result in undesirable effects on patients, and because at least some complications can be prevented (i.e. at least those complications that are caused by incidents but which are not recognised as such), it is important that incidents and complications are assessed and analysed together. In order to show up complications as incidents, the Complication and Incident Reporting and Management System (CIRMS), which is discussed in section 3.4.8, can be used. This leads to the following recommendation.

Recommendation 10. Implement a Complication and Incident Reporting and Management System (CIRMS) to assess and analyse both incidents and complications.

Such a CIRMS can initially be implemented in the OR together with the implementation in those departments OR patients are transferred from or those departments patients
are transferred to after the operation. It is necessary to chart the complete route the OR patient takes during his hospital stay in order to be able to bring to light causes for complications. In this way, risk management provides the organisation with the means to maximise their efforts to prevent incidents.

This research shows that organisational failures are a large and important category, see e.g figure 4.1 (page 104) and figure 4.4 (page 110) which leads to the following conclusion.

**Conclusion 1.** The insight that the hospital and department management strongly influences (patient) safety is important, since the management creates and controls the system within which the professionals work and within which the (primary) processes take place, and thus also determines the risks within the system. The management is responsible for organisational failures which contribute to the development of incidents.

The management is not only directly responsible for organisational failure but also—more indirectly—for other kinds of failure like human failure.

This research shows that it is quite pointless and provides a false sense of security if protocols and procedures are in place but are not observed. It is better to recognise this and, in mutual consultation, change or drop the protocols and procedures in question. Therefore, the following recommendation can be made.

**Recommendation 11.** Protocols and procedures should be effective and effectively managed.

Doctors in training may suffer from a lack of skills and knowledge, and are often inadequately informed about (organisational) protocols and procedures (see e.g. [112]). In combination with insufficient supervision, this results in unnecessary risks for patients and in incidents. This is widely known but nothing is done about it. Mulcahy [103] puts this aptly: ‘It is incumbent on leaders of the profession and senior doctors to guarantee better supervision of young doctors. Repeated research has documented their vulnerability to mistakes, because they are asked to work extraordinarily long hours, to do more than they are capable of and because senior doctors are not readily available to them. The public is sceptical of the attitude that says this is good training for young doctors. It is training at an awful price, both for patients and doctors’. This is a well-known problem, as Robinson [126] puts it, ‘the latest reports once again point out that avoidable tragedies are caused by junior hospital doctors doing work beyond their level of knowledge and experience’, and, more concretely, ‘stillbirths rose not only with holidays and weekends, but also with the arrival of a new set of house officers every six months’. This leads to the following conclusion and recommendation.
Conclusion M. Doctors in training are a risk factor.

Recommendation 12. The supervision of doctors in training should be improved.

The lack of medical skills and of organisational and medical knowledge of doctors in training should be remedied by better supervision by specialists, by more robust organisational protocols and procedures, and by a greater focus on how conversant doctors in training are with these protocols and procedures—especially if the doctors in training are new in a department.

Incidents and complications may be the result of design errors. A number of these errors were highlighted in this research. Some are presented here: the packing of ampoules which look very similar and are stored closely together; the functionality of equipment like the dialysis machines which switch themselves automatically into the general safety state and cannot be reused again right away (the technical department will have to be called in before they can be used again); failure to have uniformity in equipment like the non-standard respirator in the OR; or, at the recovery room of the OR, a tap with turning knobs instead of a handle (which is not hygienic because, just after washing your hands, you have to use those very same hands to turn off the tap instead of pushing the handle with your arms). This leads to the following recommendation.

Recommendation 13. To prevent design errors, more attention should be paid to the design of equipment and the working environment.

Design errors can be prevented by making use of ergonomics, for instance by designing ampoules which are distinctive in shape, colour and texture (see e.g. [110, 113]). The responsibility for this could be delegated to the risk manager, see also section 8.4.

In the next section, reflections about this research will be given.

8.4 Reflections about this research

This research has shown that the assessment of risks is possible but that a lot still remains to be done to implement improvements. Two possible lines of approach to this may be the findings of Koornneef’s research [80]—see below in this section—and the appointment of a risk manager as coordinator of risk management activities. Moreover, this research has left a number of issues unexplored, e.g. diagnostic failure.

Looking back on this research, it would probably be a good idea to create the function of risk manager who can function as coordinator and provide support for risk management projects both at departmental and hospital level. The dedicated support of a
8.4 Reflections about this research

A risk manager is necessary as coordinator for the successful implementation of risk management.

**Conclusion N.** A risk manager is necessary as coordinator for the successful implementation of risk management.

**Recommendation 14.** Further research needs to be done to determine the best way a risk manager can disseminate information to increase experiential knowledge within a system.

Occupational risks and hazards should be assessed and analysed; this is a legal commitment and can also be assigned to the duties of the risk manager, in this case, of course, under the supervision of the Arbo coordinator. The risk manager can then assess and analyse health and safety incidents at departmental level, whilst the Arbo coordinator supervises the occupational risks and hazards at hospital level. In this way, the understaffing problem of the Arbo department—i.e. 1 Arbo coordinator for 2,400 employees—might be eased somewhat.

**Recommendation 15.** The risk manager can assess and analyse occupational\(^{15}\) incidents at departmental level.

For instance, the CIIs—in both the OR function group and in the Haemodialysis department—can be anonymized, and presented to the employees and doctors in order to learn from them and to increase the experiential knowledge within the system.

In order to draw up a profile for a risk manager, it should be mentioned that the results of risk management and the tracing of risks depend heavily on the qualities of the risk manager—such as motivation, attitude, experience, skills and knowledge—and cooperation by the management and the organisation. So, the risk manager must be able and be authorised to make recommendations to the function group and department, and

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\(^{14}\)In this research the role of the coordinator was performed by the researcher.

\(^{15}\)The term 'occupational' is interchangeable with the Dutch term 'Arbo'.
to the hospital management, a process in which (mutual) trust is of paramount importance: the risk manager has to gain the confidence of the department management, the hospital management, the doctors, the nurses and the paramedics in order to be assured of their cooperation. The risk manager contributes expertise, assesses problems and can put forward solutions. The management decides whether certain recommendations will be carried out. To keep in touch with the function groups and departments and to keep them involved, every function group and its department(s) should have a local learning agent [80]. The learning agent receives support from the risk management department and at the same time the learning agents support the risk managers. Because patient safety is a part of quality of care, the risk manager may have to cooperate closely with the quality manager. The risk manager is responsible for the risk management duties in the department or in the hospital, and his position in the organisation must give him the power, influence and credibility necessary to perform his duties. A risk manager needs to adopt a multidisciplinary perspective, to be able to think abstractly in order to describe processes and to assess and analyse incidents, and to be able to suggest improvements. In order to achieve all this, i.e. to manage things, the risk manager needs to have a practical outlook.

Initially, more risk managers will be necessary in a missionary role to get risk management started in every function group and department, and to implement a risk management system. Once safety is being taken seriously, and a certain critical mass of prevention and risk management is in place, the risk management department can be downsized. A minimum number of risk managers the hospital needs to appoint in order to establish a risk management department would be seven FTEs. This estimate is the absolute minimum based on the thirty-one function groups of the Catharina Hospital, on the estimate of one day’s work a week per function group—a minimum—and on the overall coordination of the risk managers. This is exclusive of the staffing capacity the function group itself will have to make available, which is based on the activities which are going to be performed by the local learning agents. So, the following recommendations can be made.

**Recommendation 16.** The hospital should—initially—appoint seven risk managers to make a start with hospital-wide risk management.

**Recommendation 17.** Each function group management team should appoint a local learning agent for their function group and their department.

As already stated in section 1.6, the focus of this research was on the assessment, the analysis and the prevention of the structural causes of process deviations. This research was successful in the assessment and the analysis of incidents at both the OR and the
Haemodialysis department. The prevention of incidents was less successful in the OR because hardly any measures were taken on the basis of the results of the FMEA, the CIIs and the IRMS, see also sections 5.5 and 6.2. With regard to the measure of success in preventing incidents in the Haemodialysis department, it was not possible to determine whether the prevention was successful and measures were actually taken; this was because the risk management report about the results of the CIIs and the FMEA in the Haemodialysis department was completed and handed over to the management of the Haemodialysis department after this research was finished. However, a number of the structural causes found had already been picked up and put right by the management team, see chapter 7.

Although initially—in the case of the OR—the attitude of the doctors and employees to risk management was considered to be a problem, it turned out that it was not the attitude of doctors and employees but the attitude of the OR and hospital management which proved to be a problem. The fact that nothing was done with the analysis results of incidents is astonishing: the (OR) management team is responsible for this but nevertheless took no action. Is the management not in a position to take action? Is it a form of management failure? Is it negligence, or is it the organisational culture which is responsible for this? Is it a matter of shirking responsibilities or of sheer wilfulness? All this proves that the real problem and challenge is not to find the risks for patients but to eliminate these risks.

**Conclusion O.** Eliminating risks was problematic: the management was not ready for risk management.

Why did not the OR manager and/or OR management take upon themselves the responsibilities and tasks with regard to the initiation and implementation of improvements? The plan was that, for the duration of the reorganisation, the regulation of the problem-solving process within and between departments would automatically be enacted in the various spheres of influence within the organisation. With regard to the OR, during (the start of) the risk management project, it was clear that the responsibilities and duties with regard to the initiation and implementation of improvements rested with the OR management, but the OR management neglected these tasks. The OR management should take these tasks and responsibilities upon itself, but if it fails to do so, the board of managing directors should delegate these tasks to the OR management. One reason why the OR management neglected to take upon itself these tasks was that the OR manager and/or the OR management was/were fearful of his and/or its own position, if they would be forced to take unpopular measures, especially against the doctors, who are very strongly represented and powerful within the hospital organisation, for instance via
the medical staff. The OR manager was appointed, first on a temporary basis and later permanently, just before the risk management project in the OR started.

**Conclusion P.** During the reorganisation, there was a failure to stipulate explicitly who is responsible for solving problems.

As mentioned above, the vast majority of the incidents discussed during the CIIIs was not reported to the FONA committee (see sections 4.4.2 and 4.4.3 and table G.1 on page 314). This means that the management was not informed about these incidents and was therefore unable to take measures.

**Recommendation 18.** The hospital should adopt risk management because it is essential to provide the management with the necessary information.

**Recommendation 19.** The OR management should use the risk management information to implement improvements.

This can be achieved by drawing up a protocol requiring the management to take action (see the next item). But this can also be the subject for further research.

Because the improvement path was left unfinished in the OR, a protocol should be drawn up which, if necessary, forces the management to implement improvements.

**Recommendation 20.** A protocol should be designed and implemented which guarantees risk management improvements after risks have been assessed.

But such a protocol will probably not be enough. Koornneef’s research [80] shows that, in order to learn from incidents, an organisation ‘needs to organise the learning process and allocate learning functions’. Koornneef uses Argyris’ Model I versus Model II approach to understand the ‘passiveness throughout all levels of an organisation to learn from unintended operational anomalies’. See e.g. [60] for a further discussion about organisational learning.

The demand that there needs to be top-level commitment to making risk management work, the demand that risk management needs to be integrated into other activities and structures within the organisation, and also the lack of organisational learning and the wasted opportunities for this, are conclusions which can be drawn from this research but which are also a recurrent theme in literature, see e.g. [86, 103, 176].

It was stated on page 214 that protocols/procedures should be drawn up for a number of issues which would increase the load of paperwork to be read and used, so these protocols and procedures had best be drawn up through the participation of all persons
concerned. A problem may be that the protocols/procedures add enormously to the burden of paperwork and bureaucracy, and it is an important question whether protocols and procedures will ever be drawn up and used, given the chaotic nature of hospitals. The (hospital) management does not take problem-solving seriously enough, partly because there is no one who specifically 'owns' the problem, and it needs to put more energy, resources and commitment into improvements.

**Recommendation 21.** Generally speaking, in order to perform effective risk management in hospitals, the following conditions should be met:

- Risk management should have unqualified management support at all levels within the organisation, and unqualified support from doctors.
- It should be made clear who is responsible for risk management in the department and/or in the function group and at hospital level. This clarity should also extend to managing and performing all activities including the improvement path.
- The focus should be on collecting information about the causes of incidents and complications and not on the question of guilt. Once the information has been collected, this should also result in action.

There was no structural quality policy and quality management in the OR and in the Haemodialysis department. If risk management is regarded as a form of and a part of quality management, the conclusion can be drawn that it is possible to make a start with quality management by starting with risk management. A risk management system in the form of an IRMS may serve as a basis for further quality management activities\(^\text{16}\) or care activities\(^\text{17}\).

**Conclusion Q.** Patient safety is a part of quality and therefore risk management is a differentiation of quality management. However, risk management can be performed independently of quality management and—for instance when there is no quality management—has no need to wait for quality management. Risk management can serve as a start and booster of quality management.

Analysing incidents and focusing on effects on patients show up weak spots in quality management and in the performance of the quality system. Risk management monitors

\(^{16}\text{For instance, the risk management results can lead to cooperation across function groups, departments, specialities and disciplines to control procedures.}\)

\(^{17}\text{For instance, the risk management results can lead to Arbo care activities or to the extension of the IRMS with Arbo incidents, see e.g. also sections 3.3.2 and 6.4.}\)
the condition and performance of the quality system. A hundred per cent patient safety can—probably—never be guaranteed, but hospital management should nevertheless aim at this target, and risk management is a powerful way towards achieving it.

**Recommendation 22.** Risk management can serve as a supplement to and watchdog of quality management.

As already stated as the beginning of this section, this research left unexplored a number of issues, for instance, with regard to diagnostic failure which can cause undesirable effects on patients. A question which could be asked—for instance, in the case of an erroneously positive and a erroneously negative diagnosis of appendicitis—is how effective the diagnosis protocol used is compared with other diagnosis protocols for the same disorder—in this case appendicitis. This could be an issue for future research.

**Recommendation 23.** Research into diagnostic failure—as a special kind of incident—should be carried out.

### 8.5 Near future

Every patient has a right to optimal care and can expect a hospital to do everything necessary to achieve this level of care. However, this research shows that this is not the case. This does not only apply to the Catharina Hospital but—according to literature [103]—generally speaking, it is the rule rather than the exception in health care. Nobody makes mistakes on purpose, and every patient should receive the best possible care, i.e. the requirement of rational process control is an absolute minimum. The solution is quite simple: focus on the patient and on process control—which quality management also focuses on—and the management should ensure that the necessary changes are made. This research shows that a number of risk management methods can be used to accomplish this goal. But which recommendations can be made more for the near future?

Extrapolation on the basis of this research would result in the foundation of an Institute for Patient Safety, partly based on the recommendation of the Institute of Medicine [78] for a Center for Patient Safety in the USA, see also [136]. Among other things, such an institute could be a knowledge centre which will engage in the development and testing of risk management methods and systems, and in making these available to care institutions, but also in the maintenance and actual management of reporting systems. These reporting systems can be used not only within the scope of an organisation but also for a specific technology or product. E.g. the Björk-Shiley convexo-concave
mechanical heart valve prosthesis studies (see e.g. [33, 80]) clearly show that a global reporting system is necessary to assess and control the risks involved with a medical device which is used in a critical application. Koornneef [80] distinguishes between the various levels at which 'the "learning agency" that is assigned to learn for the organisation'\textsuperscript{18} can be situated, for instance at global, national, regional, site or organisational unit level. An example of the global level could be the above-mentioned Björk-Shiley valve [32, 33, 80]. A national reporting system can deal with the national reports and—for some technologies or products—the global reports. Koornneef writes about this: 'surprises in the operational process that involve product failure require two sorts of learning. The first recovers the process despite the product failure. The second must feed the surprise back up the chain to the product designer, manufacturer and purchaser. The question which remains open is how to design and coordinate these two learning processes'. An Institute for Patient Safety could play an important role in the design and coordination of these two learning processes.

**Recommendation 24.** An Institute for Patient Safety should be founded as a knowledge centre focusing on the design, implementation, maintenance and management of risk management systems.

This institute can—by managing the information of multiple CIRMSes from different organisations—track specific groups of patients, which might be necessary for the effective reduction of the number of complications. In order to do this, the institute should be capable of unequivocally defining and subsequently collecting incident and (especially) complication data. This would be necessary to enable the institute to compare these data both inside and between organisations in order to detect weak organisational structures and other causes. This research shows that risk management could and therefore should be performed in every hospital regardless of the level of quality management.

\textsuperscript{18}The learning agencies in the context of this research would be the risk manager(s) and the IRMS committees mainly situated at function group and departmental level.
Bibliography


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Mrs M. van Liempt  Mr H. van Tuijl  Mr W. van Vuuren
B

Contents CD-ROM

• Charts of the function group Operating Room (in Dutch).
• Charts of the Haemodialysis department (in Dutch).
• Charts of the function group Short Stay (extra, not validated, in Dutch).
• Shareware version of ‘Chartist’ for MS Windows to read the charts. Chartist can be used to create process models and causal trees.
FMEA participants’ manual

Failure Mode and Effects Analysis (FMEA)

This manual contains an explanation of the FMEA method which will be used, and an example. The purpose of the FMEA, the FMEA analysis and Risk Priority Number (RPN) determination, the FMEA form, an example and the way of operating during the remaining FMEA meetings will be successively discussed.

Purpose of the FMEA

FMEA is a method which focuses on the assessment of potential risks: FMEA spots demonstrable causes and effects before they occur, by making an estimate of the probability density. Because the ultimate goal of the risk management project is the control of the processes in the department, the process-orientated variant of FMEA is used.

Failure modes, cause analysis, effect analysis and RPN determination

FMEA uses a cause-and-effect structure and is a group activity of relevant experts. While these experts do some brainstorming, using a model which describes the processes in the department, they explore this cause-and-effect structure.

By means of the FMEA method, the following things are mapped (see also the FMEA form further on in this manual):

A. The assessment of all conceivable ‘failure modes’ of the process. By failure mode, a process deviation is meant because of which the desired result is not achieved. The failure modes/process deviations are found by asking two questions:

- In which way can the process outcome be different from what was intended beforehand?
- In which way can a problem manifest itself in the subsequent process steps, or later?
B. The assessment of the possible effects of the failure modes. These may be effects in the subsequent process steps, but also later, even after the patient has left the department.

C. The mapping of the possible causes of the failure modes. By cause, a real basic cause (a so-called root cause) is meant: the cause can be corrected by means of an intervention in the process. For each effect, all possible basic causes are indicated. Sometimes it turns out that the different effects of a failure mode can be traced back to the same causes. The six Ms can be used as an aid to building a picture as broad and as complete as possible of the causes: Man, Machine, Method, Material, Measurement, Milieu.

For a graphic representation of the connection between causes (with the six Ms), failure mode and effects, see figure C.1.

In order to be able to establish priorities, the risks are quantified. For this purpose, the following three factors are estimated and then combined in an RPN of the risk:

D. The seriousness (Ser.) of the effects on every patient.

E. The frequency (Freq.) of occurrence of the (basic) causes.

F. The extent to which causes can be corrected (Corr.). Three aspects are important in this respect:

1. The visibility of the process deviation (accuracy/measuring quality of the measurement).

2. The lead time between the moment the failure occurs and the moment the failure is discovered (this is when the measurement is taken).
3. The *frequency* with which measurements are taken: if, for instance, a measurement is taken once a day, then half a day on average passes before the process deviation is detected.

The extent to which causes can be corrected is, in this case, mainly restricted to the quality of measurement, i.e. the accuracy or *visibility* (see the first point above). This is because the visibility of the process deviation is the most important factor of the three aspects mentioned: failure to spot a process deviation can have very serious consequences! Should aspects two and three (lead time and frequency) be relevant, then these can be discounted in the value which is assigned to the visibility by increasing it by one or more points (see appendix 2 of this manual).

Points D, E and F are plotted against a scale of one to ten. This scale is not absolute (see appendix 2 of this manual).

G. *The determination of the RPN of the risks*, so that priorities can be established:

\[
\text{RPN} = \text{seriousness} \times \text{frequency} \times \text{extent to which can be corrected}
\]

For an interpretation of the value of the RPN, see appendix 1 of this manual.

After this quantification, there is a final step in which the RPN is used to establish priorities, and next for the risks with the highest RPN:

H. *The generation of measures and guaranteeing these*. In this way, an attempt is made to minimise or exclude the risks of a certain failure mode. Additionally, arrangements need to be made about how to guarantee that these measures are actually implemented.

*The FMEA form*

In the course of the meeting, the results of the group discussions are reproduced on a so-called FMEA form:

|--------------|---------|------|--------|-------|-------|-----|----------|-----------|

Note that the columns correspond with the points A–H discussed above.
An example

On the next page, two examples are presented (one non-medical and one medical), filled in on an FMEA form:
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<tbody>
<tr>
<td>Flat car tyre</td>
<td>• Arrives too late at work</td>
<td>3</td>
<td>- Sharp object in tyre</td>
<td>4</td>
<td>9</td>
<td>108</td>
<td>- Checking tyres in the evening</td>
<td>• Change behavioural patterns</td>
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<td>- Worn tyre</td>
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<td>- Defective valve</td>
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<td>10</td>
<td>90</td>
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<tr>
<td>Urinary tract infection</td>
<td>• Taking medication</td>
<td>8</td>
<td>- Damaged packing of catheter</td>
<td>4</td>
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<td>160</td>
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<td>- Contact between catheter and</td>
<td>6</td>
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<td>144</td>
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<td>non-sterile object</td>
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<td>etc.</td>
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Method of working during FMEA meetings

After this explanation about the risk management project and the FMEA method, three more meetings will take place. During these meetings, the following steps will be discussed:

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Steps</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>A  Establish failure modes</td>
</tr>
<tr>
<td></td>
<td>B  Specify effects</td>
</tr>
<tr>
<td></td>
<td>D  Determine the seriousness of the effects</td>
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<tr>
<td>2</td>
<td>C  Determine the root causes of each effect</td>
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<tr>
<td></td>
<td>E  Estimate the frequency for each cause</td>
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<tr>
<td></td>
<td>F  Establish the extent to which a cause can be corrected</td>
</tr>
<tr>
<td></td>
<td>G  Determine the RPN of each risk</td>
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<tr>
<td>3</td>
<td>H  Formulate measures and guarantee these</td>
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</tbody>
</table>

Fill in:

<table>
<thead>
<tr>
<th>Group number: 1/2</th>
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</thead>
<tbody>
<tr>
<td>Meeting</td>
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<tr>
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</tr>
</tbody>
</table>

With questions and problems, you can always call or drop by:

Bastiën van der Hoeff
Training building: 11th floor
Telephone: 8920

Literature: [143, 146].
Appendix I. Explanation of the RPN value

When interpreting the FMEA result—a table with numbers which can range from 1–1,000—it is important to keep in mind the original objective of the FMEA: detecting pitfalls or time bombs. The greatest risks, which emerge from an FMEA as greater than 100, can be divided into the following theoretical main groups:

Ser. = 10 ; Freq. = 10 ; Corr. $\geq$ 1 These are serious and frequently occurring problems, and, of course, rather well-known: the FMEA confirms the problems.

Ser. $\geq$ 1 ; Freq. = 10 ; Corr. = 10 These are not serious quality losses which, however, are hardly ever spotted and corrected. The FMEA draws attention to areas in which the patient (or a subsequent step in the process) is caused discomfort. These offer opportunities for further improvement.

Ser. = 10 ; Freq. $\geq$ 1 ; Corr. = 10 These are serious, rarely occurring disasters for which the FMEA was intended in the first place. Although risks in this category can have the same risk factor as the two preceding categories, in practice priority will be given to this category.

After a critical evaluation of the FMEA results, the risks to be dealt with first will have to be selected. Thus, the factor to be decreased can also be selected:

Seriousness This is often difficult. Decreasing the seriousness of the effects of a failure means that the process must be robust for variations in the parameters in question. Most of the time, the process needs to be changed radically.

Frequency It is easier to lower the failure frequency, for instance, by adapting the maintenance schedule.

Extent to which can be corrected This is often the easiest solution which, unfortunately, is also most often overlooked. It is about the control structure of the process.
Appendix C. FMEA participants' manual

Appendix 2. Explanation of classifying the values of seriousness, frequency and extent to which can be corrected

**Seriousness**

<table>
<thead>
<tr>
<th>Seriousness</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No effects on patient and the subsequent process steps</td>
</tr>
<tr>
<td>(2) 3</td>
<td>No effect on patient, slight discomfort possible in the case of the next steps in the process</td>
</tr>
<tr>
<td>(4) 5 (6)</td>
<td>Affects patient and/or the subsequent process steps</td>
</tr>
<tr>
<td>(7) 8</td>
<td>Temporary effects on patient</td>
</tr>
<tr>
<td>9</td>
<td>Permanent effects on patient</td>
</tr>
<tr>
<td>10</td>
<td>Fatal effects on patient</td>
</tr>
</tbody>
</table>

**Frequency**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Never</td>
</tr>
<tr>
<td>2</td>
<td>Never in our department/function group</td>
</tr>
<tr>
<td>(3) 4</td>
<td>Rarely</td>
</tr>
<tr>
<td>(5) 6 (7)</td>
<td>Regularly</td>
</tr>
<tr>
<td>8</td>
<td>Often</td>
</tr>
<tr>
<td>(9) 10</td>
<td>(Nearly) always</td>
</tr>
</tbody>
</table>

**Extent to which can be corrected**

Initially, attention is only paid to the ‘visibility’ (the value of which, if necessary, can be corrected for the aspects ‘lead time’ and ‘frequency’).

<table>
<thead>
<tr>
<th>Visibility</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (2)</td>
<td>Definitely discovered</td>
</tr>
<tr>
<td>3 (4)</td>
<td>Probably discovered</td>
</tr>
<tr>
<td>5 (6)</td>
<td>Reasonable chance of being discovered</td>
</tr>
<tr>
<td>7 (8)</td>
<td>Small chance of being discovered</td>
</tr>
<tr>
<td>9</td>
<td>Probably unnoticed</td>
</tr>
<tr>
<td>10</td>
<td>Definitely unnoticed</td>
</tr>
</tbody>
</table>
D

Classification used during the Haemodialysis FMEA

This appendix presents the values of seriousness, frequency and the extent to which can be corrected, which were used during the classification of the Haemodialysis FMEA (cf. the values described in appendix C).

**Seriousness**

<table>
<thead>
<tr>
<th>Seriousness</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No effects on patient and the subsequent process steps up to and including effects affecting patient and/or the subsequent process steps</td>
</tr>
<tr>
<td>2</td>
<td>Temporary effects on patient</td>
</tr>
<tr>
<td>3</td>
<td>Permanent effects or fatal effects on patient</td>
</tr>
</tbody>
</table>

**Frequency**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Never up to and including rarely</td>
</tr>
<tr>
<td>2</td>
<td>Regularly</td>
</tr>
<tr>
<td>3</td>
<td>Often up to and including (nearly) always</td>
</tr>
</tbody>
</table>

**Extent to which can be corrected**

Initially attention is only paid to the ‘visibility’ (the value of which, if necessary, can be corrected for the aspects ‘lead time’ and ‘frequency’).

**Visibility**

<table>
<thead>
<tr>
<th>Visibility</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Definitely discovered up to and including reasonable chance of being discovered</td>
</tr>
<tr>
<td>2</td>
<td>Small chance of being discovered</td>
</tr>
<tr>
<td>3</td>
<td>Probably unnoticed up to and including definitely unnoticed</td>
</tr>
</tbody>
</table>

299
The Eindhoven Classification Model of system failure (ECM)

Introduction

In [150], a comparison of different models for the classification of medical incident causes was made: the Eindhoven Classification Model of system failure (ECM) was found the most suitable model for classifying failure factors in the medical world. By means of this model, the found (root) causes of the FMEA and CIIs which were held in the OR were classified. This appendix will successively discuss:

- The background of the ECM.
- The ECM.
- The classification/action matrix.

The background of the ECM

The ECM was originally developed for the chemical process industry and results in a detailed classification of causes which are related to system failure. System failure is divided into:

- Technical failure.
- Organisational failure.
- Human failure.

These three classification categories are subsequently subdivided further into end classification categories, the subdivision of human failure being based on the SRK model of Rasmussen [154]. A classification/action matrix can be used to make the connection between the classification results and the proposed actions or countermeasures. In this way (a combination of classification model and matrix), a safety management tool is made available. By using clear examples for each end classification category, the model can in principle be used for process deviations in areas outside the Arbo care. In the next section, the model will be discussed, including an example from patient care for each end classification category.
The Eindhoven Classification Model

The classification model further subdivides the categories technical, organisational and human failure into a total of sixteen end classification categories: see figure E.1 on the facing page. By beginning in the top left-hand corner in figure E.1, it first examines whether a root cause is a technical failure factor, next, if it turns out not to be a technical failure factor, it examines whether it is an organisational factor. After it has been established that the factor is neither organisational nor technical, and only then, does it take into consideration human factors. This fixed order of operating is important because in general there is a tendency to classify failure factors as human failure. Within human failure there is a tendency to concentrate preferably on clearly visible skill-based elements (like pushing the wrong button) instead of the less clear rule-based elements (like planning or scheduling) or the mainly cognitive, internal ‘activities’ with regard to knowledge-based behaviour. Therefore, when using the ECM classification, the fixed order of working is proposed (moving from the top to the bottom, as indicated in figure E.1 on the next page) in order to arrive at the most suitable end classification categories for causal incident factors.

The different classification categories (with for each category an example which relates to the OR practice), will be discussed below (according to Kanse [72], pages 115 to 119).

**Technical factors** are related to the design of an apparatus, machine, tool or installation and the like, its model or the materials that have been used for it. The perspective adopted is that of the user and the patient. Therefore, human factors like designers and constructors fall under this category and not under human behaviour.

**TE** The design of the apparatus, machine, tool or installation was faulty.

**Example** The ampoule and its label are poorly designed as a result of which the ampoule can hardly be distinguished from another ampoule without reading the label.

**TC** The design of the apparatus, machine, tool or installation concerned was all right, but its construction was not in accordance with the original design. This may happen, for instance, if human limitations, ergonomic preconditions, have not been taken into account during its construction.

**Example** An additional switch is fitted on a respirator which is unique and which people only occasionally have to operate, so that now two switches have to be turned to perform a certain function rather than one switch, which is standard practice with other respirators.
Figure E.1. The Eindhoven Classification Model of system failure [154].
TM If a technical factor is involved which cannot be classified under design or construction failure, this points to defective material.

Example The intercom produces so much noise that it is impossible to work with.

Organisational factors relate to decisions (no matter how recent) made by the management at whatever level higher than that of the immediate superior of the person who is directly confronted with the incident, so mostly managers in the intermediate and top echelons of the organisation. From the perspective of the person ultimately confronted with the incident, it is reasoned out what is seen as ‘the management’ and what the procedures and priority decisions are which the management imposes on the person concerned. If an error occurs, by observing these procedures and priorities, or by the very absence of these, this is considered an organisational factor.

OP Existing procedures are not satisfactory, are no longer adequate, are too specific for certain cases or have adverse effects on the safety of the patient, or, conversely, there may be an absence of procedures. In short, the quality of the procedures in the area in question falls short of the required standard. This may be due, for instance, to the (in)completeness or the accuracy of the procedure, or to the way the procedure was presented.

Example There is no procedure for checking whether blood has been ordered for a certain operation, for subsequently checking whether the blood is in stock, and for indicating who must carry out and check this procedure.

OM Management priorities may sometimes lie in other areas than on safety. In such cases, management may put pressure on employees to (for instance) achieve a certain production target and to let the importance of this target prevail over safety.

Example The management decides not to raise the budget for the purchase of certain equipment, as a result of which not all beds are provided with the same uniform equipment: a few beds are not fitted with fixed equipment but have to make do with old, borrowed equipment.

Human behaviour as a factor which causes incidents is viewed from the perspective of the person who sees himself in the end confronted with the incident, so: his behaviour led to the root cause in question. By analogy with the subdivision in the SRK model of Rasmussen, with regard to the human behaviour category, a distinction is made between skill-based behaviour (when performing routine tasks), rule-based behaviour (in the case of frequently recurring decision-making situations) and knowledge-based behaviour (decision-making in new situation).
Knowledge-based behaviour ('K-B' in figure E.1 on page 303) calls upon (almost) a person's entire intellectual capacity. The person has to be engaged in problem-solving in what is to him a new, unfamiliar situation. A driver who during the rush hour approaches an intersection only to find the traffic lights are not working, acts at a knowledge-based level. He has to make up his mind as to whether he wants to cross as quickly as possible or wants to minimise the risk of a collision, while also deciding at the same time whether the right-of-way rules still apply, etc.

HK1 If the status or the state of the system on the basis of which a task has to be performed, is not clear to the person who has to perform the task and if, in consequence, an error occurs, this will be considered a root cause in this classification category.

Example Not being told about a patient's allergy to certain medicines.

HK2 An error in this classification category occurs if the person who makes the error, is not conversant with the exact goal or with the priority of the goals of his actions: he is not focused on the correct goal.

Example The wrong leg is amputated.

Rule-based behaviour ('R-B' in figure E.1 on page 303) is concerned with common decisions which the person in question has to make regularly. For instance, a driver who, on approaching a road crossing, combines the right-of-way rules and the traffic light signals, acts at a rule-based level.

HR1 The person who is confronted with the incident, is not or insufficiently qualified to perform the task in question. He does not have the required training or knowledge.

Example A trainee perfusion technologist assists, unsupervised, although officially he had not been given the green light for this.

HR2 The incident relates to a job situation for which permission was needed but in this specific case this permission had not been granted.

Example During an operation, a skin disfigurement situated in the proximity of the operation area is removed, although the patient had not given permission for this.

HR3 In this case, it is a matter of a person failing to consult with or communicate with others about a task which this person wishes to perform, though he obviously should have done so. In other words, the required degree of coordination is ignored.
Example Poor consultation between anaesthetist and surgeon.

HR4 This error occurs if a certain situation is not tested for the conditions applying to the activities which are to be performed, and it is unquestioningly assumed that it will meet the anticipated values.

Example Failure to read the ampoule’s label before it is aspirated into the syringe and injected.

HR5 In this case, one is concerned with errors caused by incorrect planning by the person in question. He either failed to select the right method for doing the job or failed to carry out the steps of the method in the correct order or fails to carry them out completely.

Example After intubation, neglecting to check whether the tube has been fitted properly.

HR6 Errors caused by using other than the prescribed equipment and/or information.

Example Using an instrument which should not really be used.

Skill-based behaviour (‘S-B’ in figure E.1 on page 303) is concerned with actions which are performed, as it were, automatically. An experienced driver can, for instance, simultaneously talk with a passenger and listen to the car radio while driving, because the actions needed to drive a car engage only part of his intellectual capacity.

HS1 This is about errors made ‘automatically’ when performing routine tasks; the intention of the person who makes the error was aimed at the correct action but the action is inadvertently performed poorly.

Example Making an error by jotting down the wrong value.

HS2 This is about errors made ‘automatically’ when performing routine tasks, so these errors were completely unintentional.

Example Inadvertently dropping an instrument.

The classification/action matrix

Next, the classification results will have to be translated into proposals for effective, preventive and corrective actions for the long and for the short term. To achieve this, a classification/action matrix is used (see table E.1 on the next page).
Table E.1. The classification/action matrix [154].

<table>
<thead>
<tr>
<th></th>
<th>Information &amp;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Equipment</td>
</tr>
<tr>
<td>TE</td>
<td>X</td>
</tr>
<tr>
<td>TC</td>
<td>X</td>
</tr>
<tr>
<td>(TM)</td>
<td></td>
</tr>
<tr>
<td>OP</td>
<td>X</td>
</tr>
<tr>
<td>(OM)</td>
<td></td>
</tr>
<tr>
<td>HK1</td>
<td></td>
</tr>
<tr>
<td>HK2</td>
<td></td>
</tr>
<tr>
<td>HR1</td>
<td></td>
</tr>
<tr>
<td>HR2</td>
<td></td>
</tr>
<tr>
<td>HR3</td>
<td></td>
</tr>
<tr>
<td>HR4</td>
<td></td>
</tr>
<tr>
<td>HR5</td>
<td></td>
</tr>
<tr>
<td>HR6</td>
<td></td>
</tr>
<tr>
<td>HS1</td>
<td></td>
</tr>
<tr>
<td>HS2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Communication</th>
<th>Training</th>
<th>Motivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td></td>
<td>no!</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td>no!</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td>no!</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td></td>
<td>no!</td>
</tr>
</tbody>
</table>
The rows of this matrix consist of the final end classification categories while the columns represent the five action classes which are available to the management. These action classes are [154]:

- *Equipment* redesign of hardware, software or interface parts of the man-machine system;

- *Procedures* completing or improving formal and informal procedures for efficient and safe task performance;

- *Information & communication* completing or improving available sources of information and of communication structures;

- *Training* improving (re)training programmes for skills needed;

- *Motivation* increasing the level of voluntary obedience to generally accepted rules by applying principles of positive behaviour modification.

In the matrix, the preferred action in terms of anticipated effectiveness for every classification category is indicated by an ‘X’. The ‘no!’s in the last column refer to management actions which are very ineffective but which are nevertheless often encountered in practice.
Problems found during the creation of the Haemodialysis process model

The bold acronyms below refer to the relevant process descriptions on the CD-ROM (see also appendix B). The text which was written by way of comment for a certain process or for the relevant process description, has not been integrated into the actual process description, but is presented here separately.

**hemo00**

- Sbd (in Dutch ‘sociaal-begeleider-dialyse’; in English ‘social counsellor in the Haemodialysis department’): there are question-marks about the way he performs his function!

- Medimath system. The exact amount of certain materials is hard to determine: artificial kidneys and blood lines. The frequency should be increased from two times a week to three times a week.

- CSA (in Dutch ‘Centrale Sterilisatie Afdeling’; in English ‘CSD’ or ‘Central Sterilisation Department’): certain goods are needed at 1:00 p.m., but are not delivered until 3:00 p.m., so they will arrive too late. So, a member of the central department is sent for to pick up the goods. Could not some arrangements be made about this with the tpd (transport service)? Was it impossible to arrange special deliveries?

- Causes of insufficient supplies:
  - Wrong assessment because of mutations in week planning and scheduling.
  - Sometimes deliveries arrive too late.

**hemo07**

- Hardly any use is made of the information checklist. Should the checklist be adjusted?
• It is not clear who fills in what: D-vp (Dialysis nurse) or vp-z (care coordinator nurse)?

acute00

• Patient has to wait for surgeon to fit catheter, for instance because a shunt has become blocked.

acute01

**IC (ICU)**

• In the case of an emergency, it may take up to 10 hrs. before surgeon starts to fit catheter: very often in such a situation, the patient’s dialysis has to be performed by the nurses on on-call shift at night. So: in what sense can the patient be said to be ‘acute’? Extra expenses are incurred in consequence!

• This treatment causes most problems. ICU nurses check the system. If certain actions are not performed properly or in time, all sorts of things can go wrong and a D-vp (Dialysis nurse) needs to be sent for to help out. This is very annoying if a nurse has to be called up from home because of some silly error or mistake (for instance, the failure to replace fluid bags in time, or pressing the wrong button). Problem:
  
  - In the daytime, IC-vp (ICU nurse) communicates directly with acute shift staff.
  
  - At night, IC-vp (ICU nurse) has to communicate with the on-call shift staff via the porter of A & E (Accident and Emergency).

**CCU**

• In the case of an emergency, it may take up to 10 hrs. before surgeon starts to fit catheter: very often in such a situation, the patient’s dialysis has to be performed by the nurses on on-call shift at night. So: in what sense can the patient be said to be ‘acute’? Extra expenses are incurred in consequence!

• This treatment causes most problems. CCU nurses check the system. If certain actions are not performed properly or in time, all sorts of things can go wrong and a D-vp (Dialysis nurse) needs to be sent for to help out. This is very annoying if a nurse has to be called up from home because of some silly error or mistake (for
instance, the failure to replace fluid bags in time, or pressing the wrong button). Problem:

- In the daytime, CCU-vp (CCU nurse) communicates directly with acute shift staff.
- At night, CCU-vp (CCU nurse) has to communicate with the on-call shift staff via the porter of A & E (Accident and Emergency).

pd00

- PD-vp (Peritoneal Dialysis nurse) has to check goods in stock and order additional supplies. These duties and responsibilities did not rest with PD nurses until recently, and consequently this process has had its teething troubles. In situations in which many patients have been admitted, then supplies are inadequate.

pd01

- PD-vp on duty until 4:30 p.m. If a patient returns from OR later than 4:30 p.m., a D-vp (Dialysis nurse) checks catheter.

pd10

- Is the protocol still up-to-date?
- Is the protocol readily accessible to vp-9O (nurse of department 9 East)?
- vp-9O (nurse of department 9 East) injects medication which has been prepared by PD-vp.

pd12

- In this case the vp (nurse) decides whether it is a medical problem.

pd13

- Passing on changes or mutations to many different departments and members of staff, which can easily result in things being forgotten or overlooked.
pd17

- Does the path meet the (minimum) effectiveness criteria?
G

Results of the Haemodialysis CIIs
## Appendix G. Results of the Haemodialysis CII.s

Table G.1. Overview of the number of incidents and complications discussed and described for each Haemodialysis CII, and of whether a FONA report of an incident discussed was drawn up or not.

<table>
<thead>
<tr>
<th>Interview nr</th>
<th>n of incidents</th>
<th>FONA report of incident(s)?</th>
<th>n of complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>No</td>
<td>–</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>No</td>
<td>–</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>Yes</td>
<td>–</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>13</td>
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</tr>
<tr>
<td>14</td>
<td>2</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>16</td>
<td>1</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>17</td>
<td>2</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>18</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>19</td>
<td>2</td>
<td>No</td>
<td>–</td>
</tr>
<tr>
<td>20</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>21</td>
<td>1</td>
<td>No</td>
<td>–</td>
</tr>
<tr>
<td>22</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>23</td>
<td>1</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>24</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>25</td>
<td>1</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>33</strong></td>
<td><strong>Yes = 4, No = 20</strong></td>
<td><strong>23</strong></td>
</tr>
</tbody>
</table>

*aEquates to 29 incidents.*
Table G.2. The structural causes found during the Haemodialysis CIIIs. The causes were anonymized. Similar causes have been combined. In the end, to make things easier, the causes with the same failure category were put together. The different failure categories are explained in table 7.3 on page 211.

<table>
<thead>
<tr>
<th>nr</th>
<th>Structural cause</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nurses have inadequate knowledge of subclavian catheter</td>
<td>AIIa</td>
</tr>
<tr>
<td>2</td>
<td>Haemodialysis nurses have insufficient knowledge of and experience in working with the CAVHD</td>
<td>AIIa</td>
</tr>
<tr>
<td>3</td>
<td>Knowledge and skills with regard to catheter care is not optimal: this applies to both dialysis and PD nurses</td>
<td>AIIab</td>
</tr>
<tr>
<td>4</td>
<td>Doctors in training too inexperienced in using different dialysis techniques</td>
<td>AIIIa</td>
</tr>
<tr>
<td>5</td>
<td>Doctors in training (A &amp; E, Internal Diseases, Nephrology, Surgery) have inadequate nephrological knowledge</td>
<td>AIIIabc</td>
</tr>
<tr>
<td>6</td>
<td>Surgeons in training (and operating assistants) are insufficiently conversant with the construction of a CAPD catheter</td>
<td>AIIib</td>
</tr>
<tr>
<td>7</td>
<td>Rookie doctors in training have not yet sufficiently trained, and are not conversant with organisational protocols and procedures</td>
<td>AIIaB</td>
</tr>
<tr>
<td>8</td>
<td>Better preparation and coaching with regard to the introduction of a new dialysis machine: no expert assistance available in the department at the time of its introduction, and as for the nurses, their experiential/working knowledge was inadequate</td>
<td>AIIaBD</td>
</tr>
<tr>
<td>9</td>
<td>Protocol/procedure about doctors doing their rounds was ineffective:</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>• The (unwritten) protocol that every patient is attended to during the round, is not effective: sometimes the patient is overlooked</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ineffective communication during the round: arrangements are not (properly) recorded, and can subsequently no longer be retrieved (or there is no written report). The transfer of patients is performed on the basis of memory or hearsay. If there is a change of unit team leader while doctor is doing his round, this results in communication problems because any arrangements have not been put down in writing</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Admissions board is not satisfactory: its status and working are unclear. Is the admissions board always up-to-date? Who is responsible for this? Does a mention on the admissions board constitute an explicit instruction? How does the board work exactly (for instance, if it happens to be a Wednesday, does Tuesday on the board refer to the planning of the immediately preceding Tuesday or that of Tuesday week)?</td>
<td>B</td>
</tr>
<tr>
<td>11</td>
<td>There is no protocol for keeping the admission board up-to-date</td>
<td>B</td>
</tr>
</tbody>
</table>

continued on next page
<table>
<thead>
<tr>
<th>nr</th>
<th>Structural cause</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Between nurses there is incomplete communication of arrangements which have been made with the patient</td>
<td>B</td>
</tr>
<tr>
<td>13</td>
<td>Things go wrong with arrangements which have been made with other departments because: • The other department does not comply with the arrangements which have been made • The Haemodialysis department does not make clear agreements • The nurses in question do not properly communicate the arrangement made to each other</td>
<td>B</td>
</tr>
<tr>
<td>14</td>
<td>Setting up a dialysis machine and monitoring the patient are performed by too many, different persons (one or more dialysis nurses and one or more ICU nurses)</td>
<td>B</td>
</tr>
<tr>
<td>15</td>
<td>There is no protocol for the transfer of acute patient who is unknown to the department</td>
<td>B</td>
</tr>
<tr>
<td>16</td>
<td>There is no protocol for a euthanasia wish expressed by patient</td>
<td>B</td>
</tr>
<tr>
<td>17</td>
<td>The blood product ordering procedure is unreliable; this includes the entire route from ordering to delivering the blood and blood products</td>
<td>B</td>
</tr>
<tr>
<td>18</td>
<td>There is no protocol for turning on the R.O. machine</td>
<td>B</td>
</tr>
<tr>
<td>19</td>
<td>All kinds of transfers (of patients and data) are not always performed effectively, for instance, between staff on early acute shift and staff on late acute shift, between (acting) heads, transfer by reading the patient file, oral communication of special circumstances (also to other disciplines like surgery)</td>
<td>B</td>
</tr>
<tr>
<td>20</td>
<td>There is no effective protocol for the dialysis of patients whose operation has been postponed</td>
<td>B</td>
</tr>
<tr>
<td>21</td>
<td>Unclear and incomplete CAVHD protocol</td>
<td>B</td>
</tr>
<tr>
<td>22</td>
<td>The protocol for scheduling patients for the PD training is unclear</td>
<td>B</td>
</tr>
<tr>
<td>23</td>
<td>A design error in the case of the new Integra machine: when—accidentally—pressing a certain button too hard, the machine changes into the general safety state. This points to a design error in the (new) dialysis machine, because of which the machine can too easily be turned off inadvertently. This is due to the fact that no (extra) confirmation is being asked when using the button for turning off the machine, though a confirmation is required by the machine when using many other functions. To make matters worse, recovery of this error is not possible because, in contrast to the old machine, this new machine cannot be turned on again straightaway: it takes about 30 min. to start it up again</td>
<td>C</td>
</tr>
<tr>
<td>nr</td>
<td>Structural cause</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>24</td>
<td>The difference in outward appearance between the artificial kidney which is standardly used and a non-standard artificial kidney is sometimes minimal</td>
<td>C</td>
</tr>
<tr>
<td>25</td>
<td>The CVVH treatment is performed by dialysis nurses rather than by ICU nurses. This can result in suboptimal patient-orientated treatment, because the dialysis nurse arrives too late if he has to be called up from home: this may cause an undesirable delay in the treatment of the patient because, in the case of a disruption in the blood lines, the blood may coagulate, which will necessitate the dialysis machine being set up again</td>
<td>D</td>
</tr>
<tr>
<td>26</td>
<td>On Friday afternoons, the hospital's staffing level for performing medical actions is not enough to meet the demand (the number of patients): the facilities offered by the hospital at that moment are inadequate, and this results in increased risks for the patient</td>
<td>D</td>
</tr>
<tr>
<td>27</td>
<td>The Catharina Hospital has inadequate staffing levels (there is a shortage of staff) because of (too) high a rate of sickness absence, and because there is a shortage of nurses, anyway</td>
<td>D</td>
</tr>
<tr>
<td>28</td>
<td>The scheduling of operations is not always reliable: patients' operations are regularly postponed</td>
<td>D</td>
</tr>
</tbody>
</table>
Table G.3. The recovery factors found during the Haemodialysis CIIs.

<table>
<thead>
<tr>
<th>nr</th>
<th>Recovery factor</th>
<th>Successful?</th>
<th>Recovers/is intended to recover</th>
<th>Remark</th>
<th>CII nr</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nurse knows that heparin concentration is indicated on the catheter (but does not report this to the doctor in training)</td>
<td>No</td>
<td>Lack of knowledge</td>
<td>This missed recovery factor can also be interpreted as a failure factor</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Nurse asks doctor in training for the K-percentage in the blood and, in so doing, prevents wrong dialysis</td>
<td>Yes</td>
<td>Lack of knowledge</td>
<td></td>
<td>3-1</td>
</tr>
<tr>
<td>3</td>
<td>ICU notices increasing K-percentage in blood of OR patient and takes action so that patient is dialysed all the same</td>
<td>Yes, not directly, however</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>4-1</td>
</tr>
<tr>
<td>4</td>
<td>Doctor in training is important source of recovery factors (however, the doctor in training only does a four-month stint in the department, so that the doctor in training is also, certainly initially, a risk factor)</td>
<td>–</td>
<td>–</td>
<td>This recovery factor is of general nature</td>
<td>4-2</td>
</tr>
<tr>
<td>5</td>
<td>During a check, ICU notices the presence of a clip which should have been removed, and corrects this omission</td>
<td>Yes, not directly, however</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>Surgeon discovers guide wire in catheter (just before catheter would inadvertently have been replaced for this very reason this)</td>
<td>Yes, not directly, however</td>
<td>Lack of knowledge</td>
<td></td>
<td>9</td>
</tr>
</tbody>
</table>

continued on next page
<table>
<thead>
<tr>
<th>nr</th>
<th>Recovery factor</th>
<th>Successful?</th>
<th>Recovers/is intended to recover</th>
<th>Remark</th>
<th>CII nr</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Patient indicates that 3 rather than 2 litres plasma substitute should be used</td>
<td>Yes</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>10-1</td>
</tr>
<tr>
<td>8</td>
<td>A nurse passes on information to a colleague which he had (by chance) overheard the day before</td>
<td>Yes</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>10-1</td>
</tr>
<tr>
<td>9</td>
<td>Plasma substitute is uniform and because of this interchangeable between patients</td>
<td>Yes</td>
<td>–</td>
<td>This is a(n) (accidental) fact and a recovery factor</td>
<td>10-1</td>
</tr>
<tr>
<td>10</td>
<td>ICU calls to ask what is keeping the dialysis nurse, and, in this way, initiates a dialysis treatment &lt;br&gt;Staff member of the Clinical Physical department notices that the R.O. machine has been turned off, and turns it on</td>
<td>Yes, not directly, however</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>10-2</td>
</tr>
<tr>
<td>11</td>
<td>Staff member of the Clinical Physical department notices that the R.O. machine has been turned off, and turns it on</td>
<td>Yes</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>14-2</td>
</tr>
<tr>
<td>12</td>
<td>Patient notices that the wrong artificial kidney has been used</td>
<td>No</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>17-1</td>
</tr>
<tr>
<td>13</td>
<td>Dialysis nurse notices that the wrong artificial kidney has been used</td>
<td>No</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>17-1</td>
</tr>
<tr>
<td>14</td>
<td>After the postponement of open-heart surgery, a patient is inadvertently not dialysed. ICU takes a blood sample from patient; this sample proves that a dialysis is necessary</td>
<td>Yes, not directly, however</td>
<td>Protocol/procedure failure</td>
<td></td>
<td>17-2</td>
</tr>
</tbody>
</table>

continued on previous page
<table>
<thead>
<tr>
<th>nr</th>
<th>Recovery factor</th>
<th>Successful?</th>
<th>Recovers/is intended to recover</th>
<th>Remark</th>
<th>CII nr</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Patient is not covered with blankets (normally he would be, though) and because of this a wrong connection is noticed</td>
<td>Yes</td>
<td>–</td>
<td>Deviation from protocol results in recovery</td>
<td>19-1</td>
</tr>
<tr>
<td>16</td>
<td>PD nurse notices the absence of a part of the adapter on a catheter, after this had been overlooked by three colleagues</td>
<td>Yes, not directly, however</td>
<td>Protocol/procedure failure</td>
<td>This recovery factor is not a chance factor, but concerns a structural built-in check. Nevertheless, the factor is included as a recovery factor because the deviation was not noticed until the fourth check</td>
<td>23</td>
</tr>
<tr>
<td>17</td>
<td>Patient who had been given permission to go home, faints. This results in the patient being re-examined and being admitted to hospital</td>
<td>Yes, not directly, however</td>
<td>(Medical) protocol/procedure failure + lack of knowledge</td>
<td></td>
<td>24</td>
</tr>
</tbody>
</table>

Table G.4. The complications discussed during the Haemodialysis CII.

<table>
<thead>
<tr>
<th>nr</th>
<th>Effects on the patient</th>
<th>(Possible) causes/aspects of importance relevant to explaining the development of the complication</th>
<th>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>* Inflammations</td>
<td>Construction of groin catheter</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>* Leakages</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Bad dialysis ('nine out of ten subclavians work unsatisfactorily')</td>
<td></td>
<td></td>
</tr>
<tr>
<td>nr</td>
<td>Effects on the patient</td>
<td>(Possible causes/aspects of importance relevant to explaining the development of the complication)</td>
<td>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</td>
</tr>
<tr>
<td>----</td>
<td>----------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 2  | Patient infected with hepatitis C                   | • Patient has been dialysed elsewhere  
• Blood transfusion  
• When was the turning point i.e. from which moment on were the liver functions abnormal (blood patients are periodically tested for liver functions)                                             | Yes                                                                                                           |
| 3  | Aluminium poisoning which results in brain failures, ending fatally | The dissolution of aluminium electrodes (bars) in the dialysate                                                                                                                                             | Yes                                                                                                           |
| 4  | Sudden drop in blood pressure during dialysis       | • Problems with accessing the shunt  
• Blood too “thick” (haemoglobin percentage too high and/or excessive coagulation time)  
• Squeezing too long and/or too much (mainly at home) by, for instance, hanging (shopping) bags on the shunt, the use of clips—in this hospital—to push the shunt, inflammation  
• The withdrawal of too much fluid during the dialysis                                                                                           | No                                                                                                            |
<p>| 5  | A short life span of a shunt                        |                                                                                                                                                                                                              | Yes                                                                                                           |
| 6  | The withdrawal of too much fluid from the patient during the dialysis, which is bad for the heart, for the blood vessels, and for the general wellbeing of the patient: it may result in convulsions, in a feeling of malaise, and the patient may put on too much weight | The patient is misinformed. When the target weight is too low, too much fluid is being withdrawn: the body then absorbs more fluid from the food and the patient becomes thirsty or cannot stick to the diet. At the patient's request, a new target weight is determined, by measuring (among other things) the patient's blood pressure and by taking the wellbeing of the patient into consideration. During the dialysis, too much fluid must be withdrawn from the body if the patient cannot stick to the diet. However, the patient may have the feeling that things are going well. In this sort of situation patients are often going to shift the problem and to try to get more and more fluid withdrawn: they ask whether more fluid can be withdrawn during the dialysis, especially during the first hour of the dialysis, so that, all in all, more than the maximum (around four litres) of fluid is withdrawn during the dialysis | Yes                                                                                                           |</p>
<table>
<thead>
<tr>
<th>nr</th>
<th>Effects on the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>A patient whose haemodialysis has just started, experiences emotional and psychological problems. The patient is tensed up because haemodialysis is new and unfamiliar to him: this results (among other things) in low blood pressure and nausea. Things may become so bad that the patient needs psychiatric treatment. The patient decides to discontinue the dialysis.</td>
</tr>
<tr>
<td>8</td>
<td>The clogging up of the shunt which results in physical consequences for the patient.</td>
</tr>
<tr>
<td>9</td>
<td>A shunt which is blocked, sometimes just a few days after the shunt was put into use.</td>
</tr>
</tbody>
</table>

(Possible) causes/aspects of importance relevant to explaining the development of the complication:

- The patient has received too little information about the haemodialysis.
- The patient did not have the opportunity to come and have a look round in advance, which is what patients usually do, because he entered the Haemodialysis department as an acute patient. Normally, new haemodialysis patients are dialysed in a separate room during the first couple of dialyses; owing to circumstances, this was not the case with this patient.
- The medical policy which was initiated by the specialist was too 'hard' on the patient. It started right away with a 'hard' dialysis: too much fluid and too many waste products were withdrawn in a (too) short a period of time.

In retrospect, the ward doctor and the dialysis nurses involved have failed in their supporting care for the patient. The patient's decision to discontinue the dialysis may be the result of the 'disequilibrium syndrome'; these are complaints which result from 'too heavy' dialysing.

Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
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<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Yes

- The patient temporarily suffers from too low a diastolic pressure, for instance during an operation of two hours. What are the causes of this and are they preventable? (Is the remedy, if any, worse than the complaint?)
- (Too) tight compress around a shunt as a result of which the shunt clogs up.
- Open-heart surgery in which the blood pressure (is this a factor?) is 70–40. The odds are that a shunt gets messed up. Causes?

This complication seems to occur in clusters i.e. a few blocked shunts occur simultaneously at one and the same time. Both last year and this year, this occurred a number of times in quick succession. Is this really the case? If so, how come?

No
nr | Effects on the patient | (Possible) causes/aspects of importance relevant to explaining the development of the complication | Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?

10 | Recirculation: blood drains away badly, for instance, because of a ‘false connection’. As a result, part of the blood is dialysed properly, another part is not | A recirculation test is only done if there is a suspicion of recirculation (this can be told from the blood results) | No

11 | A shortage of fluid and a drop in blood pressure: this may result in fainting. After two or three days, patient puts on four to five kilograms. The body can adapt to the treatment or resist | If too much fluid is withdrawn from the body in a short time (for instance, at a rate of 1.5 litres per hour. The minimum is 100 ml per hour because otherwise the dialysate can go to the blood side), then the fluid cannot be replenished quickly enough by the body (from outside the blood stream to inside). This is a complication incidental to the treatment. You should always be on your guard against this: you are aware of this but it still happens. At the start of the dialysis, a lot of fluid is withdrawn, at a later stage less. Try to anticipate the drop in blood pressure by starting in time to withdraw less fluid. This is not always successful and depends on the individual. The new dialysis machine indicates the amount of fluid which is still in the blood. If this falls below a certain level, the alarm goes off. The values should be recorded, and are not constant but change (they are, for instance, different in winter from in summer). However, this function on the dialysis machine is still optional, and will probably become possible in the near future. In this way, it will become possible to examine how much fluid can be withdrawn from someone and over what period of time. For this are three models: top parabola, constant, block shape (high, low, high) | No
nr  Effects on the patient

(Possible) causes/aspects of importance relevant to explaining the development of the complication

Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?

12 Subclavian catheter causes roughly two kinds of problems:
• No/insufficient flow capacity
• Inflammation

The catheter ought to be usable for about two months. However, often the catheter can no longer be (properly) used after just being used once. Sometimes, the catheter can be used a second time but there will nearly always be problems the third time the catheter is used (it may be necessary to rotate the catheter, or the catheter must be withdrawn a little bit etc.). In short, sooner or later the subclavian catheter will cause problems. The catheter is used during the period of about six weeks needed before a new shunt can be used

According to the dialysis nurse, the surgeon who constructs a catheter may be a possible cause of the problem; however, different surgeons construct catheters. However, a Tesio catheter stays in its place for months and hardly ever causes problems/complications. The dialysis nurse knows this because patients arrive with a Tesio catheter from the Sint Joseph Hospital or from the University Hospital Nijmegen, and the dialysis nurse has never experienced any problems with a Tesio catheter. Tesio catheters are not new but they appear to be expensive; the team leader of the Haemodialysis department has made inquiries about this. A number of questions can be asked about why patients at the Catharina Hospital do not get a Tesio catheter, like:
• To what extent are people in the hospital conversant with constructing a Tesio catheter?
• Would a Tesio catheter in the end not be cheaper? Would the technique not be more of a burden on the patient? Etc.
<table>
<thead>
<tr>
<th>nr</th>
<th>Effects on the patient</th>
<th>(Possible) causes/aspects of importance relevant to explaining the development of the complication</th>
<th>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</th>
</tr>
</thead>
</table>
| 13 | Haemothorax (bleeding in the chest cavity). As a result of the haemothorax, the patient had to be put on the oxygen | As a result of wrongly inserting the subclavian catheter. This can happen, for instance, because:  
• (The anaesthetic did not work adequately as a result of which) the patient moved. This is possible in theory but not very likely  
• The surgeon cannot feel very well whether the catheter is or is not within the blood vessel, and inadvertently pricks through the blood vessel  
• The position of the vessel is abnormal because of the patient’s abnormal anatomy (this is theoretically possible but not very likely). This could be examined in advance and thus become preventable. The problem with this would be that an X-ray contrast fluid would need to be injected into the vessel, and locating the vessel is precisely the problem! So, examining the patient in advance (about whom—in contrast to what was the case here—it is known that it is extremely important that nothing goes wrong with the access process) is practically not feasible  
• The condition of the vessel is poor (this is the most likely cause according to the dialysis nurse) | Yes |

continue on next page
14 Needle slides out of the patient's blood vessel. If the needle slides out at the supply end, a quick drop in pressure occurs and the alarm goes off. If the needle slides out at the drain end, it takes longer before the alarm goes off because the decline in pressure is less. The danger then is that the patient is asleep and that it takes longer before being noticed (too much loss of blood which necessitates an (emergency) transfusion: the dialysis nurse has so far never experienced this before)

(Possible) causes/aspects of importance relevant to explaining the development of the complication

The plaster comes off as a result of which the needle cannot get a proper hold. This is difficult to detect (in advance). Probable causes:

- Patient is restless
- Is engaged in an activity (e.g. making sandwiches)
- Warmth, as a result of which the plaster comes off
- Hairy arms as a result of which the plaster will not stick well. A solution might be to shave the arms. However, in the circumstances, this is not possible, or the patient does not fancy having this done because:
  - The shunt may become more conspicuous (so for cosmetic reasons)
  - Shunt may become damaged while the patient is being shaved, so small wounds may result

There are two needles: one for the supply and one for the drain. In the view of the dialysis nurse, both come off just as often (no difference in location and/or pressure on the supply/drain; location and pressure are different). Patients make allowances for the problematic adhesiveness of plasters by omitting creams. The adhesiveness is not improved by using grease absorbents like alcohol, which is used anyhow to disinfect a part of the attachment area

Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?

Yes
<table>
<thead>
<tr>
<th>nr</th>
<th>Effects on the patient</th>
<th>(Possible) causes/aspects of importance relevant to explaining the development of the complication</th>
<th>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</th>
</tr>
</thead>
</table>
| 15 | Getting a low blood pressure in spite of the fact that this has been anticipated | Important are (probably):  
• The condition of the patient  
Patient has been under observation before the dialysis: his blood pressure is measured, and if this is low, then this will be known and the doctor in training is told. This may, for instance, depend on medication which the patient is taking or on the patient's retaining fluid (dialysis patients do not urinate)  
More generally: the patient is observed and examined. This produces values and aspects which may pose problems for the dialysis. If there is a problem, then this needs to be solved before the dialysis can be started. If there is no problem, the dialysis can be started. The measured values and aspects can be registered as part of complication registration: at a later stage, these data can provide valuable information for the purpose of explaining the origin or development of complications. This may be more epidemiological research than research at management level  
• The patient's age  
• The patient's case history  
• Arteriosclerosis  
• Age: older patient | No |
| 16 | Drop in blood pressure                      | Poor accessing of the shunt by the dialysis nurse                                               | No |
| 17 | Accessing a shunt can spoil the shunt. The patient is afraid of the shunt being pricked by certain nurses. In consequence, the patient becomes nervous, and sometimes, because of this, the nurse is nervous | |

continued on next page
nr Effects on the patient

(Possible) causes/aspects of importance relevant to explaining the development of the complication

Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?

18 In the case of poor accessing, it is possible to prick through the vessel, which results in bruises for the patient

The patient may have a 'difficult shunt': by this is meant a bad passage in the shunt when strictures are present in the shunt. What are the possible causes of poor accessing? It may depend on the nurse's skills. A good shunt is straight and does not have any strictures. The accessing of a shunt needs to be learned by practise on a patient. A technique for this exists, and skills are developed by practising them a lot. In the case of a bad shunt poor accessing is always a possibility. If several nurses have problems accessing a shunt, this should be examined to determine the cause of the poor accessibility of the shunt. It may be that only a certain nurse has trouble in accessing a specific shunt. If other nurses have no problems, then nothing is wrong with the shunt: other nurses access the shunt in question, and the dialysis nurse tries to improve his skills. But if the shunt is indeed defective, then it may be put right via percutaneous angioplasty. If percutaneous angioplasty is not possible, a new shunt can be constructed. In many cases, nurses indicate that a shunt is difficult and that poor accessing occurs frequently (in the case of incorrect accessing, a piece of skin may get lodged in the shunt, as a result of which the shunt may get clogged up). If the doctor waits too long applying for and doing a follow-up examination, percutaneous angioplasty may sometimes be precluded and the shunt will have to be replaced. If the response had been more prompt, the shunt would perhaps not have needed to be replaced. This sort of thing often happens in the case of certain patients when constructing a shunt turns out to be problematic

Yes

19 In the case of inserting a subclavian catheter, the following two complications (among others) are possible: pricking through/pneumothorax (about 10% chance of occurrence) and haemothorax (much smaller chance of occurrence) * Bad oral communication of special circumstance * Careless reading of the patient file

Yes

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<tr>
<th>nr</th>
<th>Effects on the patient</th>
<th>(Possible) causes/aspects of importance relevant to explaining the development of the complication</th>
<th>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</th>
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<tr>
<td>20</td>
<td>A leaking catheter just after it has been inserted: this concerns the leaking of wound fluid or PD fluid. However, little cracks in the peritoneum can occur which, depending on their location, can result in a rupture, in fluid in the scrotum (only in the case of men) or in little cracks in the pleura as a result of which fluid can develop near the lungs, making breathing more difficult for the patient. These complications often occur within a few weeks after the construction of the PD catheter. The recovery from an operation for remedying a rupture takes six weeks; the PD patient receives haemodialysis during that period. If the complication is a pleural rupture then this can be recovered and occur again. Then, in the case of yet another pleural rupture, this can again be recovered, but, if after two recoveries the rupture re-occurs, the patient is urgently advised to switch to haemodialysis</td>
<td>As time goes by the chance of these complications occurring decreases. The complications are rinsing liquid dependent: as the glucose concentration increases, so the chance of this complication occurring also increases. This complication is dependent on: * The glucose concentration mentioned of the PD rinsing liquid * The presence of a scar from an earlier rupture * Lifting * Other physical activities. These are largely patient-related in the sense that they depend on the weak spot or spots which a patient may or may not have, and on the activities the patient engages in</td>
<td>No</td>
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Effects on the patient

(Possible) causes/aspects of importance relevant to explaining the development of the complication

Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?

Peritonitis. The patient immediately notices this from the outflow bag in which the fluid becomes turbid; the patient may suffer from abdominal pain. The peritonitis which is caused by the first three causes, can, in general, be treated pretty effectively; the peritonitis which is caused by the intestinal bacterium E. coli cannot be treated so effectively. After an infection, scar tissue is formed in the peritoneum, as a result of which the PD may become less effective.

The extension line of the catheter must be replaced every six months. The order of the different parts is as follows: catheter--titanium adapter--extension line. A tap/turning clip is fixed to the extension line and is subject to wear. It may have occurred occasionally that, after a change of extension line, the patient had a peritonitis the day after. The procedure for changing of the extension line has been laid down in a protocol. If the turning clip is defective, the patient phones the hospital about this and is then given a new extension line in the department. Peritonitis can be caused by the change of extension line, but also by actions the patient may have engaged in at home as part of his PD. The incubation period of peritonitis is short and can cause problems the very day after the infection occurred. Peritonitis can be caused (among others) by the following causes:

- Infection of the peritoneum with Staphylococcus aureus
- Infection of the peritoneum with bacteria which are found in the mouth and bronchial tubes. This is also the reason why a mouth mask is worn if the cap is not on the catheter: an infection can be caused via coughing
- Inflammation of the catheter entrance or catheter tunnel
- Infection of the peritoneum with E. coli. This can happen in the case of an intestinal perforation or enteritis

The patient himself performs the PD treatment at home; for this purpose, an extension piece is connected to the disposable line set. During the treatment, contamination may occur (including infection via E. coli, for instance by a failure to wash one's hands properly after going to the toilet)

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<th>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</th>
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<td></td>
<td>Larger chance of infection of the catheter entrance</td>
<td>When taking a shower, the patient did not remove a plaster on the catheter entrance. The plaster should be removed before taking a shower for two reasons: • Showering the catheter entrance is important because this results in a better perfusion and thus reduces the chance of infections. The perfusion while taking a shower is less if the plaster is not removed • An accumulation of dirt may occur if the plaster is not changed until after taking a shower, because in this way the skin underneath the plaster is not cleaned, which is important because it concerns a catheter entrance</td>
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<td>22</td>
<td></td>
<td>If the plaster is not changed after taking a shower, the plaster will remain wet and moisten. The plaster should be changed every day; this is not explicitly specified in the protocol (in the information file)</td>
<td>Yes</td>
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<th>(Possible) causes/aspects of importance relevant to explaining the development of the complication</th>
<th>Complication contains elements of an incident: did it stem from an incident and was it (therefore) preventable?</th>
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<tr>
<td>23</td>
<td>A repositioning of a catheter in the course of which a blood vessel is damaged, resulting in internal bleedings for the patient. The patient's abdomen does not empty very well: the patient is in pain, has a swollen belly and the dialysis fluid has a red colour. The tip of the patient's catheter was situated in the navel rather than in the Douglas' pouch and does not drain the abdomen properly. However, at that moment, there was no time to treat the patient and it took two days (!) before the repositioning was performed: this was in the period between Christmas and New Year's Day, and the delay was too long. The hospital was faced with an acute problem: the patient has probably not been dialysed for two days. During the repositioning of the catheter which took place in the OR and in which a scope was used, a blood vessel was touched. (The peritoneum was strongly perfused and probably a blood vessel was punctured.) As a consequence, the PD had to be suspended for a while, and the patient received haemodialysis via a subclavian catheter. If the repositioning of the catheter had been successful, then the patient could immediately have resumed the CAPD</td>
<td>The repositioning of the catheter is not a standard operation (so the operation was not scheduled in advance and in consequence the operation could not be cancelled), and a large hospital like the Catharina Hospital should have the resources to perform this operation on the very same day rather than admit the patient for two days</td>
<td>Yes</td>
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H

Results of the Haemodialysis FMEA
Table H.1. The results of the FMEA in the Haemodialysis department. The page with the process description (on the CD-ROM, see also appendix B) that the failure mode relates to, is represented in brackets in the column ‘Failure mode of the process/problem’. The abbreviations ‘Ser.’, ‘Freq.’, ‘Corr.’ and ‘RPN’ stand for ‘the seriousness of the effects’, ‘the frequency of occurrence of a certain cause’, ‘the extent to which a certain cause can be corrected’ and ‘Risk Priority Number’ respectively.

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<tr>
<td>1. Using the wrong artificial kidney (hemo02)</td>
<td>* Suboptimal dialysis result</td>
<td>1</td>
<td>− Failure to look at the patient's day list</td>
<td>1½</td>
<td>2</td>
<td>3</td>
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<td></td>
<td></td>
<td></td>
<td>− 'Cristal' artificial kidneys differ only in number and colour of packing: outward appearance is identical</td>
<td>1½</td>
<td>2</td>
<td>3</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>− The outward appearance of 'Aepal' artificial kidneys is very similar</td>
<td>1</td>
<td>2</td>
<td>2</td>
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<td>2. Number (spare) dialysis machines inadequate (hemo02)</td>
<td>* Physical discomfort for patient</td>
<td>1</td>
<td>− Inadequate resources</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>* More machines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Patient has to wait</td>
<td>1</td>
<td>− Inadequate resources</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td></td>
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<tr>
<td></td>
<td>* Dialysis lasts longer than anticipated</td>
<td>1</td>
<td>− Inadequate resources</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td></td>
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<tr>
<td>3. Blood supply insufficient (hemo03)</td>
<td>* Ineffective (sometimes no) dialysis (possible)</td>
<td>2</td>
<td>− Bad shunt</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>* Quicker intervention by surgeon/the person who examines</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>− Catheter is not working properly</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Creating new entrance</td>
<td>2</td>
<td>− Bad shunt</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<tr>
<td>4. High venous pressure (hemo03/04)</td>
<td>• Long wait before the construction of new entrance</td>
<td>2</td>
<td>• Catheter is not working properly</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<tr>
<td></td>
<td>• Extravasations of blood</td>
<td>2</td>
<td>• Needle through the vessel</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>* Depending on the cause</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Need to access the shunt again</td>
<td>1</td>
<td>• Needle through the vessel</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td></td>
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<tr>
<td></td>
<td>• Shunt can temporarily not be used optimally</td>
<td>2</td>
<td>• Needle through the vessel</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td></td>
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<tr>
<td></td>
<td>• Longer wait, treatment takes longer</td>
<td>1</td>
<td>• Needle through the vessel</td>
<td>2</td>
<td>1</td>
<td>2</td>
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<tr>
<td>5. Failure to mention in the day report that the artificial kidney is becoming clean (hemo05)</td>
<td>* Patient's losing blood goes unnoticed for a long time, which can result in anaemia, in patient having to be given a blood transfusion, and in the addition of EPO</td>
<td>2</td>
<td>• Dialysis nurses underestimate the importance of making a note about an artificial kidney becoming clean</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>* This should be pointed out once again to nurses</td>
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| 6. Doctor arrives too late for consultation/not doing rounds in accordance with the planning schedule (hemo01) | - Patient is (possibly) left with unanswered questions, the dialysis treatment is (possibly) not adjusted, results are not scrutinised and/or not communicated to patient | 2    | - Bad planning and/or bad organisation: number of doctors available is too small | 2     | 1    | 4   | • Discuss in quality consultations  
• Nurse should point this out to doctors | |
| 7a. On Saturday mornings, one doctor does his rounds, the other does not but is on call (hemo01) | - Patient is (possibly) left with unanswered questions, the dialysis treatment is (possibly) not adjusted, results are not scrutinised and/or not communicated to patient, and if the patient is out of luck—i.e. if he also needs dialysis on Saturday—then there is a chance that the patient goes a whole week without being seen by a doctor | 2    | - Saturday is seen as part of the 'weekend' resulting in a shift of standards: care aspects which are considered important on weekdays, are apparently not important during the weekend | 3     | 1    | 6   | • Consultation with doctors  
• Head of Dialysis department | |

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<tr>
<td>7b. On Saturday afternoons, no doctor does his rounds (hemo01)</td>
<td>• Patient is (possibly) left with unanswered questions, the dialysis treatment is (possibly) not adjusted, results are not scrutinised and/or not communicated to patient, and if the patient is out of luck—i.e. if he also needs dialysis on Saturday—then there is a chance that the patient goes a whole week without being seen by a doctor</td>
<td>2</td>
<td>– Saturday is seen as part of the 'weekend' resulting in a shift of standards: care aspects which are considered important on weekdays, are apparently not important during the weekend</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>• Consultation with doctors</td>
<td>• Head of Dialysis department</td>
</tr>
<tr>
<td>8. Examination room is often occupied (examination room is also used for PD) (hemo01)</td>
<td>• Patient has to wait and is being dragged around in search of an examination room. In the worst case, the examination is made in the (screened off) dialysis chair</td>
<td>1</td>
<td>– Not enough room in the Dialysis department</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>• This should be taken into account when drawing up future plans for extending the hospital</td>
<td></td>
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<tr>
<td>9. Patient has to wait too long for the urologic and cardiology examination results (hemo01/pd11)</td>
<td>• There is a delay in the patient being put on the transplant waiting list</td>
<td>2</td>
<td>– Urologists and cardiologists underestimate the importance of the examination</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>• Nephrologists should emphasise the importance of expediting examinations (patient is put on transplant list sooner) to urologists and cardiologists</td>
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<tr>
<td>10. Nurses do not read the nursing file carefully (hemo01)</td>
<td>• Evaluation/appointment is not made</td>
<td>2</td>
<td>- Overlooking, underestimating the importance of working carefully</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>* This should be pointed out once again to nurses</td>
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<tr>
<td></td>
<td>• Patient is bothered longer than necessary by complaints</td>
<td>2</td>
<td>- Underestimating the importance of proper reporting in the Dialysis department</td>
<td>1½</td>
<td>1</td>
<td>3</td>
<td>* This should be pointed out once again to nurses</td>
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<td></td>
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<td></td>
<td>- Perception among the nurses that the things which need to be reported are already known anyway</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<td>11. Incomplete reporting of treatment by the nurses (hemo01)</td>
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<td>12. 'Self-mutating' policy: temporary actions become permanent policy (hemo01)</td>
<td>• Patient is bothered longer than necessary by complaints</td>
<td>2</td>
<td>- No clear distinction between what is temporary and what is permanent, so temporary components become permanent</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>* This should be pointed out once again to nurses</td>
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<tr>
<td></td>
<td>• Patient is 'overtreated' which is stressful</td>
<td>2</td>
<td>- No clear distinction between what is temporary and what is permanent, so temporary components become permanent</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<td>13. Policy changes are not recorded in the computer system (hemo01)</td>
<td>• Patient can get no medication for a couple of weeks</td>
<td>2</td>
<td>- Wrong reporting by nurse</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>* Should be raised during the periodic discussions of progress</td>
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<td></td>
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<td></td>
<td>- Incorrect/no input by nurse</td>
<td>2</td>
<td>2</td>
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<tr>
<td>14. Failure to pass on message that the patient needs another treatment session (hemo01)</td>
<td>* Cancellation of an examination because the dialysis takes priority</td>
<td>1</td>
<td>− Poor communication within Dialysis department</td>
<td>1</td>
<td>½</td>
<td>½</td>
<td>* Discussion about ways of improving the transfer of information</td>
<td></td>
</tr>
<tr>
<td>15. Irregular, incomplete or no reporting by social counsellor about dialysis patients (hemo00)</td>
<td>* Inadequate social support</td>
<td>2</td>
<td>− Uncertainty about function and job description of social counsellor</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>* ?, function partly taken over by nurses</td>
<td></td>
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<tr>
<td>16. Frequency of delivery of artificial kidneys and blood lines is too low (hemo00)</td>
<td>* Dialysis starts later and lasts longer</td>
<td>1</td>
<td>− For reasons unknown, the sterile supply room does not cooperate</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>* Frequency of delivery of artificial kidneys and blood lines should be 3 times a week</td>
<td></td>
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<tr>
<td>17. Goods are delivered too late by the transport service (hemo00)</td>
<td>* Dialysis starts later and lasts longer</td>
<td>1</td>
<td>− Delivery frequency of Medimath is too low</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>* Frequency of delivery should be 3 times a week</td>
<td></td>
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<tr>
<td>18. Failure to fill in the form 'waiting room' (pre-dialysis)</td>
<td>* Patient is informed too late about the treatment plan and the patient may get the wrong treatment plan</td>
<td>2</td>
<td>− Doctor in training is not conversant with the form (organisational procedure)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>* Form should be included in the file of doctor in training</td>
<td></td>
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<tr>
<td>19. Incomplete or no communication of the information collected during first and second dialysis and pre-dialysis stage (information during dialysis)</td>
<td>* Patient may be bothered by complaints longer than necessary</td>
<td>2</td>
<td>− No regulations about the communication of information in the information protocol concerned</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>* Adjustment of protocol * Clearer instructions to waiting room nurse * Head of Dialysis department</td>
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<tr>
<td>20. Nurses hardly, if at all, make use of the information checklist (information during dialysis)</td>
<td>• Patient may be bothered by complaints longer than necessary</td>
<td>2</td>
<td>• Insufficient awareness of the importance of working with a checklist</td>
<td>2</td>
<td>2</td>
<td>8</td>
<td>• The usefulness of checklist should be brought up for discussion. Possible solution: adjustment of checklist</td>
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<td>21. Patient does not contact the doctor directly and is put through to doctor in training who is insufficiently conversant with dialysis or to dialysis nurse who is not allowed to make a diagnosis (acute00)</td>
<td>• Patient has to wait longer and gets the feeling he is being sent from pillar to post</td>
<td>1</td>
<td>• Patient does not dare to phone the doctor in attendance</td>
<td>2</td>
<td>1</td>
<td>2</td>
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<td></td>
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<td></td>
<td>• It is not clear who is the doctor in attendance</td>
<td>1</td>
<td>3</td>
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<td>22. Dialysis nurse connects and disconnects patient. ICU nurse supervises the subsequent treatment and calls in dialysis nurse in case of problems. However: the ICU nurse does not perform his monitoring tasks properly, as a result of which the dialysis process is disrupted too often (acute01)</td>
<td>• Unnecessary loss of blood</td>
<td>2</td>
<td>• ICU nurse is insufficiently conversant with the CVVH treatment</td>
<td>2</td>
<td>2</td>
<td>8</td>
<td>• Hand over CVVH treatment to ICU</td>
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<td>• Forgetting to change fluid bags</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>• Head of Dialysis department consults with nursing manager ICU</td>
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<td></td>
<td>• Incorrect operation of machine (instructions are indicated in big letters on machine)</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<tr>
<td></td>
<td></td>
<td>• Interruption of continuous dialysis treatment</td>
<td>2</td>
<td>• ICU nurse is insufficiently conversant with CVVH treatment</td>
<td>2</td>
<td>2</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Forgetting to change fluid bags</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Incorrect operation of machine (instructions are indicated in big letters on machine)</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The entrance to the bloodstream may get blocked</td>
<td>2</td>
<td>ICU nurse is insufficiently conversant with CVVH treatment</td>
<td>2</td>
<td>2</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unnecessary loss of blood</td>
<td>2</td>
<td>Insufficiently familiar with treatment</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td></td>
<td>Periodic training and/or additional training</td>
<td></td>
</tr>
<tr>
<td>• Interruption of continuous dialysis treatment</td>
<td>2</td>
<td>Insufficiently familiar with treatment</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td></td>
<td></td>
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<tr>
<td>• The entrance to the bloodstream may get blocked</td>
<td>2</td>
<td>Insufficiently familiar with treatment</td>
<td>3</td>
<td>2</td>
<td>12</td>
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23. CCU nurse performs his monitoring duties of a CAVHD treatment unsatisfactorily (acute01)

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<tbody>
<tr>
<td>24. Supplies of fluid in the PD chamber at 9 East are inadequate: PD nurse should check stores and, if necessary, order additional supplies when a large number of patients is being admitted (pd00)</td>
<td>• Patient cannot change until later and/or with other fluid/concentrations</td>
<td>1</td>
<td>• Frequency of occurrence of the treatment is too low to ensure a good level of quality</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>• Frequency of delivery by Medimath is too low</td>
<td>• Frequency of delivery should be 3 times a week • When a large number of patients is being admitted, additional supplies should be laid in</td>
</tr>
<tr>
<td></td>
<td>• For reasons unknown, the sterile supply room does not cooperate</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. PD nurse does not know date of the CAPD catheter implantation (pd001)</td>
<td>• The catheter has not been constructed in the right place because it was not clearly marked off</td>
<td>2</td>
<td>• Date was not passed on by the doctor in training to the PD nurse</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>• Proper induction should be given to novice doctors in training</td>
<td>• Submit to PD unit</td>
</tr>
<tr>
<td></td>
<td>• Nurse of 9 East does not contact PD nurse</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient needs to be given a new catheter again</td>
<td>2</td>
<td>• Catheter is not in the right place</td>
<td>½</td>
<td>1</td>
<td>1</td>
<td>• Surgeon marks off place himself</td>
<td></td>
</tr>
<tr>
<td>26. Patient is given no prophylactic antibiotics (pd001)</td>
<td>• Patient can get peritonitis</td>
<td>1</td>
<td>• Doctor in training failed to give instructions about this to the nurse of 9 East</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>• Effective instructions to novice doctors in training • Nurses of 9 East/Dialysis (also) have to make arrangements/follow checklist</td>
<td>• Should be included in the file for doctor in training • Head of Dialysis department, discuss this in PD unit</td>
</tr>
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<tbody>
<tr>
<td>27. Patient's data are not present or are incomplete and/or the doctor in attendance is not present and/or the care nurse is not present (pd08/hemo000)</td>
<td>* MDO is postponed</td>
<td>1</td>
<td>− Poor planning</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>* Central planning by the secretary instead of by each care nurse individually</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>− Failure to pass on changes in planning and scheduling to other disciplines</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Patient’s questions remain unanswered</td>
<td>1</td>
<td>− Poor planning</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>− Failure to pass on changes in planning and scheduling to other disciplines</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Patient has to wait a long time in the Dialysis department for doctor’s arrival (pd12)</td>
<td>* Medical policy for patient is started after a delay</td>
<td>1</td>
<td>− Doctor in training has too much on his plate</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>* This should be discussed in quality consultations</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>− Patient does not stick to the arrangement to phone for an appointment</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td></td>
<td>* Patient has a problem in regard to his changing time (CAPD)</td>
<td>1</td>
<td>− Patient has too wait for too long</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>− Doctor and/or patient make insufficient allowances for the patient's changing times</td>
<td>2</td>
<td>1</td>
<td>2</td>
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29. (According to the PD unit) there is inadequate staffing capacity to train several patients simultaneously (pd02)

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<tbody>
<tr>
<td></td>
<td>• This results in a waiting list</td>
<td>2</td>
<td>- Insufficient insight into the possibilities and limitations of the availability of training staff, which is twice 8 hrs. a day (so far no research has been conducted into this)</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>- Should be looked into at management level</td>
<td>Head of Dialysis department</td>
</tr>
<tr>
<td></td>
<td>• Patient must temporarily change over to haemodialysis because the PD treatment still cannot start yet: first the catheter needs to be inserted</td>
<td>2</td>
<td>- Insufficient insight into the possibilities and limitations of the availability of training staff, which is twice 8 hrs. a day (so far no research has been conducted into this)</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td></td>
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</tbody>
</table>

*NB* The FMEA team is aware that psychological effects which have been ignored in this research, can result in physical effects. For instance, a patient who has to wait for an hour may become stressed, and this may cause high blood pressure.

The following failure modes are not related to (potential) undesirable physical effects on the patient, but were generated in the course of the FMEA meetings.

xx. Secretary submits too high/too little claim for EPO (pd09)

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</thead>
<tbody>
<tr>
<td>• Patient/insurer pays too much/too little</td>
<td>2</td>
<td>- Changes in EPO doses are not passed on by doctor (and patient does not tell, either)</td>
<td></td>
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</tbody>
</table>

xx. Patient’s record is incorrect, as a result of which secretary bills incorrectly (pd13)

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</thead>
<tbody>
<tr>
<td>• Patient receives incorrect bills</td>
<td>2</td>
<td>- PD nurse has to jot down/enter/pass on changes in patient’s record in/to as many as three different places, which makes it easy to forget one</td>
<td></td>
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</tr>
<tr>
<td>xx. Clearing out current patients' records</td>
<td>* Perhaps: patient may receive phantom bills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- PD nurse considers this of minor importance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- It is not clear who is responsible for this</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
I

The final IRMS reporting form (including the possibility to report Arbo incidents)
INCIDENT REPORTING FORM
(for an elucidation see the reverse side of this form)

DATE OF INCIDENT:  
(TIME OF INCIDENT:  
LOCATION OF INCIDENT:  
IP NUMBER:  
NAME OF PATIENT:  
DATE:  
REPORTER:

DESCRIPTION OF INCIDENT*: ________________________

________________________
________________________
________________________
________________________
________________________
________________________
________________________
________________________
________________________

(only for Arbo incidents, if applicable, tick:)
☐ this Arbo report is only allowed to be given to the Arbo coordinator if rendered anonymous.**

(RECOVERY ACTIONS*: ________________________

________________________
________________________
________________________
________________________
________________________

* For extra writing space, p.l.o.  

Figure I.1. The front of the IRMS reporting form.
Appendix I. The final IRMS reporting form

(to prevent:)

POSSIBLE SUGGESTIONS:


(if applicable:)

REMARKS/SPECIAL CIRCUMSTANCES:


* EXTRA WRITING SPACE:


Elucidation

Location of incident: Where in the OR did the incident occur?

Description of incident: Describe in detail what happened and why this happened. Please base this only on facts. Also fail recovery actions are of importance, see below. In case of an incident, describe the (possible) effects on the patient, and in case of an Arbo incident, describe the (possible) effects on yourself and/or others.

Recovery actions: What caused the incident to turn for the better? Describe (if applicable) by which this incident turned out well. In other words: without this action, the incident would have had more serious effects. An incident can also be recovered by accident.

Suggestions: Any suggestions about how this incident could have been prevented.

Remarks/special circumstances: Any further remarks here (this includes information about any special circumstances surrounding the incident).

** All reported incidents fall under the responsibility of the IRMS. In principle, this confidentiality does not extend to Arbo incidents. Nevertheless, if you wish the reported Arbo incident to be treated confidentially (and therefore to be rendered anonymous), then you can indicate this by ticking the relevant box.

1 The procedure which must be observed in the case of a prick incident, is to be found in the infection folder.

Please put form in the IRMS box, secretariat OR

Figure I.2. The back of the IRMS reporting form.
The number of doctors and employees who reported one or more incidents
Table J.1. Number of reporters who have submitted a certain number of incident reports for the first 345 to the IRMS reported incidents in the OR. The reporters are divided into doctors and employees (t = 14 months, total n of doctors = 70, total n of employees = 140, n of doctors who report = 26, n of employees who report = 81, n of incident reports submitted by doctors = 82 with mean = 3.2 and S.D. = 3.5, n of incident reports submitted by employees = 338 with mean = 4.2 and S.D. = 6.0, n of incident reports submitted by doctors and employees = 420 with mean = 3.9 and S.D. = 5.5; a number of incident reports was submitted by several persons). E.g.: over the period of 14 months, 1 doctor submitted 17 incident reports. (For the sake of completeness: for all doctors the mean n of incident reports per doctor = 1.2 with S.D. = 2.6, for all employees the mean n of incident reports per employee = 2.4 with S.D. = 5.0, and for all doctors and employees on aggregate the mean n of incident reports = 2.0 with S.D. = 4.4.)

<table>
<thead>
<tr>
<th>n of incident reports</th>
<th>n of doctors who submitted this number of incident reports</th>
<th>n of employees who submitted this number of incident reports</th>
<th>n of doctors and employees who submitted this number of incident reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13</td>
<td>28</td>
<td>41</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>2</td>
<td>5</td>
<td>7</td>
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<tr>
<td>6</td>
<td>1</td>
<td>6</td>
<td>7</td>
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<tr>
<td>7</td>
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<td>2</td>
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<tr>
<td>8</td>
<td>1</td>
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<td>1</td>
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<tr>
<td>9</td>
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<td>3</td>
<td>3</td>
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<tr>
<td>11</td>
<td>–</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>–</td>
<td>1</td>
<td>1</td>
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<tr>
<td>13</td>
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<td>1</td>
<td>1</td>
</tr>
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<td>17</td>
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<td>1</td>
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<td>21</td>
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<td>1</td>
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<td>–</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>41</td>
<td>–</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>81</td>
<td>107</td>
</tr>
</tbody>
</table>
Summary

Theory and practice of in-hospital patient risk management

N.W.S. van der Hoeff (for enquiries: info@vanderhoeff.com or www.vanderhoeff.com)

All kinds of factors can lead to undesirable consequences for patients, or to incidents and complications. For effective quality management in hospitals, the registration and analysis of incidents and complications are necessary. In order to gain an insight into the origin and registration of incidents and complications, two models have been developed.

This research focuses on the development and testing of several risk management tools and methods with the aim of pursuing effective risk management. For this purpose, a framework for these tools and methods was designed, using retrospective, real-time and prospective methods. The tools and methods were used in the function group Operating Room (OR) and in the Haemodialysis department of the Catharina Hospital in Eindhoven, the Netherlands, and included:

- A model, based on concepts from system theory, of the processes taking place in a department, which can be used with a Failure Mode and Effects Analysis (FMEA). Of both the function group OR and of the Haemodialysis department, a process model was created.
- An FMEA (prospective method). An FMEA was used to assess the risks for patients in both the OR and in the Haemodialysis department.
- A number of Critical Incident Interviews (retrospective method). Two rounds of interviews were held: 20 interviews in the OR, 25 interviews in the Haemodialysis department. Causal Tree Analysis was used for the processing of these interviews.
- Voluntary incident reports (real-time method). In the OR, a voluntary incident reporting and management system was designed and implemented. The result was a database containing more than five hundred reported incidents collected over less than two years.

The results of this research are not only the found causes of incidents and the opportunities for reducing patient risks, but also the performance of the tools and methods used. The research shows that, after patient risks had been identified, it proved difficult to implement improvements, mainly because the management was not ready for it. All the tools and methods used in this thesis can be applied in other hospitals.
Samenvatting

Theorie en praktijk van risicomanagement ten behoeve van ziekenhuispatiënten

N.W.S. van der Hoeff (voor inlichtingen: info@vanderhoeff.com of www.vanderhoeff.com)

Allerlei mogelijke factoren kunnen resulteren in ongewenste gevolgen voor patiënten, of in incidenten en complicaties. Voor effectieve kwaliteitszorg binnen ziekenhuizen, zijn de registratie en analyse van incidenten en complicaties noodzakelijk. Om het ontstaan en de registratie van incidenten en complicaties inzichtelijk te maken, zijn twee modellen ontwikkeld.

Dit onderzoek richt zich op de ontwikkeling en toetsing van verscheidene gereedschappen voor risicomanagement met het oog op doelmatig risicobeheer. Hiervoor werd een kader van gereedschappen en methodes ontworpen, gebruikmakend van retrospectieve, real-time en prospectieve methodes. Deze gereedschappen en methodes werden gebruikt in de functiegroep OK (Operatiekamer) en op de afdeling Hemodialyse van het Catharina Ziekenhuis in Eindhoven en omvatten:

- Een model – gebaseerd op concepten uit de systeemkunde – van de processen die op een afdeling of in een functiegroep plaatsvinden en dat gebruikt kan worden bij een Failure Mode and Effects Analysis (FMEA). Van zowel de OK als op de afdeling Hemodialyse werd een procesmodel gemaakt.

- Een FMEA (prospectieve methode). Een FMEA werd gebruikt om de risico’s voor patiënten in te schatten, zowel op de OK als op de afdeling Hemodialyse.

- Een aantal Critical Incident Interviews (retrospectieve methode). Twee reeksen van interviews werden gehouden: 20 interviews op de OK, 25 interviews op de Hemodialyse afdeling. Causal Tree Analysis werd gebruikt voor de verwerking van deze interviews.

- Vrijwillige melding van incidenten (real-time methode). Op de OK werd een vrijwillig incidentmeldings- en incidentbeheersysteem ontworpen en geïmplementeerd. Het resultaat was een database van meer dan vijfhonderd gemelde incidenten die over een periode van minder dan twee jaar verzameld waren.

De resultaten van dit onderzoek omvatten niet alleen de aan het licht gekomen oorzaken van incidenten en de mogelijkheden om risico’s voor patiënten te verminderen, maar ook hoe de gebruikte gereedschappen en methodes in de praktijk presteerden. Het onderzoek laat zien dat, nadat de risico’s voor patiënten waren vastgesteld, het toch moeilijk bleek om verbeteringen door te voeren, voornamelijk omdat het management hier nog niet aan toe was. Alle in dit onderzoek gebruikte gereedschappen en methodes kunnen ook in andere ziekenhuizen toegepast worden.
Acknowledgements

This thesis would not have been possible without the (financial) assistance from the Catharina Hospital, the Scientific Foundation of the Catharina Hospital, and the help of many people over the last few years; see also the list in appendix A. I hope the list includes everyone; my sincerest apologies for any omissions.

I am especially grateful to Albert van den Akker, Astrid van den Hurk, Ger van Venrooij, Karin Mattheeuwissen, Ruud van der Putten and Wim Klaasen for their help in the OR and in the Haemodialysis department. The opportunity for conducting this research in the first place I owe to G. van den Broek: thank you for your trust and support. Peter Timmermans did a major part of the work in the OR, Johan Abels and Lilianne Heemels supported the OR project in every possible way, and Miriam Kroeze and Sjoerd van der Horst helped to eliminate the backlog in the OR and assisted in the reporting of the findings: many thanks for your help, guys. My dear ‘colleagues’ Ad Schakenraad and Winfred ‘Guru’ Gorissen: thank you, those were the days.... Fulco van Westrenen, Wouter Oepts, Eddie Saudrais, Mats Frendahl and the Internet community: thanks for helping me with using LaTeX. Floor Koornneef introduced me to Gerard op de Weegh and the Catharina Hospital, and helped me to get going in the OR. Tjerk van der Schaaf was my tutor during the first few years: I learned a lot from him. Bas de Mol and Andrew Hale: thank you so much for your guidance and for reviewing my writings. Harry Janssen did the final editing of my writings into real English. I also wish to thank Jan Dijkstra and his staff of the EUT’s ICT-institute for their support on statistics. And last but not least, Gerard op de Weegh, my mentor. We started this project together, and now we are finishing it. This would have been impossible without your help: thanks!

To my home front: Riet, Joyce, mum and dad, Selena, Brendan and Sue-Ann, many thanks for your love and support. And, of course, Cheryl, darling, things will never be the same....: thanks for your trust, support, patience and love!

Eindhoven,
17 September 2003,

Bastiën
Curriculum vitae

Bastiën van der Hoeft was born in Culemborg (the Netherlands) on the 27th of June 1968. After V.W.O. (1980–1986) at the ‘Koningin Wilhelmina College’ in Culemborg, he studied Electrical Engineering at the Eindhoven University of Technology (EUT) for one year (1986–1987). From September 1987 to January 1995—with an interruption in 1989—he studied Industrial Engineering and Management Science at the EUT, finishing with a Master’s thesis about risk management in an OR department. This Master’s thesis was awarded by the Mignot foundation as best EUT Master’s thesis of 1995 (second prize). After graduation he worked as a researcher and risk manager at the Catharina Hospital in Eindhoven (the Netherlands) from January 1995 to June 1999. The data and information collected during this period resulted—in cooperation with the Safety Science Group of the Technology, Policy and Management Faculty of the Delft University of Technology—in this thesis. From January 1997 to April 2001, he worked for Ambulancehulpverlening Aven Zevenaar, first as quality manager and shortly after as joint director. Subsequently, he has been working as freelance consultant. At the moment he is working at Atrium Medical Centre in Heerlen (the Netherlands) and with CBO (Dutch Institute for Healthcare Improvement).
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Risk management of patient risks is an important, underexposed part of quality management in healthcare and is by and large still in its infancy. In order to be able to pursue an effective risk management policy, an assessment of the risks the patient runs during his stay in the hospital is necessary. Different risk assessment tools and methods are used in the OR and in the Haemodialysis department of Catharina Hospital in Eindhoven (the Netherlands).

This thesis and CD-ROM do not only give a detailed description of the risk assessment tools and methods used but also contain the data which result from the use of these tools and methods. This should enable readers to improve risk management and to use these tools and methods within their own organisations.