Registration to aid Patient Safety in the Netherlands

A Study into Patient Safety in the Netherlands, with an Emphasis on the Added Value of Registration

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Executive Summary

Patient safety is defined as “Freedom for a patient from unnecessary harm or potential harm associated with health care”\(^\text{iii}\). This research focuses on obtaining patient safety data through registration. Therefore the main research question is:

*How can patient safety be aided by registration, within the constraints and requirements formulated by hospitals, the Dutch government and medical associations?*

To gain insight into patient safety this study has reviewed patient safety theories, hospital registration systems, and the national environment of patient safety and registration. This study concludes that more national guidance should be provided for patient safety. The recommendations made in this study can result in a health care sector in which, instead of being used to assess blame, events will lead to an improvement of medical practice.

Motivation: The publication *Onbedoelde schade in Nederlandse Ziekenhuizen* has estimated that 1734 people died in 2004 after medical errors. These errors cost the sector 167 million euros (1.1% of total budget)\(^\text{i}\). Also in 2004, Shell published a report about safety in Dutch health care\(^\text{ii}\). As a result of this publication Dutch hospitals are, as of January 1\(^{st}\) 2008, obliged to use a registration system to cover all events. The goal of such systems is to gain insight into events to improve current practice.

Results: The goal of registration is to improve medical care by learning, not through assessing blame. Based on the ICPS model of the World Health Organization\(^\text{iii}\) it is concluded that registration systems should focus on system factors, not on human error. Dutch registration systems, however, focus predominantly on the event, the patient and the medical characteristics. Contributory Factors – such as fatigue, workload, and organizational culture – are underrepresented as possible causes of medical events.

The World Health Organization\(^\text{iv}\) has concluded that in the Netherlands not all events are reported. A reason for this inadequate reporting is that hospitals and health care professionals are reluctant to share information. As registration data is hardly protected from use in legal procedures in the Netherlands, information can be used to apportion blame. Secondly, quality is judged by the number of reported events. This implies that not reporting leads to the perception of a higher quality.

To provide a structure for assessing patient safety a model has been developed in this study; the Patient Safety Loop. This model highlights the difference between the direct derivation of quality from the number of events and a more intricate process to assess quality. In this model, not the number of events is important, but the insights gained from them. Based on such insights improvements can be formulated to enhance the level of patient safety, and thereby the overall quality of care.

The process suggested in the PSL can be advanced by national patient safety initiatives. Two national initiatives with a focus on the quality of care – the *Veiligheidsprogramma* and the *Prestatie Indicatoren* of the *Inspectie voor de Volksgezondheid* (IGZ) – have been analyzed as to their acknowledgement of both the system factors derived from the ICPS model and the Patient Safety Loop. The *Veiligheidsprogramma* has been developed by the health care sector with the objective of decreasing the number of adverse events by 50% in the next 5 years\(^\text{v}\). The goal of the IGZ is to assure a minimum level of care.
The Veiligheidsprogramma does acknowledge the existence of non-medical factors and defines several risk reduction actions. But to assess the quality of care, the number of events is predominant. Neither does the program take into account the effect of risk reduction actions.

The Prestatie Indicatoren of the IGZ also rely on the number of events to determine the quality of care. For several indicators it can be stated whether improvement measures have been formulated, but no further explanation is required. This prevents best practices from being shared through the Prestatie Indicatoren. Neither does it provide insight into the effectiveness of improvement measures.

Conclusions: Registration can aid patient safety if the following problems are addressed: inadequate reporting of events and the fragmented handling of patient safety.

Three important reasons for underreporting have been identified. Firstly, registration data is not legally protected from unintended use. Registration data can be used to assign blame and accountability. Secondly, it is not clear how data will be used in for instance quality assessments. These two reasons combined lead to the third reason for inadequate reporting: there is no openness of information in the Netherlands. Both hospitals and physicians are reluctant to share information derived from their registration systems to avoid unintended use of information. This does, however, limit the potential for learning from registration data.

The second problem is the fragmented state of patient safety in Dutch health care. Patient safety is a local topic; every hospital can design its own registration system. As no national taxonomy exists, the various registration systems differ in focus, input, output and use. Not only does this limit gaining insight on a national level, but it has also led to registration systems that focus primarily on the event, and not on the system factors that are present in taxonomies such as the ICPS model.

Recommendations: More national control is needed to enhance patient safety. A safety theory discussed in this study, High Reliability Safety Theory, indicates that although safety can be handled decentralized, it should start centralized to make sure everybody has the same understanding of the matter; in Dutch health care only a limited number of centralized standards have been formulated as yet.

Secondly, national control should focus on the creation of a national patient safety taxonomy – this study recommends the ICPS model – and the acknowledgement of the Patient Safety Loop. A national taxonomy will lead to uniformity in output of local registration systems. A national taxonomy combined with the acceptance of the Patient Safety Loop, will also result in a deeper understanding of the system factors involved.

Thirdly, national regulations should be formulated that deal with the use of data, e.g. the protection of data.

2 Willems, R, (2004), Sneller Beter – De veiligheid in de zorg, Hier werk je veilig, of je werkt hier niet, Eindrapportage Shell in opdracht van het Ministerie van VWS, November 2004
5 VMS Zorg (2007), Veiligheidsprogramma: Voorkom schade, werk veilig in de Nederlandse ziekenhuizen, 12 juni 2007
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Preface

This is the final report of my thesis project, part of my Master of Science study Systems Engineering, Policy Analysis, and Management. The research has been carried out between October 2007 and May 2008.

The initial focus of this research was on the overlap between different registration systems. Gradually this focus has shifted to regard patient safety in a broader scope. A scope needed to explain the actual registration systems and the environment in which they operate. The report, however, is not structured accordingly. Only the final research focus has been used in this report.

The research area is Dutch health care, yet the report has been written in English. One of the implications of this decision has to do with the use of terminology. In the Netherlands a clear distinction is made between different types of events. An explication of medical events can be found in Appendix 4.7.

Secondly, no translations have been sought for unique Dutch medical terminology. Instead these words have been printed in italic font. These terms are commonly known in Dutch health care, translating them could lead to confusion. Therefore all Dutch terminology – words such as *Maatschap, decubitus,* or *Prestatie Indicator* – have not been translated.

I would like to thank those who have helped me during my research. Firstly, I could not have finished this research without the assistance and advises of my supervisors. The process might have been difficult at times; the input did always help in bettering the research.

Secondly, I would like to thank Matthieu for convincing me that patient safety is much more interesting than aviation safety.

Although the research has not focused on the particular situation in these hospitals I would like to thank the St. Antonius Ziekenhuis in Nieuwegein and the Mesos Medisch Centrum in Utrecht for their assistance in this research. I could not have performed this research without them. Everybody was always willing to provide me with information and documentation. I would especially like to thank Els en Berthel for their immense patience in answering all my questions and providing me with the necessary insight into the world of Dutch health care.

Finally I would like to thank my friends and family for their support and advice during this project. Although not featured in my report, I am also very grateful to all those who shared their experiences with Dutch health care with me. Your stories provided the much needed nuances no article or book can reproduce.
Problem Definition

Chapter 1. Introduction

This research focuses on patient safety in the Netherlands. Patient safety is a relatively new term in medicine. It gained exposure after the Institute of Medicine’s report *To err is human* (Kohn, 2000) which estimated that approximately 98,000 people die every year due to medical errors, in the United States alone. In the Netherlands patient safety became part of the health care debate after the Sneller Beter report by Rein Willems (Shell Netherlands) *Hier werk je veilig, of je werkt hier niet* (Willems, 2004). This report estimated that – in the Netherlands – about 1500-6000 patients die every year due to a medical error (Willems, 2004).

The research *Onbedoelde schade in Nederlandse Ziekenhuizen* estimated that 1734 people (95% CI 1482-2032) died due to medical errors in 2004 (Bruijne, et al, 2007). Further conclusions of this report were that (Bruijne, et al, 2007):

- Approximately 30,000 patients experienced preventable errors (2.3% of total patients)
- For approximately 10,000 patients this resulted in permanent harm, in 6,000 cases it was deemed probably that this harm could have been prevented
- The hospital stay of patients experiencing preventable errors increases on average with 10 days (costing on average 5600 euro extra per patient)
- Hospitals had to spend 167 million euros on handling preventable events (1.1% of total budget)

These figures suggest that there is room for improvement with regard to patient safety in the Netherlands. This research will provide the health care sector with tools that can aid in the improvement of patient safety.

1.1. A Culture of Safety

"The safety culture of an organization is the product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety programmes. Organization with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures."

Reason, 2000, cited from the UK’s Health and Safety Commission

To achieve such a culture of safety Reason argues that a safety information system is of critical importance and that such a system should primarily focus on organizational incidents instead of individual incidents (Reason, 2000). For an information system to function as intended a proper safety culture is required. He defines five crucial characteristics of such a safety culture.

- “Any safety information system depends crucially on the willing participation of the workforce, the people in direct contact with the hazards. To achieve this, it is necessary to engineer a reporting culture – an organizational climate in which people are prepared to report their errors and near-misses” (idem).
- To achieve a reporting culture the organization furthermore needs a just culture. "An atmosphere of trust in which people are encouraged, even rewarded, for providing
essential safety-related information – but in which they are also clear about where
the line must be drawn between acceptable and unacceptable behavior” (idem).

- A third characteristic is the flexible culture an organization should have. This
characteristic has been derived from high-reliability organizations where power is
diverted to the Experts on the spot in case of an emergency. This topic will be further
discussed in Part III, Chapter 10 where it is called ‘Deference to Expertise’.
- Fourthly, an organization needs to adopt a learning culture. People must be willing to
learn from events, but equally the means necessary must be provided to derive
conclusions from information systems and to implement these insights.
- “All of these activities can be said to make up an informed culture – one in which
those who manage and operate the system have current knowledge about the
human, technical, organizational, and environmental factors that determine the
safety of the systems as a whole” (idem).

Within health care the described safety culture will be further demarcated to patient safety.

### 1.2. Definition of Patient Safety

There is not one definition of patient safety. Many researchers have tried to come up with an
all-inclusive definition. This research will not propose yet another definition of patient safety,
but instead two definitions are presented. Both definitions are accepted in the medical field.
The first one has been defined by the World Alliance for Patient Safety of the World Health
Organization; in this committee patient safety Experts from all over the world take seating.
The second definition has been created by another Expert and this definition has been used
in many patient safety documents (e.g. Pronovost, 2005).

<table>
<thead>
<tr>
<th>Patient safety:</th>
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<tbody>
<tr>
<td>1) “Freedom for a patient from unnecessary harm or potential harm associated with health care.” (WHO, 2005)</td>
</tr>
<tr>
<td>2) “The absence of the potential for, or the occurrence of, health care associated injury to patients created by avoiding medical errors as well as taking action to prevent errors from causing injury.” (Marx, 2003)</td>
</tr>
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</table>

Although the term ‘patient safety’ suggests patients to be the core component of patient
safety this is not the case. The subject in patient safety is the medical staff. They create a
safe or unsafe situation for the patient. The patient is just the object that undergoes the
treatment (lijdend voorwerp in Dutch). Patients want good care but other than not
consulting a certain physician they have hardly any influence over their own patient safety.
Most measures to improve patient safety are directed at the care giver as the medical staff
can improve the overall patient safety situation.

Based on the definitions above it can be concluded that in order to improve patient safety at
least the causes of the unsafe situation – the potential for harm – need to be known. To gain
this insight data is needed, data that can be derived through the registration of events.
Therefore the main patient safety measure in this research is the registration of events.

### 1.3. The Progress of Health Care

Through registration insight into the medical process can be gained. The process of hospital
care usually follows the following steps:

- Intake of the patient
Yet what exactly goes on during treatment and nursing is often not known. The most important reason for this is that not every event or (near) mistake can be recorded. Health care incorporates a lot of tacit knowledge; experience determines action as much as more formal guidelines. Secondly, every patient and every treatment incorporate a certain risk, which can result in unwanted outcomes. Therefore the care process is deemed a 'black box'. Although parts of what happens are known, many issues remain uncertain or unknown.

Unsafe events can happen at any time during this process. It is important to note that unsafe events are not always caused by human actions. If a patient has an allergic reaction – while no-one, including the patient knew of this allergy – it is also classified as an unsafe event, even though no-one can be held accountable for the occurrence of this allergic reaction.

1.4. Medical events

In Dutch health care a clear distinction has been made between different medical events. Events during the process of care are called ‘incidents’ and events relating to the outcome of care are called ‘adverse events’. An overlap between the two is possible. Such events are called preventable adverse events.
This research mostly follows the terminology provided by Wagner (Wagner, 2005). A more thorough explication of medical events can be found in Appendix 4. In this appendix it is also explained where and why this research deviates from the terminology as proposed by Wagner.

1.4.1.1. **Adverse Event**

"Een onbedoelde en ongewenste uitkomst tijdens of volgend op het handelen van een zorgverlener, die voor de gezondheid van de patiënt zodanig nadelig is dat aanpassing van het (be)handelen noodzakelijk is dan wel dat sprake is van onherstelbare schade." (Wagner, 2005)

1.4.1.2. **Incident**

"Een onbedoelde gebeurtenis tijdens het zorgproces die tot schade aan de patiënt heeft geleid, had kunnen leiden of (nog) kan leiden." (ibid)

1.4.1.3. **Near Miss**

"Een onbedoelde gebeurtenis

a. die voor de patiënt geen nadelen oplevert omdat de gevolgen ervan op tijd zijn onderkend en gecorrigeerd (near miss),
b. waarvan de gevolgen niet van invloed zijn op het fysiek, psychisch of sociaal functioneren van de patiënt." (ibid)

1.4.1.4. **Preventable Adverse Event**

"Een onbedoelde uitkomst die is ontstaan door het niet of onvoldoende handelen volgens de professionele standaard en/of door tekortkomingen van het zorgsysteem met schade voor de patiënt zodanig ernstig dat sprake is van tijdelijke of permanente beperking, verlenging of verzwaring van de behandeling dan wel overlijden van de patiënt." (ibid)

Some examples of incidents:
- Giving food to a patient right before surgery
- A patient falling out of bed

Some examples of adverse events:
- A wound gets infected after surgery
- An allergic reaction which leads to prolonged stay
- An bleeding due to an unintended puncture during surgery
1.5. The Medical Sector

A hospital is a private organization; healthcare is mostly paid for by private institutions (insurance companies) and yet healthcare is a public good. A hospital has to be run like a regular business, with a cost efficient business model. So care becomes an efficiently distributed resource, which can result in management decisions to schedule as little nursing staff as possible to serve as many patients as possible.

There are discrepancies though. First, care cannot be refused, even if the patient is not sufficiently insured and cannot afford it. Second, extra care – possibly but not necessarily as a result of complications (even when inflicted by the patient) – is not always completely refunded by insurance companies.

Thirdly, the healthcare industry is gradually adopting a free market system. Acute care and high risk care remain public care duties, whereas planable care is more and more left to the market. This is care on which (higher) profits can be made and it is moving from specialized hospitals to general hospitals to private practices.

Fourthly, insurance companies are gaining more power. They try to create a system in which they only pay for care received in hospitals with which they have an agreement. They state the selection of approved hospitals will be based on quality of care (FD, 03-12-2007, Willems, 2004). How the market will progress and how quality will be measured remains uncertain. It does mean, however, that a debate will commence on how to measure quality and what should be considered part of the equation. All of these developments could have severe implications for the status, funding and working possibilities of hospitals.

Healthcare is becoming a “consumer good”, patients know what they want and are becoming more demanding and outspoken. Patients are much better informed when they arrive in the hospital. This changes the doctor-patient relationship to a more advising role (St. Antonius Ziekenhuis, 2007). This development can have both negative and positive influences on patient care.

Patients are seen as the last chain in the process of insuring patient safety. Many project groups are working nationwide to create awareness among patients. Patients can and should speak up when they – for instance – find unexpected medication on their bedside table. On the other hand, because patients are becoming more demanding and outspoken, they feel ill treated more quickly and are more likely to press charges if they are not content with the medical care received. This development can be seen in the United States, but in the Netherlands too patients can and do press charges against physicians1.

Another implication of this change in patient’s perspective on care is that hospitals nowadays have to ‘prove’ their quality. This can, for instance, be seen in listings of ‘the best hospital’2. Whether these tests give a correct ranking is debatable. In a recent test in the United States, the best hospital in the state dropped from one year to another to a much lower ranking, purely because they “implemented standardized surveillance” (Berenholtz, 2007). This was done to learn from errors and in fact the care given was still of high quality.

An example from the Netherlands is the ranking of the Volkskrant of retirement homes3. This comparison did not take into account that some homes actively report incidents where others do not. Homes with a policy to improve reporting have a higher number of reported events, but whether these homes experience more events than other homes cannot be assessed based on this data. Even so, not reporting resulted in ending at the upper part of this ranking as the study assumed that the number of reported events is equal to the number of occurred events. It is easy to question the reliability of this ranking as not

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1 Mss. S. Hankes uses the media to attract attention to her case.
2 Algemeen Dagblad, Elsevier, and Volkskrant (beste verzorgingshuis)
3 www.volkskrant.nl/achtergrond/binnenland/verpleeghuizen/ (11-03-08)
registration does not equal not happening. Reporting at least provides insight, which in turn gives way to improvement. These examples illustrate the distorted image (commercially developed) rankings of such a difficult to rank industry as healthcare can potentially produce.

### 1.6. Research Objective

Registration of causes of medical events is relatively new in Dutch healthcare. Traditionally registration was focused on the impact events had on patients and – if applicable – the persons responsible for the event.

A desired method to improve patient safety has been defined by the government; hospitals have to register every event and lessons have to be learned. This will improve the level of patient safety and thus the quality of care (Willems, 2004).

A large part of this research will constitute the analysis of the present system and the prospective environment in which registration has to be implemented. What is reported and how it is reported depends on the conditions present or defined by the sector itself. Therefore specific attention shall be paid to the context in which registration of events has to constitute.

The goal of this research is to provide the Dutch healthcare sector with a more conclusive insight into patient safety. This research will not provide a functional design for patient safety nationally; it will highlight all relevant issues, within the identified constraints. This will constitute an analysis that will provide:

- The requirements derived from patient safety theories for a registration system
- The coverage of these requirements in the Netherlands
- The requirements/constraints presented by stakeholders with regard to the use of registration systems
- The requirements/constraints of using registration data
- Insight into the handling of patient safety in other countries

### 1.7. System Boundaries

This research will focus on the position of registration of medical events in the Netherlands. The focus of this study has been limited on a number of issues:

- This research will only deal with patient safety
- The research will only focus on the process of care, not the actual care and cure provided
- The research will focus on data gathering through registration
- The research will only focus on the obtainment of data, the use of data will not be discussed
- This research will not discuss the organizational structure of hospitals
- The research will not provide quantitative proof of conclusions

These demarcations stem from the following considerations. Every hospital has a unique structure and culture, therefore no conclusions with respect to the organizational layout will be formulated. Every hospital should be able to use the conclusions made in this research and evaluate to what extent they are apparent or implementable in their organization. What hospitals do have in common is the fact that none will ever be error free. Not without reason does the title of one of the most influential patient safety studies read “to err is
human (Kohn, 2000). This research will first address the lowest level of patient safety (the micro level). This constitutes patient safety and the obtainment of patient safety data. In order to formulate improvement measures proper data is needed. This will be the first focus point of this study.

Another factor that is equal for all health care organizations is the national environment of health care (the macro level) in which they have to function. National rules, regulations, and initiatives are the same for every hospital and thus determine how each individual hospital will deal with patient safety. This environment and the impact it has on registration will be the second focus point of this study.

1.7.1. Different Types of Safety

A constraint is that this research will only deal with patient safety. In a hospital several types of safety exist. Occupational safety is targeted at personnel; this type of safety is covered in the ARBO wet. (Occupational Health and Safety Act). Safety of equipment is a very different field of research. It can touch upon patient safety or occupational safety but has a different focus. Other issues generally associated with the term safety also are not relevant for patient safety; so evacuation plans, construction, building etc. are not considered.

1.7.2. Process of Care & Cure

Adverse events can happen without an actual incident taking place, e.g. infections can develop and treatments incorporate certain risks. Such adverse events can occur even though the care and cure provided were excellent, therefore they are deemed unintentional and unavoidable. Other adverse events do stem from the provided care and cure; they are deemed unintentional yet avoidable (de Bruijne, 2007).

A second difference is made between medical factors and non-medical factors. Medical factors lead to unavoidable adverse events and will not be taken into account in this research. Non-medical factors relate to the process of care. Making the wrong diagnosis, communication difficulties, fatigue, or equipment failures can occur in any process of care or cure. They can lead to avoidable adverse events and incidents. They happen regardless of the patient. Consequently process improvements focus not so much on the actual care or cure but much more on the organizational aspects of providing care and cure. This research will only focus on the added value registration can have in identifying such non-medical factors.

1.7.3. Registration

There are many instruments to gather data about the quality of health care. Valuable insight can be gained through interviews, safety WalkRounds (WHO, 2005), focus groups, Expert analysis of medical records, Bow-tie analyses, or observation.

This research will only focus on registration systems. The Sneller Beter report by Shell (Willems, 2004) advised that health care organizations should implement registration systems to gain insight into patient safety. As a result since January 1st 2008 it is compulsory for hospitals to have such a registration system. This research focuses on the added value such registration systems can have for patient safety.

All the other data gathering methods can be used alongside registration systems to provide a complete overview of the quality of health care.

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4 English saying, Dutch equivalent: ‘vergissen is menselijk’
1.7.4. **Focus on Data Gathering**

The research conducted in this study only focuses on data gathering. Using the data is equally important, but the assumption is made in this research that ‘good improvement measures can only be created and evaluated if proper data is available’. This use of data does provide requirements for data gathering, when applicable such requirements will be discussed. Further research should be conducted into the use of data, the implementation of improvement measures, and the evaluation of improvement measures.

1.7.5. **The Organizational Structure of Hospitals**

This research will only regard registration of medical events in hospitals. Health care provided in nursing homes, general practitioners offices, private practices (health care clinics that specialize in a specific type of care, for instance cosmetic plastic surgery), or other health care facilities will not be discussed.

Hospitals in the Netherlands can be divided into three types. Academic hospitals perform specialized care and are connected to a university; top clinical hospitals provide specific specialized care; and general hospitals provide basic care to a certain geographical area. Another difference between hospitals is the existence of Maatschappen. In top-clinical and general hospitals the physicians often work in legally independent entities called Maatschappen. No indication has been found to conclude that the existence of Maatschappen impacts the level of patient safety.

Therefore this research will not discuss this specific part of the structure of hospitals. Since the organizational structure of hospitals is not regarded as a deciding factor for patient safety and the structure will not be further elaborated upon no further research has been conducted to test this assumption. Secondly, the conclusions made with regard to patient safety should be applicable to all hospitals; regardless of their organizational structure.

1.7.6. **Quantitative Data**

This research is of a qualitative nature. Registration of events is not standardized in Dutch Health Care. In the annual report of the Inspection, for instance, it is concluded that not every hospital uses the same detection measures for decubitus⁵ (IGZ, 2006). Secondly, reporting is voluntary and it is known that not everything is reported (Berenholtz, 2007). The implication of these observations is that data from different hospitals cannot be compared. Hospitals do not report the same incidents based on the same categorization; therefore separate hospitals cannot be compared as the comparison data is different.

Next, this difference in reporting also means that no national insight can be provided. The data of different hospitals cannot be combined and analyzed. Since the data is not of the same nature this would lead to distortions in the outcomes, making the outcomes less reliable. The IGZ does require hospitals to provide certain Prestatie Indicators annually to assess the quality of health care in the Netherlands. Part IV will discuss these Prestatie Indicators.

Data will neither be analyzed within a single hospital. The World Health Organization has concluded that there is inadequate reporting in the Netherlands (WHO, 2005). Several health care specialists have provided the same statements. Not all incidents are reported, some incidents are reported more accurately than others, and the ratio reported/unreported incidents in unknown. An added issue is that reputation is very important in health care – as will be discussed in Part III and Part IV – so hospitals are weary of providing details about incidents.

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⁵ decubitus is commonly known in Dutch language as ‘doorligwonden’.
Therefore a quantitative research will not be performed. First the data has to improve. It does provide an interesting topic for further research.

### 1.8. Introduction to Technological, Institutional and Process Perspective

The problem of patient safety registration in the Netherlands has been evaluated from three different perspectives in this research: the technological, the institutional, and the process perspective. Since the report will not be structured in accordance to these perspectives, this paragraph will address where these perspectives can be found in the report. The actual structure of the report will be explained in a subsequent paragraph.

As stated this research has a qualitative nature. The result of this decision is that technological analyses are concluded with qualitative overviews. Both the analysis of patient safety taxonomies in Part I as the analysis of the application of registration systems to the research problem in Part II are largely the result of technological analysis methods. In Part I the multi criteria analysis results in a choice for a patient safety taxonomy that can be regarded as the basis for the remainder of the research. In Part II the analysis elaborates on the registration systems in the Netherlands. Their function, outline, overlap and coverage are discussed.

The inclusion of non-medical causes in registration systems is in part dependent on the institutional context in which registration takes place. The institutional analysis of the research problem is mostly found in Part IV which deals with the national rules and regulations concerning patient safety and registration data. This perspective has also contributed to the other Parts.

Part III deals with patient safety and registration in a hospital. The insights presented in this Part are mostly the result of the process perspective on the research problem. This part contains a stakeholder analysis of the hospital, alongside with a discussion about the implications this multi-actor context has on the registration of events. All actors want to provide the best quality of care, but they also have personal goals that need to be fulfilled at the same time.

### 1.9. Research Questions

This research deals with the position of patient safety in the Netherlands. To gain insight into this patient safety the research will focus on the use of registration systems. These systems can provide insight into the causes and outcomes of events; thus in the level of patient safety.

The main research question in this research will be:

*How can patient safety be aided by registration, within the constraints and requirements formulated by hospitals, the Dutch government and medical associations?*

To structure this research the parts address the following questions (sub research questions):

- **Part 1.** What does patient safety constitute?
- **Part 2.** Do the different registration systems together provide a coherent insight into the identified causes of patient un-safety?
Part 3. What are the challenges and opportunities for registration created by the hospital environment in which registration should commence?

Part 4. What are the challenges and opportunities for registration created by the Dutch government and medical associations?

1.10. Research Methods

For this research the following research methods have been used:
- Literature Research
- Interviewing. Both medical and registration Experts have been interviewed.
- Expert analysis. Assessments made of the registration systems have been checked by Experts.
- Multi Criteria Analysis
- Stakeholder Analysis

Several of these methods can be found throughout the report. The report is structured according to the problem layout, not chronologically. Therefore all research methods can and have been used simultaneously.

1.11. Output of this Research

This research has resulted in the following output:
- A recommendation for a suitable patient safety taxonomy to be used in the Netherlands
- Insight into the implications of the multi-actor context of the Dutch health care system on patient safety initiatives
- A model – the Patient Safety Loop – to be used in the assessment of quality
- Insight into the current assessment of patient safety both locally and nationally
- The positioning of Dutch patient safety initiatives within the patient safety focus world wide

1.12. Report Structure

The main subject in this research is the added value of registration for patient safety. The structure of this report can be represented as four layers (see Figure 3: Layer Model).

Each layer explains the environment in which the underlying layers operate. The report starts with patient safety. Next the registration systems, aimed at increasing the insight into patient safety are discussed. After that the context in which registration takes place – the hospital – is addressed. With special emphasis on the impact hospital personnel has on patient safety. Finally the national context of health care and patient safety is discussed.

1.12.1. The Added Value of Registration

The first two parts of this report will discuss patient safety and registration. The first part deals with patient safety. The focus on patient safety in the Netherlands has not lead to the
national creation of a patient safety taxonomy. Therefore several international patient safety taxonomies will be discussed and analyzed on their usefulness. Several criteria have been formulated and the taxonomies will be analyzed in a multi criteria analysis.

Part II will deal with registration. To gain insight into patient safety medical events are reported in the Netherlands. For this purpose several registration systems have been designed. Some of these are hospital bound, others are nationalized. These registration systems should provide the data needed to gain insight into patient safety. Together they should cover the entire patient safety cycle. Therefore these registration systems are assessed on their accordance with the patient safety taxonomy chosen in Part I.

In these parts both patient safety and registration are evaluated without regard for their context. The analyses are carried out in a perfect setting, with no exterior influencing factors. This is not a correct representation of the health care system. One of the problems identified with regard to the registration of events is, for instance, that not everything is reported. Such exterior influences will determine the successfulness of registration systems.

1.12.2. The Position of Registration and Patient Safety in the Context of Dutch Health Care

The last two parts will focus on the environment in which registration and patient safety take place. Part III will focus on registration in a hospital. This part will discuss the stakeholders in a hospital, their dependence on each other and the environment in which patient safety and registration take place. The discussion of the environment in a hospital will be structured based on the safety theory: High Reliability Organization Theory.

Based on the insight gained safety theories and the stakeholder the Patient Safety Loop has been designed. Often quality is assessed based on errors; the more errors the lower the quality of care. The Patient Safety Loop replaces this direct relationship with a more complicated loop. Not the number of errors is deemed important, but the insight gained from events and the actions taken accordingly to heighten the level of patient safety. This then determines the quality of care.

Assessing quality through the Patient Safety Loop is also a national issue; a hospital cannot design all its rules and regulations. Health care is governed by the government, medical interest groups, and other interest groups that define the playing field in which hospitals deal with patient safety issues. Therefore Part IV discusses patient safety in the Netherlands. Patient safety is an important topic in Dutch health care. Many initiatives have been formulated in recent years targeted at patient safety and the current State Secretary for Health Care (minister Ad Klink, Ministerie van Volksgezondheid, Welzijn en Sport) has made patient safety one of the core issues of his term (Klink, Speech, 2007). Several initiatives will be discussed in more detail, especially their accordance with the Patient Safety Loop.
PART I: Patient Safety

In the Problem Definition two definitions of patient safety have been given. Furthermore the research has been demarcated to focus primarily on data gathering. Regardless of the event, any event can be the result of multiple causes and can lead to multiple outcomes. To gain insight into these causes and outcomes internationally several patient safety taxonomies have been created. Since there is no standard Dutch patient safety taxonomy, these international taxonomies are reviewed in this part for their potential application to Dutch health care.

To gain insight into the problem of patient safety the following research question will be answered. This question is further specified into three sub-questions.

<table>
<thead>
<tr>
<th>What does patient safety constitute?</th>
</tr>
</thead>
<tbody>
<tr>
<td>❖ What is meant by patient safety?</td>
</tr>
<tr>
<td>❖ There are different patient safety taxonomies, what are the differences and similarities between these systems?</td>
</tr>
<tr>
<td>❖ Why is the chosen taxonomy more applicable in the context of this research than other models?</td>
</tr>
</tbody>
</table>

This part will commence with a discussion of three patient safety taxonomies or models. Each of these models will be rated based on several criteria. Based on this multi-criteria analysis one of the models will be chosen as the basis for patient safety insight throughout this research.
Chapter 2. Patient Safety Models

In order to improve patient safety internationally many research institutions have tried to create comprehensive and usable patient safety models or even more elaborate taxonomies. Some models have been derived from medical practice, others from other industries, mainly high reliability organizations. Only three will be further elaborated upon. The mentioned models all focus on patient safety and provide much the same insights.

- The PSET model, created by the Joint Commission for the Accreditation of Health care Organizations (JCAHO), United States of America (Chang, 2005)
- The ACM model, created by Woloshynowych M, ed al, for the National Health Service, Great Britain (Woloshynowych M, 2005)
- The ICPS model, created by the World Health Organization (WHO). This model is fairly new and is still under construction. It is a combination of best practices of several of the mentioned models.

Other patient safety models or taxonomies are:
- The AIMS model, created by the National Centre for Classification in Health Care, Australia (Runciman, 2006)
- The PRISMA model, created by T. van der Schaaf, TU Eindhoven, based on the chemical industry (Schaaf, van der, 2005)
- The models of Helmreich and McFadden, both based on aviation safety. (McFadden, 2004; Helmreich, 2000)

The PSET model focuses on the entire spectrum of patient safety, including causes and impact, but also associated risks and prevention methods. The ACM model focuses on the causes of the event, leaving all other issues unattended. It is, however, much more explicit about possible causes than the PSET model. The ICPS model is based on both the ACM and PSET model. It provides the overview of the PSET model, while maintaining the level of detail of the ACM model.

The choice for the ACM and PSET models is based on the following arguments. Firstly, both were created by highly esteemed governmental agencies; the same counts for the AIMS model and in a lesser extent for the PRISMA model. This model was created at the Technical University of Eindhoven, but is used throughout Dutch health care to evaluate incidents.

Thirdly, within the spectrum of patient safety models the PSET and ACM models can be seen as representatives of two extremes. Where the PSET model does not go into detail, but focuses on the entire domain of patient safety, the ACM is specifically interested in the causes of an event, not taking into account the actual incident or its impact.

Fourthly, the ACM model and the AIMS model are both based largely on the models and frameworks by Rasmussen and Reason, depicting causative factors. Analyzing both is therefore unnecessary, so one was chosen.

All these arguments are also applicable to the ICPS model. Since this model has been based on the ACM model, PSET model, AIMS model, and PRISMA model, it has not been used in the argumentation above.

A detailed explication of all models can be found in Appendix 2. In this chapter the models are described in more general terms.

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6 Appendix 4 will elaborate on Reason’s model and describe these factors in more detail
2.1. ACM Model

The ACM model has been developed in Great Britain by the National Health Service (NHS R&D Health Technology Assessment (HTA) Programme). The model is based largely on human factors engineering. This school of research is described as “a hybrid discipline that focuses on the human component within complex socio-technical systems” (Vincent, 1998). The specific goal of this model is that there should be “less focus on the individual who makes an error and more on pre-existing organizational factors that provide the conditions in which errors occur” (Vincent, 1998).

The ACM model only looks at the causes of an event and the barriers in place to prevent the incident from happening. The impact or prevention measures to prevent it from happening again are not addressed. The model does not acknowledge that incidents can happen without the involvement of an active failure made by care givers.

One of its main features is the explicit depiction of causal relations between different causes. The model depicts how the organizational culture creates an environment in which certain contributory factors can take place, thus leading up to a situation in which errors can be made. Latent failures stemming from the organizational culture can be present in an organization for years without leading to incidents. Within the organizational culture contributory factors can be identified. These contributory factors have been divided into five groups. Factors can relate to the work, the team, individuals, the task, or the patient.

Several of these – often intertwined – factors create the opportunity for a care giver to make an active failure, which in turn can lead to the incident. Throughout the organization barriers and defences are devised to prevent an active failure from causing an incident; e.g. double checking medication before administration.

Figure 4: ACM model, depicted after Woloshynowych, et al, 2005

2.2. PSET Model

The PSET model was created by the JCAHO (Joint Commission for the Accreditation of Health care Organizations7) in the United States of America. The goal of the model – to provide a national basis for data collection – has lead to a general terminology. Compared to the ACM model it does not provide the same insights for care givers. The result of this aggregation level could be that the model leads to a classification of events, without providing insight into improvement measures.

The model is a typical example of a root cause analysis methodology. Such models aim at identifying a single cause or a few causes of an event; they do not provide the opportunity to trace an event back to a multitude of intertwined conditions.

7 www.jointcomission.org (viewed on 15-04-2008)
The model depicts the same kind of causes as the ACM model. It does not depict the sequential appearance of causes, but it does differentiate between human error and latent factors. It also explicates the three types of human error defined by Rasmussen.

The PSET model does not depict the incident itself, but categorizes it according to the type of process that led to the incident and the impact it has had. The impact is categorized on the harm caused to a patient; other outcomes are not taken into account.

The degree of harm to a patient is susceptible to subjective interpretations. It is a gliding scale with five options: none – mild – moderate – severe – death. This is a typology seen in many taxonomies and registration systems. However, such a scale has to leave no doubts about for instance the differences between mild or moderate impact.

The PSET model deals with the overall patient safety cycle; this includes the risks created by certain causes or types of events and the prevention and mitigation measures needed to decrease these risks. These prevention and mitigation measures have already been defined (Chang, 2005). They are more specific than the other parts of the model, e.g. one of the prevention measures is ‘improve the accuracy of patient identification’.

### 2.3. Differences between the PSET and ACM Model

The PSET model depicts the overall system, including prevention and mitigation measures, but as the aggregation level is higher it might not provide useful insights to a department of a single hospital. The ACM model provides a very thorough insight into the causes of an event, but not into how to deal with them.

A difference between the PSET and ACM model is the positioning of human error. In the PSET model a human error (for instance: a misinterpretation of a medication prescription) is a human failure leading up to a communication type event. The ACM model regards the same event as a failure in communication creating the opportunity for human error. Basically there is a difference of opinion as to what can be deemed the cause and what the resulting effect.

### 2.4. ICPS Model

The World Health Organization has started the World Alliance for Patient Safety (WHO, 2003), to create the International Classification of Patient Safety (WHO, 2006). An improvement is the visual differentiation between medical issues, contributory factors and risk assessment parts in the overall model (see Figure 6).
The goal of the ICPS is to “enable the global health care community to review, evaluate and learn from near miss and adverse event data at the international level as well as develop evidence-based preventive strategies by eliciting, capturing and analyzing factors relevant to patient safety in an adaptable yet consistent way across the entire spectrum of health care and across cultures and languages” (WHO, 2006).

The most important classes of the model are the Incident Type and Patient Outcomes. These classes do not only function as ranking variables to cluster events into groups, but they are also used to identify events (WHO, 2006).

The ICPS covers the same Contributory Factors as the ACM model. One of the insights provided by the ACM model is that the organizational structure or culture creates an environment in which certain contributory factors appear, which in turn can lead to personnel committing errors. The ICPS positions all these factors on the same level, insinuating they happen and appear simultaneously. A possible explanation is that the depiction of this causal relation is not possible in a root cause analysis structure, a treelike depiction of causes.

Once an incident occurs, there are different ways of detecting it and different actions that should be taken immediately to limit the impact of the incident. The model explicitly lists the impact incidents can have on the organization. Based on the information gathered from incident reports Risk Reduction Actions can be taken. These actions are not specifically targeted at a specific incident, but aid in identifying and limiting the impact of Contributory Factors, and improving Detection and Mitigation. Risk Reduction Actions can focus on the patient, staff, the organization and its environment, or equipment.

In 2005 the Drafting Group released a first version of the ICPS. This version has been thoroughly tested in a two round Delphi survey; each round lead to numerous adjustments (WHO, 2007). For further details see references, this research will use the latest released version of the ICPS. This is the classification depicted in Figure 6.

Proper medical conduct – unintentional and unavoidable events – is not addressed in the model. Two classes of Incident Type acknowledge proper medical conduct. In the class ‘Medication’ an ‘Adverse Drug Reaction’ can be identified as the problem. Also ‘Blood/Blood Products’ provides the opportunity to categorize a problem as an ‘Adverse Effect’. The other Incident Types do not have an equivalent problem categorization.
The ICPS attempts to classify the event, its causes, and its impacts as objectively as possible. No blame is appointed, no opinions asked. This is needed to assess events without personal opinion. Only events dissected on objective assessment criteria can be compared objectively which in turn leads to generally applicable Ameliorating Actions. Yet the model has copied the Patient Harm scale of the PSET model, which is prone to subjectivity.

The final remark about the ICPS model is the impact events have on staff. The classification does list ‘Staff Counseling’ and ‘Training’ as ‘Ameliorating Actions’. Also the ‘Actions to Reduce Risk’ lists ‘Training’, ‘Supervision’ and ‘Assistance’ as actions that can reduce the possibility of the event happening again. But the impact an event can have – both physical and psychological – on staff is not dealt with in the model.
Chapter 3. Multi Criteria Analysis

To assess which patient safety taxonomy provides the most promising basis for patient safety in the Netherlands the described models will be analysed in a multi criteria analysis. First, the analysis method will be explained. After which the analysis itself is presented.

3.1. Analysis Method

Three patient safety classifications have been discussed. Each one has benefits and drawbacks. To assess which classification is most appropriate for usage in the evaluation of Dutch patient safety registration systems a multi criteria analysis is conducted. In this analysis all three models are assessed on their accordance with the defined criteria; an explanation of the criteria can be found in Appendix 3.

For this multi criteria analysis all criteria have been valued equally. The analysis has not regarded potential scenarios or strategies. Stakeholders can adjust the table to reflect personal requirements. Physicians, for instance, might value the 'acknowledgement of proper medical care' higher than the 'inclusion of near misses'. Such preferences can be included into the table by adding weights. Such weights can change the conclusions depicted in Figure 7.

The goal of this study is not to assess the system from the view of one stakeholder, therefore such personal requirements have not been taken into account and all criteria are regarded as equally important.

Possible scenarios have neither been taken into account. Future developments can alter the importance of certain criteria. If legal liability, for instance, becomes more important in the Netherlands, anonymity will become an important issue with regard to registration data. This study only explicates the current situation in the Netherlands. No scenarios are discussed; therefore their impact on the analysis is not included.

The analysis has been done in a qualitative way. The compliance of each model with a criterion can be valued as YES, PARTLY, or NOT.

3.2. Criteria

The three models have been assessed on their usability for the registration of medical events in the Netherlands. This assessment is based on several criteria. These criteria have been derived from literature and will feature in several other chapters as well (more in Appendix 3).

Not all criteria purely focus on the registration of events. After registration the model should also provide assistance in dealing with events. This might not be of importance directly to this study, but it does provide essential insights for hospitals. Therefore not incorporating these factors would limit the model to a scientific exercise, not appropriate for practical usage.

The criteria that will be used for this assessment are:

- A. Objectivity
- B. Coverage of entire patient safety quality cycle
  - a. Incorporate prevention measures
  - b. Incorporate detection measures
- C. Address contributory factors
- D. Acknowledge causal relations
- E. Identify the incident
- F. Move beyond human error
a. System error
b. Type of human error

G. Anonymity
H. Include both incidents and adverse events
I. Address near misses
J. Acknowledge proper medical care
K. Overall provide detailed insight

Table 1 classifies whether the models comply with the defined criteria. As can be seen neither model covers all criteria.

The ACM model represents a very complete classification of the causes leading up to an event. Especially the causal relation between different levels of factors can provide insight into patient safety. A shortcoming of this model is that does not incorporate adverse events, in which no error has been made, but where the harm to the patient has been a result of adverse effects. Another drawback with this model is that is only depicts the causes of an event. It does not represent the impact or prevention measures.

The PSET model provides a taxonomy of the entire patient safety field. It does so at a very high aggregation level, this makes the model unsuitable for single health care organizations. Many issues associated with patient safety are not represented in this model; this could be the result of the aggregation level.

The third model is the ICPS model. The ICPS model has been based on four existing classifications, among which the ACM and PSET models. The model does not include the causal relations of the ACM model. To provide more insight into the incident the ICPS model (as does the PSET model) requires details about the location of the incident and those involved. This could be a threat to the anonymity of the reporter. This issue could be solved with adequate guidelines for using filed data. More on this subject can be found in Part IV.

### 3.3. Conclusion regarding the MCA

The assessment table has been condensed to provide more insight; this is shown in Figure 7: MCA chart. Based on the insight gained in all models the ICPS model is found to be the most complete patient safety classification. It covers the entire patient safety field and manages to do so in a detailed manner. This makes the classification suitable for national and local (meaning one health care organization) use.

In Part II a Dutch system used for the registration of medical events will be discussed. The basis of this assessment will be the ICPS model. The ICPS model does not cover all identified criteria. It does not acknowledge the causal relation between causes. This can provide a problem with analyzing data to derive
insights needed to improve current practice. It does not hamper the registration of events. Therefore this issue will not be a problem for the remainder of this study. Several issues are partly addressed by the ICPS model. These issues can impact the usability of the ICPS model, for instance the objectivity of the model. These issues will be discussed in subsequent chapters.

**Chapter 4. Conclusion Part I: Patient Safety**

The main question asked in Part I was:

> What does patient safety constitute?

To answer this question Part I started with a general demarcation of the research field. Patient safety is a relatively new field of research in health care. There is not yet a single, universally accepted, definition of patient safety. From the presented definitions it can be distilled that patient safety firstly focuses on the causes of an event. To gain insight into these causes several taxonomies and classifications have been devised. By means of a Multi Criteria Analysis it has been concluded that the ICPS model provides the most exhaustive depiction of patient safety and related issues. This model covers the entire quality cycle and addresses causes, the incident, impact, and risk reduction acts. This model shall be used throughout the rest of this research. The most important asset of the ICPS model is that it carries enough detail to be of use on a decentralized level, while at the same time providing insights useful on a hospital wide or national level.

In the Problem Definition the research area has been demarcated to the registration of events. Patient safety can be improved through Risk Reduction Actions. To formulate these actions insight is needed into the causes of patient safety. To gain this insight information is essential. Since patient safety is a new subject in Dutch Health Care this research focuses on this first step: the collection of proper information. Therefore only the top part of the ICPS model – the incident and its characteristics – will be taken into account in the remainder of this research.

One aspect shared by all reviewed taxonomies is a focus on latent (or system) factors. Factors present in the organization that create the opportunity for staff to commit errors. Traditionally medicine regards errors as medical issues, focusing on the human error involved (Rhodes, 2003). All taxonomies move away from this view. Throughout this study specific attention shall be paid to the contributory factors that create the situation in which an error was committed. Appendix 4 also explicates the different errors humans can commit. Not every human error is equal. Focus does not need to be on the specific error committed, but needs to shift to the underlying reasons for committing the error. A differentiation is provided into skill based (slips), routine based, and knowledge based errors.

This part of the research has provided insight into the causes of medical events. Different reasons why events happen have been discussed. What is clear from all literature is that the problem in health care errors is not the level of Expertise of staff. Medical and nursing staffs are Experts and the care they provide is generally of high standard. Still events happen. Patient safety initiatives aim to create insight into the reasons behind these events, thus providing health care organizations with practical tools to improve their quality. Therefore health care should become more concerned with patient safety, more explicitly with the underlying factors creating unsafe situations.
PART II: Registration

The previous part discussed patient safety and how factors related to patient safety can be categorized. The first step towards improving patient safety is the registration of events. Learning and improving upon incidents and adverse events entails knowing what is happening; this can be achieved through registration. Therefore this part will deal with the actual registration of events. This part will answer the following research questions.

Do the different registration systems together provide a coherent insight into the identified causes of patient un-safety?

- What is the goal of registration?
- Which concepts of the event and its characteristics as found in the ICPS model are represented in the registration systems?
- All systems are in use in the same hospital, with the same patients, what is the connection between the systems?

To answer these questions the registrations systems found in a Dutch hospital will be evaluated on their compliance with the ICPS model, since registration systems in the Netherlands have been designed separate of the ICPS model.
Chapter 5. Registration Systems

In this research the following definition of a registration system will be used:

"While an individual report may contain important information about a specific incident or event, the notion of a reporting system refers to the processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response, and dissemination of lessons learned from reported events."

WHO, 2005

This chapter will first elaborate on what a registration system should entail, after which Dutch registration systems will be discussed.

5.1. Background

The goal of registration is learning. Learning lessons based on a number of incident reports. The added value of regarding multiple events together is that event specific information is filtered out. The larger the database, the easier it will be to deduct latent factors from the data. Regarding multiple events together might reveal unexpected trends and hazards. This can also lead to the identification of system failures (WHO, 2005).

Events can be prevented through identification of and insight into the causes of errors. Prevention of events can have many advantages. Tucker (Tucker, 2004) conducted research into the time of nurses consumed by dealing with the consequences of errors. She found that “on average 9% of nurses’ time was wasted on failure resolution activities such as calling the pharmacy for medications that should have been – but were not – in a patient’s medication drawer” (Tucker, 2004).

In a different research Runciman (Runciman, 2002) attempted to prioritize adverse events based on both their severity and their resource consumption. He found that “most resource use (60%) was by adverse events which led to minor disabilities, 36% was by those which led to major disabilities, and 4% by those associated with death” (Runciman, 2002). His research also estimated that more than 10% of yearly hospital bed use is the result of adverse events (Runciman, 2002). He therefore proposed more attention should be paid to minor adverse events. Registration could aid this goal, as registration can aid in identifying contributory factors.
5.2. Characteristics of Successful Registration Systems

In 2005 the World Health Organization published a report concerning patient safety registration systems (WHO, 2005). In this report, the most important requirements of successful registration systems are defined based on prior research by L.L. Leape.

| Registration systems should be non-punitive. No person involved should be punished as a result of reporting. |
| Anonymity should be guaranteed. Identities of patients, reporters, and those involved should not be made public to third parties. |
| “The reporting system must be independent of any authority with the power to punish the reporter or organization with a stake in the outcome.” |
| Analysis by (medical) Experts is needed. Firstly, reports must be analyzed. Just collecting data does not better the situation. Secondly, analysis must be performed by Experts who know the material, situation, and who can recognize the underlying system causes. |
| This will create trust of medical staff in the outcomes of analysis. |
| Analysis should be done promptly. |
| Feedback and recommendations should not be directed at individual issues. Insight should be provided into how to change systems and processes. |
| The analyzing agency shall provide recommendations; participating organizations shall implement these recommendations. |

WHO, 2005; Leape, 2002

A final requirement for registration systems, not mentioned by Leape, has been derived from human factors engineering:

- The systems should comply with the mindset of the recording party.

Human Factors Engineering aims to adjust systems to their users, not the other way around. One of the well known disciplines within this school of research is ergonomics, but the theoretical notions go further than equipment design. Scanlon defines HFE as “a systems orientation and recognition that technologies, cultures, procedures, processes, environments, and people do not exist in isolation and that effective design must take into account the implication of their interactions” (Scanlon, 2006).

With regard to registration systems this definition results in the observation that only if staff understands what is meant by a question, useful insight can be derived. If the system provides incorrect or incomplete data, the data cannot be used for analysis. Therefore the meaning of all items in the system as well as the system itself must be well understood by those that report on events.

5.3. Registration Systems in Dutch Health Care

Registration of events is not new. Most Dutch hospitals already had registration systems for incidents, yet these were often paper based. But as of January, 1st 2008 the government has made the registration of incidents compulsory. In Appendix 4 it is described that the health care sector in the Netherlands makes a very clear distinction between adverse events and incidents. Due to this difference and the structure of Dutch hospitals (more in Part III) two separate registration systems are created; one for incidents and another for adverse events.
Some hospitals – for instance the UMCU – have designed their own registration system. Others have outsourced the development of a registration system. One of the companies building and maintaining medical registration systems is PMC Advies. Due to the freedom granted to hospitals by the government in designing registration systems it is assumed that many different versions of registration systems are presently operational in the Netherlands. All these systems display, categorize, handle, and provide information differently. One consequence of this diversity is that it is not possible to evaluate registration data on a national scale.

5.4. The Analyzed Registration Systems

To assess the coverage of the ICPS model by Dutch registration systems the total range of registration systems found in a single hospital (the St. Antonius Ziekenhuis) will be regarded. This included more than just the registration system required by law. Other systems include national registration systems for medication incidents or post-surgical wound infections, protocols, the electronic patient files, local complaint databases, and personal registration systems from departments such as Technical Support.

The registration system of PMC Advies is currently in operation in more than twenty Dutch hospitals\(^8\). This makes it a close resemblance of a national version of a registration system. This research will use this system as a reference model for registration systems in the Netherlands. There might be differences between this system and others, but since it is a widely used system, it is the closest to a standard as possible.

The system of PMC Advies is called VMOS\(^5\). The total VMOS contains more than just registration tools for medical events, but only three of the registration tools will be discussed in this research.

- The MIP-Expert\(^\text{®}\) (incident registration)
- The CR-Expert\(^\text{®}\) (adverse event registration)
- The PAR-Expert\(^\text{®}\) (pro-active patient risk assessment)

The VMOS is a hospital based registration system. There are also several national registration systems; for instance medication errors and post-surgical wound infections are collected in a national database. Such systems are equally important to provide insight into patient safety.

A more detailed decomposition of these registration systems can be found in Appendix 4. In the following chapter the analysis of these models can be found.

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\(^8\) Among which are the Reinier de Graaf Groep, Delft/Voorburg; Het Catharina Ziekenhuis, Eindhoven; Het Onze Lieve Vrouwe Gasthuis, Amsterdam.
Chapter 6. Coverage of the ICPS Model

The ICPS model covers the entire patient safety chain, including causes, detection outcomes, and risk reduction actions. No registration system, available to hospitals, covers all different aspects at the same time. Each system focuses on its own type of event – incidents, adverse events, etc – and adjoining risk reduction actions. The combination of these systems should cover most aspects as described in the ICPS model to provide hospitals with a complete overview of their patient safety status. This chapter will evaluate whether these systems fulfill this task.

6.1. A Decomposition of the ICPS Model

This chapter provides an overview of the decomposition of the parts of the ICPS model that will be evaluated. In Appendix 2 a complete overview can be found.

1.1.1. Incident Type

Events have been categorized into fifteen different Incident Types. Incidents can be classified as:

- Medication
- Documentation
- Clinical Administration
- Healthcare Associated Infection
- Clinical Process/Procedure
- Blood/Blood Products
- Oxygen/Gas/Vapour
- Nutrition
- Medical Device/Equipment
- Patient Behavior
- Fall
- Patient Accidents
- Infrastructure/Building/Fixtures
- Resources/Organizational Management
- Pathology/Laboratory

An important notion is that the Incident Types are non-exclusive. This means that an incident can be part of several categories (WHO, 2007).

1.1.2. Patient and Incident Characteristics

Both Patient and Incident Characteristics mostly serve to describe part of the environment in which incidents occur.

The main categories of the Patient are:

- Patient Demographics (age, gender...)
- Reason for encounter
  - Procedure
  - Primary diagnosis

The main categories of the Incident are:

- Care Settings (hospital, disability service, etc)
- Treatment Status
  - Inpatient
  - Outpatient
- Discipline Involved
- Person Reporting
- People Involved
- Timing of Incident
- Date of Incident
- Country
1.1.3. Contributory Factors/Hazards

The classification of Contributory Factors is quite extensive. The classification of Contributory Factors in the ICPS is:

- **Staff Factors**
  - Cognitive Factors
  - Performance Factors
  - Behavior/Violation
  - Communication Factors
  - Patho-Physiologic/Disease Related Factors
  - Emotional Factors
  - Social Factors
- **Patient Factors** (same as Staff)
- **Work/Environment Factors**
  - Physical Environment
  - Remote/Long Distance from Service
  - Environmental Risk Assessment/Safety Evaluation
  - Current Code/Specifications/Regulations
- **Organizational/Service Factors**
  - Protocols/Policies/Procedures/Processes
  - Organizational Decisions/Culture
  - Organization of Teams
  - Emergency/Excavation/Disaster Plan
  - Resources/Workload
- **External Factors**
  - Natural Environment
  - Products, Technology & Infrastructure
  - Services, Systems & Policies

1.1.4. Detection and Mitigation

Through detection the initial error can be prevented before it harms a patient. After an event is detected Mitigation Factors prevent it from causing more harm. A Mitigating Factor is “an action or circumstance which prevents or moderates the progression of an incident towards harming the patient” (WHO, 2007).

Detection is defined in the following classes:

- **People Involved**
- **Process**
  - Error Recognition
  - By Change in Patient’s Status
  - By Machine/System/Environmental Change/Alarm
  - By a Count/Audit/Review
  - Proactive Risk Assessment

Mitigation Factors are defined as follows:

- **Directed at the Patient**
  - Good Supervision/Leadership
  - Good Team Work
  - Effective Communication
  - Relevant Person(s) Attended
  - Relevant Person(s) Educated
- **Directed at Staff**
- **Directed at Organization**
  - Good Luck/Chance
  - Effective Protocol Available
  - Product/Equipment Availability/Accessibility
  - Documentation Error Corrected
- **Directed at an Agent**
6.2. Availability of Registration Systems

Not all models discussed in Chapter 5.3 are operational already. The MIP Expert® is available; therefore accurate insight can be given as to what parts of the total ICPS model are covered by this registration system for incidents. The pro-active risk assessment system is not operational yet, but construction is under way. The assessment of this system has been based on the preliminary overviews of the system, as provided by the builder, and insights gained during participation in the meetings of the PAR working group.

The final layout of the adverse event registration system is not yet known. Conclusions about adverse event registration have been based on the functional requirements formulated for the CR-Expert®, insights gained from the CR working group meetings, expert opinions, and the documents available from the Orde (including the Generiek Datamodel and the Masterclassificatie). Based on these sources the relevance of the CR-Expert® to the coverage of the ICPS has been estimated. It is expected that the CR-Expert® will contain more details than needed for the ICPS model. The estimated coverage of the CR-Expert® is prone to adjustments, due to the unfinished state of the registration system.

For the purpose of this research all other systems have been grouped together in a fourth category. As described these systems are very specifically targeted at one subject, thus irrelevant to most parts of the ICPS model. It will be made clear whenever a specific system is used for the evaluation. Examples of specific systems are the PREZIES system and the CMR.

Since several of the evaluated systems are not operational yet, the analysis made has been discussed with Experts from the hospital. They confirmed that the preliminary evaluation of what the CR and PAR cover is correct.

6.3. Research Method

The coverage of the ICPS model by the registration systems has been analyzed by means of the analysis table presented in. In this chapter the analysis has been limited to the main classes in each ICPS category, and further limited to the incident and its characteristics.

<table>
<thead>
<tr>
<th>ICPS</th>
<th>MIP</th>
<th>CR</th>
<th>PAR</th>
<th>OTHER</th>
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</thead>
<tbody>
<tr>
<td>Incident Type</td>
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<tr>
<td>Patient Characteristics</td>
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<tr>
<td>Incident Characteristics</td>
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<tr>
<td>Contributory Factors</td>
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<td>Detection</td>
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<tr>
<td>Mitigation</td>
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</tr>
</tbody>
</table>

The level of coverage is depicted using a color scheme, as can be found in Fout! Verwijzingsbrong niet gevonden.. The color scheme consists of two parts. The first part expresses the actual level of coverage. Each category in the ICPS model consists of several subcategories; coverage can range from 0% to 100%. For example, coverage of 80% is depicted using a yellow color.

Health care is an industry heavily relying on the Expertise of its workers, so not everything can be written down in rules and guidelines. Nursing staff for instance needs to assess the mental state of a patient upon arrival. Much of this assessment is based on tacit knowledge.
They recognize certain features in the patient and estimate the condition of the patient. Such information is recorded, but not actively pursued through specific registration systems. When such Expertise is used, the concepts receive the color purple.

6.3.1. General Remarks
Not every category is and has to be present in each registration system. If a category is present in one of the systems, the box of that system is colored. The rest is left blank as the item can be registered when occurring and that only needs to be done once. Hence, the item is considered covered. The systems together should provide a complete overview of patient safety related data; the level of coverage by each individual system is of inferior importance. If a category is not covered by any of the systems, the entire row is colored red. No conclusions are drawn as to which system should cover the category; this is for the hospital to decide.

Coverage is assessed on a first-degree basis. This means that only straightforward similarities are taken into account. If both the ICPS model and the registration model lists ‘Falling’ as an Incident Type, it is considered to be covered. There are factors that are not present in the registration systems as such, but that could be derived from the combination of two or more variables. This can for instance be done using statistical analysis methods such as factor analysis. Such factors are not taken into account in this analysis.

Preliminary, already several reasons can be given to explain why some items in the ICPS model are not covered by the registration systems. Firstly, some factors as identified by the ICPS are not of interest to Dutch hospitals. The ICPS model has been designed for patient safety in the entire health care system. This research focuses only on hospitals, so any factor related to nursing homes, general practitioner’s offices, etc, is not included in the registration systems and does not have to be. Such factors are not taken into account in the evaluation of the registration systems.

The ICPS differentiates between item and problem. For instance, each Incident Type is divided into Characteristics and Problems. In Dutch registration systems these two are often not filed in the same system. Protocols can be found on the Intranet, problems relating to protocols can be found in the MIP-Expert®. Therefore coverage of the same Incident Type can be the result of several systems.

The incident related classes of the ICPS are discussed below. Tables are provided as well. These, visually, represent which classes are matched by the registration systems, and which ones are not.

6.3.2. Coverage of the Incident Types
The ICPS covers 15 different Incident Types. The Incident Types comply with Incidents in the Dutch registration systems. Although the rest of the ICPS does apply to adverse events, these cannot be positioned in the several classes of Incident Types of the ICPS.

The MIP-Expert® does not address all Incident Types. The MIP-Expert® addresses the Incident Types: Medication, Blood/Blood products, Falling, and Nutrition. With respect to incidents relating to Blood or Blood products the type of blood product is not addressed. Neither is the way in which a patient fell (stumble, slip, etc) addressed with regard to the Incident Type ‘Falling’. Problems associated with documentation can only be recorded if they relate to either Blood Products or Medication. Both cover different documentation incidents.
Other incident sheets do not provide the opportunity to record documentation errors. Whether these issues should be incorporated will not be discussed in this report. This decision is left to the hospital.

All Incident Types relating to the organization of the hospital or specifically related to the patient are not covered in the MIP-Expert®. Neither is the Incident Type – ’Resources/Organizational Management’ covered by the registration systems. Incidents relating to Workload, Bed Availability, Staff Availability or the Organization of Teams are not represented.

The Incident Type ‘Health Care Associated Infections’ is regarded as an adverse event in Dutch health care. Infections are to be reported in the PREZIES database, the Masterclassificatie also addresses infections. Since, the CR-Expert® is constructed based on both national registration systems and the Masterclassificatie it is expected that the CR-Expert will address this Incident Type.

Events relating to the Clinical Administration cannot be found in the registration systems, but some can be found in the complaint databases. This system is currently not connected to the incident database.

All incidents relating to Infrastructure/Buildings/Fixtures are reported directly to the appropriate supporting hospital departments. Such incidents are not reported in the registration systems.

Incidents relating to oxygen are not represented in the registration systems. Oxygen is administered throughout the hospital via a central system embedded into the walls. Every bedside has a wall socket for oxygen, in this wall socket only the plug of an oxygen hose fits. No other plug will fit. This prevents administering the wrong kind of gas. Rigorous rules and guidelines apply to prevent contamination of the gas; therefore incidents relating to oxygen hardly ever happen.

If such incidents do happen they should be recorded and analyzed, but due to the centralized design of the system they will most likely affect more than one patient, they might even affect the entire hospital. This will have such consequences that a single incident report cannot cover the material. One of the aims of a registration system is to gain insight into commonly occurring, minor impact incidents. They happen often, they consume the larger part of resources (Runciman, 2002), and yet precise insight is not available. Thus they cannot be improved upon.

A hospital in the Netherlands, the St. Elisabeth Hospital in Tilburg, experienced such a near miss in 2007. A supplier of health care gases tried to connect the wrong tank to the oxygen supply. The incident was stopped before it could harm any patients.

(Volkskrant, 24 april 2008)
In Table 4: Coverage of Incident Types the coverage of the Incident types is depicted.
6.3.3. Coverage of the Patient and Incident Characteristics

The patient characteristics can automatically be retrieved from other systems. These only need to be reported once. Patient Demographics are part of the MIP- Expert® and CR- Expert® because they are used as categorization labels in the database. The PAR also uses the procedure as a categorization label.

All identified concepts of the Incident Characteristics are represented in the registration systems. The ICPS model has been designed for use in the entire health care sector; as a result it distinguishes ten different Care Settings. This research only deals with one of these settings. Other characteristics included in the registration systems include the people involved, the reporting person and the treatment status of the patient. The information about the person reporting can be used for categorization purposes. Through this categorization, departments or Maatschappen can gain insight into the specific events happening in their work.

6.3.4. Coverage of Contributory Factors

The registration systems do not address Staff or Organization related Incident Types. Neither do they address Staff or Organization-related Contributory Factors. This ICPS model classifies staff and patients in the same way with regard to Contributory Factors. Both can be ill or tired, suffer from communication difficulties, or emotional factors.

Patient Factors are not specifically addressed in the registration systems but are assessed continuously by nursing staff. Whenever one of these factors is identified it will be noted down. Therefore these issues are considered acknowledged.

The MIP- Expert® does provide Communication as a possible cause of an incident but it does not specify whether this was with either staff or patient. Neither does it specify what method of communication is referred to. Staff Factors, such as fatigue or distraction, are also not featured in the registration systems (see Appendix 4).

Human Error can be separated into knowledge based, rule based or skill based error. Each of these types requires different improvement measures. Which type of error was involved cannot be extracted from the registration systems.
A notion here is that some factors may be very difficult to address in a registration system as staff might not be able to assess factors relating to the organization of the hospital objectively (Pronovost, 2005). Staff is for instance used to the local organization of teams, which makes it difficult to assess the contribution such a factor has had on an event. Other data gathering methods such as interviews can aid in identifying these Contributory Factors.

### 6.3.5. Detection

Protocols are available for the detection of incidents and adverse events. Ways of detection are not distinguished in the registration systems. Only in the Medication sheet of the MIP-Expert can the way of detection be recorded. This sheet specifically asks how the error was detected. The other sheets do not acknowledge this part of the patient safety cycle.

Mitigation concerns what the organization does once an event has been detected. With respect to patients there are protocols available about Mitigation Actions once an incident is acknowledged. Staff is well equipped with knowledge for dealing with events and is equally used to responding to the discovery of an event. Mitigation directed at staff or organization is not included in the registration systems.
Chapter 7. Conclusion Part II: Registration

The main question posed in Part II was:

Do the different registration systems together provide a coherent insight into the identified causes of patient un-safety as found?

Due to the structure of the Dutch health care sector two separate registration systems are in operation. The first one, MIP- Expert®, is targeted at the registration of incidents and all data entered is the property of the hospital. The second one, CR- Expert®, is targeted at the registration of adverse events. A third system – the PAR- Expert® – assesses the condition of the patient upon entry. This system decreases the chance of a patient experiencing certain types of incidents.

7.1. Coverage of the ICPS

This part of the conclusion consists of three parts. Firstly, the issues that the registration systems do cover will be listed. Next, the issues not featured in the ICPS yet present in Dutch registration systems will be discussed. The third part will conclude which factors of the ICPS are not covered by the registration systems. This part will also discuss whether these factors should be covered by one of the systems.

7.1.1. Coverage of the ICPS

The registration systems focus mostly on the event. All identified Patient and Incident Characteristics are covered by the registration systems.

The MIP-Expert® addresses four of the Incident Types as defined in the ICPS. With respect to these Incident Types the MIP- Expert® covers most of the concepts within these types.

The registration systems only partly cover the defined Contributory Factors. Many of the concepts referred to in the ICPS in Contributory Factors – Patient Factors are not specified as such in Dutch health care. The current state of the patient is assessed by the nursing staff, based largely on their Expertise. This leads to many insights that are classified in the ICPS but not acknowledged as specific concepts in Dutch registration systems. The role of Expertise and tacit knowledge is difficult to incorporate into registration systems as its prime characteristic is that it cannot be assessed as such. As a consequence these factors are not literally covered by the registration systems, but are referred to as covered since other systems take over this role.

7.1.2. Not present in ICPS

The PAR- Expert® specifically addresses risks embedded in the patient, risks relate to age, number of prescription drugs and number of diagnoses. These risks are not incorporated into the ICPS model. The model does not acknowledge that patients bring risks with them that could be the cause of an incident. The Patient Characteristics are purely meant to depict the patient, defining the patient in question.

Secondly, the ICPS model does not mention decubitus as an Incident Type. Decubitus is a focus point in Dutch health care. It is a kind of incident that happens quite frequently and that can be prevented or minimized if care givers have more insight into the patient situation. The proneness to decubitus is considered a Patient Characteristic in Dutch health care.
Thirdly, the ICPS does not acknowledge the ‘loss of corpus alienum in a body’ as an incident. Medical equipment and materials do get left behind in patients. These incidents are currently reported in the registration systems, but cannot be classified according to the ICPS model.

7.1.3. Not Present in Registration Systems

The registration systems all evolve around the events that happen and list, in generic terms, its outcomes for the patient. There is no structured registration of action, the process of detection, or contributory factors.

The current registration systems mostly focus on the incident and patient related characteristics. All contributory factors relating to culture, staff, or organization are not incorporated. Some of these might be difficult to incorporate in the registration systems, yet they do provide insight into the occurrence of incidents and therefore should be regarded as such. They could be derived from other systems, but currently no other systems are known that record these contributory factors.

The registration systems regard equipment failure as a possible cause of an event. However, it is not possible for an incident to be an Equipment failure, which did not lead to an incident involving a patient. The MIP Expert explicitly requires any incident to be related to a patient. Such equipment incidents are reported directly to the technical department, but their registration system is not one of the patient safety registration systems. This system has not been further explored.

Events relating to the Clinical Administration cannot be found in the registration systems. They can be found in the complaint databases, if the patient files a complaint. Such systems are not routinely connected to the incident database.

The registration systems aim to be consistent in their coverage of different types of incidents. There are some inconsistencies though. Some of the problems recognized for blood products are not recognized as problems associated with nutrition. These issues include:

- Wrong Patient
- Wrong Storage
- Wrong Frequency

Other problems identified in the ICPS model for Incident Type – Blood Product, but not covered in the registration systems include:

- Omitted Medicine (Blood)
- Expired Blood/Blood Product
- Adverse Effect

Guidelines for dealing with blood are very strict in the Netherlands. These guidelines do prevents many blood related incidents from ever occurring, yet it cannot be guaranteed that they will never happen.

7.2. Connection between the Registration Systems

All registration systems, protocols and guidelines are aimed at improving the quality of care in a hospital. Some streamline the process of care, others provide insight in the events that happen during this process of care or in the reasons why the outcome of care is not as desired. What they all have in common is that they are aimed at the same patients, in the same hospital.
They all focus on very different events. From the decomposition of the *Masterclassificatie* and the ICPS model it can be concluded that incidents and adverse events are very different events. The Incident Types and the identified Adverse Events are completely different.

What all events have in common are the non-medical causes and impact they can have. Both a medication incident and a worsening of an infection can be the result of bad communication between staff. The events are very different, but they share the same underlying organizational factor.

The same holds for outcomes. Both a medication incident and a worsening of an infection can have the same outcomes for patient and hospital. Each one can result in harm to the patient and in reputation damages for hospital and – when applicable – Maatschap.

### 7.3. The Added Value of Registration

Two main goals of registration systems can be derived from Part I and Part II. Registration systems should:

- Provide insight into the occurrence of events.
- Provide insight into the causes of events.

The current focus of both the MIP-Expert and the *Masterclassificatie* is on the medical aspects and characteristics of incident and patient. This does provide insight into the occurrence of events as the types of possible events are quite exhaustive, especially with regard to adverse events. But the focus lies on medical events; organization related incidents are not acknowledged. And only a few non-medical factors – Contributory Factors in the ICPS model – are present in the systems. Therefore the second goal of registration systems has not been fulfilled.

The added value registration can have for patient safety is the incorporation and acknowledgement of non-medical factors. Such factors can be present throughout any organization; they are not specific for a hospital, any organization can suffer from communication errors. Secondly, they touch upon every part of the organization. Since they are non-medical in nature they are not restricted to a single department or Maatschap. Thirdly, since they are non-medical in nature data from several departments and/or Maatschappen could be used in the same analysis. The actual event they lead to is of inferior importance in dealing with the factor. Any event can be caused by communication failures. Fourthly, such factors say nothing about the quality of care provided; therefore they do not pose a treat of reputation damage. Yet improving upon them does prevent future events, thus improving patient safety, thus improving the reputation of hospital and/or Maatschappen.

To maximize the insight in such non-medical factors data from different registration systems should be combined. For analyses both incident, patient and staff specific information is not needed. No blame will be assessed, only lessons learned, so any identification information should be removed.
PART III: Patient Safety in Dutch Hospitals

So far, this research has not taken the environment – in which registration of medical errors commences – into account. Part III will explore this environment: the hospital. This part will regard the hospital as an organization, more than as a provider of care. The focus will therefore be primarily on the non-medical factors impacting patient safety.

Part III will discuss the following research questions:

What are the challenges and opportunities for registration created by the hospital environment in which registration should commence?

- A hospital has a unique organizational structure, what is this structure and what are the implications for patient safety registration?
- Who are the stakeholders involved in patient safety issues in the hospital? Of special interest: what is their view on the registration of medical events and the use of this data?
- Health care is not the first industry to focus on safety, are there lessons to be learned from other industries?
- What can be the added value of registration for hospital stakeholders?

These chapters will deal with registration in a Dutch hospital. Subsequently the position of stakeholders, their views, and boundaries they have created against registration will be discussed.

The main research question deals with the added value of registration for patient safety. This part will discuss the goal of registration and the positioning of registration in a hospital. Boundaries to registration will also be discussed.

The last chapter of Part III introduces a new model, based on both the stakeholder analysis and safety theories; the Patient Safety Loop. This model depicts how quality should be derived from events.
Chapter 8. A Dutch (General) Hospital as an Organization

The most important aspect of a hospital is that it is a provider of care. Before anything else, that is the main purpose of the company. This has lead to a view on hospitals as sole providers of health care, not as companies.

The conclusion of Part II was that the added value of registration is to provide insight into non-medical causes and impacts of events. Regardless of the specific incident or adverse event it could have been caused by a lack of communication and it could lead to a loss of reputation. Such issues are completely separate from the quality of the business (care); a lack in communication does not give any insight into the medical quality of the work performed.

This difference between medical business and organization is not acknowledged in health care. In health care everything is regarded as health care. Or as Gaba puts it: “error in medicine is almost always seen as a special case of medicine rather than as a special case of error” (Gaba, Chapter 11, in Bogner, 1994).

Realizing this difference could aid patient safety as it implies that making a mistake does not have to damage a reputation. An incident does not imply that the persons involved are bad medics. It might simply imply that the communication is lacking; which is an error but an error related to being human not to being a doctor. Moreover, it is an error resulting from the organizational culture, not an error merely stemming from the malfunctioning of a specific individual.

Throughout Part III of this research the focus will be on the organizational factors impacting patient safety.

8.1. Organization

The organization of hospitals is different than that of most other companies. Several examples will be provided.

Firstly, hospitals are characterized as professional organizations (Mintzberg, 1983). P companies employ a lot of Experts. These professionals are mostly self regulating – not in the least because they have such Expertise that no manager can effectively manage them. This also means that the organization has a relatively small management layer.

Secondly, not every hospital is organized in the same way. As already stated in the Problem Definition a difference between academic hospitals and general hospitals is the employment of physicians. These professionals are not employed by general hospitals. They are organized in legally, separate entities.

Thirdly, there are several possible organizational structures in use in hospitals in the Netherlands. Hospitals can, for instance, be grouped according to field of Expertise or according to ‘care paths’.

8.2. The Position of Maatschappen

The number of Maatschappen – and thus the complexity of the organization – differs per hospital. In general hospitals, such as the St. Antonius Ziekenhuis, the structure is more
complicated. Academic hospitals do not have independent ‘Maatschappen’. The number of maatschappen differed between 7 and 33 in 2006\(^9\).

Since Maatschappen are separate entities they do not fall under the management of the board. This creates a situation of mutual interdependence. The care is the hospital can be seen as governed by two powers. Board and Maatschappen are alike in strength and power. They have different objectives and goals, but are dependent on the proper functioning of the other; this will be discussed further in subsequent chapters.

Another complicating matter in health care is the fact that physicians see physicians in other hospitals as their peers, not the physicians in other Maatschappen within the same hospital.

The national quality evaluation – done by the Inspectie voor de Gezondheidszorg – makes the relationship between management and Maatschappen even more complicated. Each year the quality of every hospital is evaluated by the IGZ based on pre-defined criteria (Prestatie Indicatoren). This creates a situation in which the hospital is evaluated on the quality of the work of its physicians over whom the hospital has no immediate power.

These evaluations and the pressure created by the introduction of free market segments have somewhat changed the relationship between the board of directors and the Maatschappen. It has given the board more influence over the performance of its physicians. The board has to intervene if a Maatschap delivers low quality of care, and has much influence in the appointment of new specialists. The board is on the selection committee and has to grant the Maatschap extra facilities in the hospital for any extra physician to work in.

### 8.3. Hospital Culture

The culture in most hospitals can be deemed ‘closed’ (Buchanan, 2004) as opposed to an open culture in which information is shared and discussion is possible. An open culture is a basic characteristic of an environment in which errors are considered learning opportunities. The Sneller Beter report formulated it as follows:

"Juist doordat medische professionals streven naar de best mogelijke zorg, lijkt er geen ruimte voor het erkennen van fouten. Dit taboe moet doorbroken worden, om tot structurele verbeteringen te kunnen komen." (Willems, 2004)

This closed culture is also created by the fear of liability claims. Physicians will not provide information that can be used to put blame on them. In Part II the requirements of Leape for registration systems have been introduced. Several of these requirements dealt with the use of registration data. Not only should registration be blame free, data should also not be provided to authorities with punishing powers.

Registration systems in the Netherlands are not closed as was recently proven in a legal case (Molendijk, 2008). A judge ruled in favor of a patient, giving the family insight into the adverse event registration. The judge acknowledged that this registration is and should be closed to third parties; if, and only if, the patient can find adequate information relating to his or her treatment in the patient files. In this case the patient files were lacking in information; hence the decision to grant the family insight.

Rulings like this threaten the willingness of medical personnel to report on events as the report can lead to assigning guilt or blame, even though hospitals try to prevent this as registration systems are designed for learning, not for appointing blame.

Or as the KNMG concluded: "Eén enkele reactie op een incident van een instelling of externe toezichthouder kan door medewerkers als zo onrechtvaardig worden ervaren dat de

\(^9\) [http://www.igz.nl/loketzorgaanbieders/indicatoren/ziekenhuizen#](http://www.igz.nl/loketzorgaanbieders/indicatoren/ziekenhuizen#) (16-04-2008) on this website information for hospitals is located, including excel sheets with all acquired data
bereidheid incidenten te melden (tijdelijk) sterk afneemt. Instelling en toezichthouders dienen hierop alert te zijn” (Legemaate, et al, 2008).

To conclude the Sneller Beter report stated the following about Dutch healthcare: "In Nederlandse ziekenhuizen overlijden elk jaar tussen de 1500 en 6000 mensen als gevolg van medische fouten die voorkomen hadden kunnen worden. Doordat de incidentenregistratie gebrekkig is, weten we eigenlijk niet goed wat er mis gaat. Veel ziekenhuizen hebben een gesloten bedrijfscultuur, waardoor incidenten niet gemeld worden. Bovendien zijn de verantwoordelijkheden voor kwaliteit en veiligheid niet helder gedefinieerd. Het resultaat: van incidenten wordt niet geleerd” (Willems, 2004).
Chapter 9. Stakeholders

Many different stakeholders have been mentioned in this report. This chapter will discuss the stakeholders found ‘inside’ a hospital. Their playing field is in part created by governing institutions such as patient associations, medical associations (Orde) or the government. These national stakeholders will be discussed in Part IV alongside their influence on hospital practices. This chapter will only deal with stakeholders within the hospital.

9.1. Method of Analysis

This stakeholder analysis is based on a literature study, interviews and expert analyses. To structure the information an analysis has been made of the factors influencing the position of the stakeholder with respect to patient safety, registration systems, and the use of registration data. This information has been condensed into causal reasoning models. These models provide insight into how factors influence each other, e.g. if an increase in factor A will lead to an increase in factor B this is represented with a positive arrow. These models allow for a more insightful comparison of stakeholder views.

The main focus of this stakeholder analysis is the view of different stakeholders concerning patient safety, and registration of medical errors in particular. Every stakeholder discussed will have opinions about many other interesting subjects related to care, these shall not be considered in this research. Neither are not directly to patient safety related factors taken into account.

The analysis therefore only takes certain influencing factors into account; other factors will have impact as well yet these factors are not directly related to the view on patient safety and thus are represented.

9.2. Patients

The object in patient safety is the patient. A patient enters the hospital in a suboptimal state and expects to be leaving the system in a better state of physique. Patients not only expect good care, they demand it. Patients have become more demanding and outspoken and expect proper information about their treatment (Legemaate, 2006) and – when applicable – on events. If patients feel ill-treated they are more likely to press charges than they used to do.

A patient is only interested in information concerning his or her personal treatment. So the need for information is very detailed information about one person.

Patients (and related stakeholders) will not be further discussed in this research as they are not involved in the registration of medical errors. Their main interest is in medical details, not in non-medical organizational issues. They do not have access to data recorded in registration systems.

9.3. Medical Personnel

9.3.1. Nursing Staff

Nursing staff has the most direct contact with the patients. Patients typically see their physician only a few times, whereas the nursing staff takes care of all the smaller care tasks
such as administering medicine, washing, feeding, measuring vital bodily functions, etc. In order to do their job nursing staff needs a vast array of information about patients. With respect to registration 90% of all incidents are reported by nursing staff. The most reported types of incidents constitute incidents relating to falling accidents or medication accidents (St. Antonius Ziekenhuis, 2006).

The major issues concerning reporting are the lack of feedback – reporting an event is done in part because the reporter would like to change the situation so it will not happen again – and the pressure of work. Nursing staff typically has to take care of many patients simultaneously which does not leave them much time per patient. Registration of events and near misses creates more work pressure and takes up time. At the same time registration of events accompanied by adequate action can decrease the workload as well. Tucker concluded that nursing staff spend around 9% of their time on error resolution (Tucker, 2004).

From a registration system nursing staff expects feedback and insight. This insight should incorporate much detail.

9.3.2. Physicians

Unlike the nursing staff physicians are not employed by the hospital. They are self employed and work in social partnerships called Maatschappen. A Maatschap is a body of physicians that share the same specific medical Expertise (gynaecology, pediatrics, cardiology, etc.). Maatschappen are separate legal entities that operate within the hospital. Within a Maatschap every physicians is equal, the structure is horizontal and the same output is expected from all. This structure is a unique feature of Dutch health care. It stands in contrast to other countries, where similar partnerships of physicians exist, but where the structure is much more hierarchical.

With regard to medical care the independent status of Maatschappen results in physicians aiming for two – possibly conflicting – goals. They want to provide the best care they can to patients, yet they also have to make a profit from practicing.

In order to provide good care to their patients, physicians need proper insight into the state of the patient. For this they heavily rely on a well functioning nursing staff, as the nursing staff has up to date information available about the condition of the patient.

The need for information of physicians is almost as detailed as that of the nursing staff but they might need different information about a larger number of patients. Based on the Masterclassificatie it is concluded that physicians are more interested in the impact of the incident on the patient – as this has a direct impact on the treatment – than in the causes of the incident.

Many Maatschappen have a personal registration system for adverse events. Among the reasons for the lack of reporting incidents is that they do not feel the need to report them in the MIP-Expert®as important events are already reported in their own registration system. These registration systems are separate, Maatschap owned, and closed for hospital systems. Providing insight into the medical functioning of the Maatschap can damage reputation, both internally and externally.

Within the hospital, a proper insight into the functioning of a Maatschap could hamper their expansion; the hospital has to grant them the space and supporting staff for an extra physician. On the other hand, if the quality is deemed high, insight could accelerate expansion.

Externally information could be used to assess the quality of care. Insurance companies, for instance, use the quality of care to decide which hospitals to work with and commercially
developed rankings base their ranking predominantly on the number of events. External openness also influences the position among peers and the attractiveness to new physicians.

**9.4. Board of Directors**

As described every hospital has a different structure and thus a different decomposition of responsibility. Every hospital does have a Board of Directors. Hospitals will have many committees dealing with patient safety subjects; these will not be discussed.

In Appendix 6 a case study is provided. This case study describes the structure of a Dutch top clinical hospital – the St. Antonius Ziekenhuis in Nieuwegein. Furthermore the management layers found in this specific hospital are described. This will provide some insight into the possible layout of a hospital.

At the top of the organization is the board of directors. Since a hospital is a business, it needs to make a profit, while at the same time providing as much care of as high a quality as possible.

What complicates this situation is that the hospital itself cannot directly influence the quality of the care provided and thus its own reputation. The care is provided by physicians and nursing staff.

The board cannot easily influence the way in which physicians do their job as physicians are legally separate from the hospital. The board has some indirect influence measures, but direct influence is not possible.

Care is also provided by nursing staff. They do fall under the board of the hospital. Yet – assuming the quality of the nursing staff is excellent – it might not be possible for the nursing staff to perform at their best, due to decisions made by the board. The quality of their work depends, in part, on the workload and availability of equipment and resources. These are factors the board can use to improve the quality of care, but this will negatively influence the profit of the business. More equipment or more staff will be more expensive, while the same amount of care (thus revenues) is provided (Tucker, 2004). Therefore ‘profit’ is deemed the most important factor in assessing the reasoning of the board.

**9.5. Use of Registration Data**

What is apparent in the stakeholder analysis is that for both hospital and physicians the quality of Care & Cure is an important factor in the execution of their work. However, quality is difficult to assess and no objective assessment criteria have been formulated yet. To assess the quality of Care & Cure the number of events is used; both the IGZ and commercially developed rankings make use of the number of events to estimate quality. For this the number of reported events is used; the more reported events, the lower the quality. Consequently the perceived quality of care can become more important than the actual quality.

Patients can choose their physician or hospital based on this perceived quality of care, rather than on the actual quality, so openness could damage reputation.

Another issue with regard to registration systems is that it is not clear what data will be used for. The registration systems require the name of patients and those involved for classification purposes. As long as it is not guaranteed that this data will never be used to appoint blame, physicians might not file reports on events. Some hospitals provide the data from the MIP-Expert® directly to the IGZ in case of an investigation. This means that
reporters can be prosecuted based on the data they provided in the belief that registration was for learning purposes only. The registration data is not protected from use for liability claims in the Netherlands either. Physicians and hospitals can fear for liability claims if they admit to making mistakes.

Concluding, errors are seen as a measurement for quality of Care & Cure in the Netherlands. Quality in turn influences reputation. A good reputation will attract more patients, which will lead to more revenues. A good reputation also provides opportunities for research grants, which in turn can heighten the quality of work performed. Yet the potential use of registration data is unclear. Data could damage reputation. This creates an environment in which both hospitals and physicians fear openness of information. A complicating matter is that Maatschappen are legally independent entities, so the hospital cannot easily force them to register in hospital wide systems or to give insight into their own registration systems. Everything registered in these systems is the property of the Maatschappen.

In Figure 8 this has been depicted. The (perceived) quality of Care & Cure is derived from the number of events. The higher the quality is valued, the higher the reputation of hospital and Maatschap. A good reputation will attract more patients, generating more profits. The last arrow indicates that the more patients are treated, the more events can take place, due to scale reasons.

This diagram\(^{10}\) indicates why both hospitals and Maatschappen fear an openness of information. If quality is directly derived from the number of events, openness about events can harm the organization. Equally so, if little events happen openness can benefit the quality. But since no objective assessment criteria have been developed and not the actual number of events is taken into account but the reported number of events (more in Part IV), hospitals and Maatschappen fear openness.

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\(^{10}\) In this diagram only the issues concerning patient safety are depicted. Many other factors equally determine the position of hospital and Maatschappen, but since these do not directly influence patient safety (for instance, number of physicians in Maatschap, patient mix, or complaints of patients) they have not been depicted.
Chapter 10. An Alternative View on the Structure of Hospitals: HROT

"The hallmark of an HRO is not that it is error-free, but that errors don't disable it."

(Weick, 2007)

The call for safety regulation is not new. Over the last 70 years many industries have made safety considerations part of their core business. HROT is the common name for a theory based on the way High Reliability Organizations perform. These high reliability organizations – nuclear power plants, aircraft carriers, fire fighters – work in a very dangerous environment, yet they have very few accidents and the errors that do happen do not cascade into major life threatening situations. Researchers concluded that "[a] proper organization of people, technology and processes can handle complex and hazardous activities at acceptable levels of performance" (Gaba, 2002). Many of its concepts are not (yet) introduced into health care in the Netherlands. Some of these concepts could be of interest to hospitals in the Netherlands.

This chapter will discuss this theory and the possible implications it can have for health care in the Netherlands.

Errors, incidents and complications will always be part of the work in hospitals. It is not a feasible goal to expect any hospital to be error-free. Therefore the best way to approach safety is to create an environment that is flexible enough to deal with errors, but where errors will never dictate the work; in other words create an environment where ‘errors do not disable the organization’ (Weick, 2007). This is precisely the kind of environment HROs strive to create. There are differences in abundance between naval carriers, nuclear power plants, fire fighters and hospitals; yet this culture of pre-occupation with failure is evident in all.

High Reliability Organization Theory has been derived from the practice at several high risk industries. These industries appear to be very different. They operate in completely different segments, with different products, goals and Expertise. Yet what they have in common are the characteristics of the environment in which they have to operate. This environment can be described as highly complex, dynamic, and dangerous.

The insights into patient safety worldwide have come mainly from this field of research. Researchers started to apply this theory to hospitals and found that hospitals share many of the characteristics of HROs, yet have not implemented the safety enhancement strategies of such organizations (Roberts, 2001; Weick, 2001, 2007; Helmreich, 2005; mcfadden, 1999, 2001, 2006; Amalberti, 2005).

The focus on patient safety in the Netherlands is commonly ascribed to the report Hier werk je veilig, of je werkt hier niet by Rein Willems, CEO of Shell, Netherlands (Willems, 2004). It is not surprising that the government asked advice from the petro-chemical industry about patient safety. This is one of those sectors that for over 30 years have made dealing with safety their core business.
10.1. Other Safety Theories

Other safety theories have been applied to health care as well. Among these are Normal Accident Theory and Resilience engineering. They are not considered any further in this research though. There are several reasons for this. Firstly, the patient safety system (VMS) is based on best practices of Royal Dutch Shell (Willems, 2004). They in turn have learned a lot from the aviation industry. Both these industries have contributed greatly to the development of HROT. Therefore this theory is deemed to be a good start to use in this report. Secondly, one of the most important aspects of the VMS as described by Willems is ‘blame free reporting’, which is a key characteristic of HROT.

Thirdly, the Netherlands is not the first country to look into patient safety. Much international research has been conducted into the subject and many of these authors explicitly based their research on HROT (McFadden 1999, 2001, 2007; Helmreich, 2000; Weick, 2001, 2007). Following this trend seems a proper way forward. Fourthly, the culture is a hospital can be characterized as ‘closed’. Next to that, health care is quite conventional, if only because care givers would never (unnecessarily) risk their patient’s lives. Therefore applying a theory – accepted by peers in other countries – will probably be received less skeptical. Finally, reputation and liability are important issues in health care. HROT emphasizes anonymity and blame free reporting, and as mentioned is has proved successful in other countries. This again will make care givers more receptive to the theory than when a completely new – and thus unproved in health care – theory would be suggested. The patient safety movement already changes the work of care givers, this change can then better be based on trusted theoretical notions; especially when theories are used that are not common material for health care personnel.

10.2. Principles of HROT

Weick is one of the leading Experts in the field of HROT, in his book (Weick, 2007) he defines "the five defining principles of HROs as:

1. A pre-occupation with failure
2. Resistance to simplification
3. Sensitivity to the details of operations
4. Commitment to resilience
5. Deference to Expertise" (Reason, J., in Weick, 2007, pp. ii)

In this chapter these five principles will be further explored, after which their implications for hospitals will be discussed. The following part will combine these insights with the assessment made of the hospital (‘s management). This will reveal discrepancies, while at the same time offering insight in how to deal with these issues.

10.2.1. A Pre-occupation with Failure

The most important characteristics of HROs are that they not so much look for failure, they are pre-occupied with failure. Even the smallest deviation of the normal situation is taken seriously and will be looked into. “Catastrophe often starts with a small problem, which soon escalates into a big problem in a chain of events” (Roberts, 2001).

The problem with minor failures is that they often have a counter effect somewhere else in the organization. In order to respond effectively to minor errors the organizational culture needs to be open. Therefore communication about errors should be encouraged. This often involves a central registration system. A pitfall is that (central) reporting systems tend to become counting mechanisms. Where they are much more, they can identify vulnerabilities in the system and thus trigger systems-based action (Bagain, 2006).
A reporting system for errors should never be used to answer questions of guilt; this is called ‘blame free reporting’. When these two are disconnected incident investigation can focus on finding system failures, not individual failures and only then will errors be reported. The most unwanted situation is one in which employees cover up incidents and thus prevent trial-and-error learning for the entire organization (Bain, 1999).

### 10.2.2. Resistance to Simplification

In order to stay pre-occupied with failure it is vital that personnel do not simplify what they see. It is a common characteristic of humans to look for evidence confirming their suspicions, i.e. to ignore counter evidence (Weick, 2007). Not doing so is called ‘mindfulness’. It implies to stay alert to details – also details you did not expect – and not to normalize an event into a familiar concept. Because odd things can occur – especially in medicine which deals with very uncertain material: patients – staff always needs to be “on the lookout for odd and unusual things instead of assuming that they don’t matter or are not important” (Roberts, 2001). The different types of human error have been discussed, including the danger of relying on routine. One threat to being watchful is an excessive workload. Especially when people are distracted, hurried or overloaded, they tend to rely on expected chains of events. This tendency is also increased when they cannot exert influence over the event.

### 10.2.3. Sensitivity to Operations

A third lesson is not to simplify the details of operations. As Weick puts it: “Sensitivity to operations is about the work itself, about seeing what we are actually doing regardless of what we were supposed to do based on intentions, designs and plans” (Weick, 2007). Staying sensitive is especially important during normal procedures. They are known and almost always go according to plan so people tend to trust on routine and standards (Gaba, 2000). This results in failing to notice small errors and thus failing to act upon these errors. In organizations where small errors could potentially have devastating results, people should be extra alert. This means noticing small errors – and act upon them – and also regarding every near miss as an adverse event that failed to materialize (Chang, 2005), not proof of the organizations ability to avoid disaster.

### 10.2.4. Commitment to Resilience

Once an error has occurred HROs try to contain the problem by being resilient and by deferring to Expertise. Being resilient implies that HROs remain functioning even when adverse events take place; they recover and bounce back (Weick, 2007). To prevent the same error from occurring again it is vital to learn and grow. This does, however, not imply creating procedures to deal with this kind of error. Any new rule will focus too specifically on the occurred error, making it difficult to stay flexible enough to deal with new unpredictable errors (Weick, 2007). The complexity of the environment results in ever changing problems. Creating rules implies knowing what is going to happen; which will never be true for HROs. Another risk of creating rules is that too many rules and regulations make the system unnecessarily complex. In such a system “risks cannot be seen anymore and adequate response strategies get lost in the total rulebook” (Amalberti, 2005).

### 10.2.5. Deference to Expertise

The person most likely to notice an unanticipated event is probably not the person highest in rank. If the person who notices the unanticipated event has no means of power to act upon the event, the event can escalate into disaster. To overcome this, HROs have a strong

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tendency to defer to Expertise in critical circumstances. "Expertise is not necessarily matched with hierarchical position" (Weick, 2007).

A striking example is provided by Landau and Chisholm (in Weick, 2007) in their report on a seaman on the nuclear carrier Carl Vinson. This man was very low in hierarchical rank, yet when he reported the loss of a tool “all aircraft aloft were immediately redirected to land bases until the tool was found”. Afterwards – the carrier having a blame free culture – “the seaman was commended for his action – recognizing a potential danger – the next day at a formal ceremony.”

Roberts gives another example: "Nurses often have better knowledge about the state of their patients than do doctors, and when empowered to act, can respond rapidly to the complex and rapidly changing circumstances that often occur in an ICU” (Roberts, 2001).

10.3. Interesting Issues of HROT for Dutch Hospitals

In Part III of the research the current structure of hospitals has been described. Yet this structure can equally be seen as one of the biggest threats to patient safety. A safety theory, HROT, has been presented that provides a new view on patient safety measures in hospitals. This part will discuss some of the differences between Dutch hospitals and HROs.

Four specific issues concerning differences between Dutch hospitals and HROs are highlighted in this section. The theory does prompt additional issues. This reflection does not attempt to be comprehensive. The chosen issues have been selected because they address issues relevant for registration. This also means that they can be present throughout any hospital or organization. They are not department, specialism, or sector specific.

Next to these lessons health care could learn from other HROs there are also constraints; factors that will make the application of HROT principles difficult and potentially impossible. Health care is a very specialized business and therefore some rules apply here that are not apparent in other high reliability organizations. These will be discussed as well.

10.3.1. Organization

"Op onze beurt willen wij onze Expertise delen met de zorgsector. Niet omdat wij beter weten dan de medisch professional wat er nodig is in een ziekenhuis. Wel omdat de principes van veiligheidsmanagement universeel zijn en in alle sectoren navolging verdienen."

(Willems, 2004)

As discussed in Chapter 8 a hospital can be divided into the company side and the business (hospital) side. The company side is not specific for a hospital. As HROT has shown there are more companies that operate in complex, error-prone, safety focused environments.

The first steps concerning this issue have been made. Several hospitals have started working together with petro-chemical industries located in proximity\(^\text{11}\). Other improvement measures taken from these HRO industries include the adjustment of the aviation program ‘Crew Resource Planning’ (Scanlon, 2006) for hospitals. No insight can yet be given into the actual results of these measures.

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\(^{11}\) Samenwerking ziekenhuizen en de petrochemische industrie, [www.vmszorg.nl](http://www.vmszorg.nl), viewed 11-12-2007
If hospitals start adopting organizational issues of HROT, this will improve the acceptance of non-medical causes of events. This in turn can improve the willingness to use registration system, resulting in an improvement of patient safety.

10.3.2. Culture

One of the most prominent barriers to patient safety is the organizational culture. The pre-occupation with failure of HROs is most of all a cultural attitude. The registration systems in health care are technologically quite advanced, but the current organizational acceptance can hamper a proper use of the system.

Implementation and correct use of the registration systems will depend largely on the attitude of hospital personnel towards these new systems. Becoming more active in risk assessment will enhance the pre-occupation with failure. A cultural change aimed at becoming more open is equally important. Only when mistakes are recognized, can improvement commence.

A barrier to recognizing mistakes is the fear present throughout the sector. Both hospitals and Maatschappen need to protect their reputation. In Chapter 12 it has been discussed that reputation is very important in this sector. Yet at the same time research has shown that patients are less likely to press charges if physicians or hospitals admit a mistake was made and that subsequently lessons have been learned. The fact that the same mistake at least will not happen to another patient again, is often enough consolation (Willems, 2004). This change in recognizing mistakes can also be found in the ICPS model. One of the Mitigating Factors targeted at the patient is “Apology”.

10.3.3. (De)-centralization

"One of the biggest problems for patient safety is not the malpractice of clinicians but the structure of the organization and the industry.”  

(Gaba, 2000)

This relates to both medical care nation wide and medical care within a single hospital. Medical care is decentralized. As a result standards and procedures vary between hospitals, departments within hospitals and between similar departments in different hospitals. In order to improve patient safety, HROT suggests beginning with safety improvements in a centralized manner so “people [will] use similar decision premises and assumptions so that when they operate their own units, those decentralized operations are equivalent and coordinated” (Gaba, 2000).

This will be very difficult in the Netherlands as the government has not yet developed specific guidelines for registration. As will be discussed in Part IV the government has created general guidelines for registration, but mostly about the responsibilities related to registration. No specific rules about what to record, how to record, or how to use data have been formulated.

Implementing centralized standards will also be very difficult in most Dutch hospitals. Not only are Maatschappen legally separate entities, they have a very high level of autonomy. To improve patient safety, standardization and less variation in staff is needed. This does, however, mean that physicians need to abandon “their status and self-image of craftsmen and instead adopt a position that values equivalence among their ranks” (Amalberti, 2005).
10.4. Constraints

Yet there are also reasons why it cannot be expected of hospitals to change their ways of working. There are constraints in place that prevent hospitals from moving in the direction of high reliability organizations.

10.4.1. Health Care as a Public Good

The first reason has already been mentioned. Health care is a public good and hospitals have to and will help a patient in need (Amalberti, 2005). While most HROs can apply strict work schedules to make sure staff does not work too long and stays focused, this is a difficult issue in health care.

Another issue related to the public nature of health care is the cost of service. No costs are spared to make nuclear power plants as safe as possible. One accident can result in the loss of many lives and resources. One accident in health care will generally result in the loss of one life and some resources. Even though the total number of accidents in health care can result in comparable losses of lives and resources the same cost statement cannot be made about health care. Health care has to be available to all and therefore has to be affordable. Providing affordable care means using resources as efficiently as possible (Tucker, 2004). Yet both the number of patients and the level of care needed by these patients is uncertain and will change continuously. The result is that hospitals cannot estimate their staffing needs as can other high reliability organizations.

10.4.2. The Product in Health Care: the Patient

Thirdly, the product in health care is highly uncertain. In the petrochemical industry, every drum of oil equals the next drum of oil (Willems, 2004) and even though scientists still do not understand everything about nuclear energy the process is roughly the same every day. This is not the case in health care. Every patient is unique and therefore requires specific attention. There is no place for routine in health care as every patient bears a unique combination of risks and advantages. This not only makes it more difficult to streamline health care, it also makes it more difficult to convince the Experts to streamline their work.

Fourthly, a hospital cannot refuse patients because they bear too much risk (Amalberti, 2005). A naval carrier will only select the best pilots to fly the best airplanes; all to minimize the risk of failures and the adjoining loss of resources. A hospital cannot choose its patients or refuse patients on the basis that they bear too many risks. This is a very different situation from that in many other high reliability organizations.

The fifth barrier also stems from the product in health care: the patient. Patients are human and have human demands, unlike the product in any other high reliability organization (Amalberti, 2005). Not only do they demand good care, they also have an opinion about the physician that should help them. Many initiatives are undertaken to allow patients to choose a hospital based on the perceived quality of care of a certain procedure (commercial rankings, websites). Patients feel a connection with their physicians. They do not want to be treated by one gynaecologist on the first meeting and by another during appointment two. They demand ‘their’ gynaecologist. This puts a burden on the planning of hospitals, a burden which does not exist in most other high reliability organizations.

Finally, the level of risk can differ tremendously between departments within the same hospital (Amalberti, 2005). Risk reduction actions therefore have to be different for every department. This makes a challenge for the management of health care.
Chapter 11. Patient Safety Loop

A conclusion based on the descriptions of the hospital and its stakeholders is that everybody and everything is intertwined in health care. Eventually, all stakeholders share the same key goal: they want to provide the best possible care to patients. Alongside this shared goal every stakeholder has personal goals.

To achieve these personal goals each stakeholder is dependent on the cooperation of other stakeholders. The hospital is only as good as the quality of care provided by nursing staff and physicians. Maatschappen can be limited in their growth by the support – expressed in availability of nursing staff, resources and facilities – by the hospital and the quality of care provided by the nursing staff. And nursing staff can only provide the best care possible if their superiors provide sufficient staff and resources, and if physicians provide good cure.

Based on the stakeholder analysis it has been concluded that the board of directors and the Maatschappen share many goals. Both value reputation and quality and both are judged based on their perceived quality. Figure 8 shows the quality cycle that is apparent in both the vision of the board of a hospital and the maatschappen. In both views the assumption is identified that there is a direct relation between the number of errors and the quality of care.

11.1. A New Approach

"The systems approach is to analyze the situation, decompose it to the level at which the function associated with the error occurred, identify those factors that precipitated the error, bring those factors to the attention of the appropriate responsible party for action to remove or alter those factors, and evaluate the impact of the resultant action on the future incidence of error. The key to the viability of this approach is information."

Bogner, Chapter 17, in Bogner, 1994, pp. 378

The view presented in Fout! Verwijzingsbron niet gevonden. has been constructed before the inclusion of patient safety in the equation. This study has lead to the development of a more complex relationship between events and quality. Berenholtz states: “health care organizations may be better served by monitoring how often they learned from mistakes identified through reporting systems rather than evaluating rates constructed from these reports” (Berenholtz, 2007).

These two statements, the stakeholder analysis, and HRO theory indicate that there is no straight forward relation between events and quality; quality cannot be derived from the number of (reported) events. Another measure, the percentage or ratio of the number of events/number of treatments, neither provides a conclusive insight into quality. Both measures focus on the occurred events, not on the lessons learned from them.
The inclusion of patient safety practices in the assessment of quality is depicted in Figure 10. Several specific issues are of interest in this depiction. Patient Safety Theories stipulate that arrow (1) should be replaced with loop (2). Errors should be recorded in registration systems. Subsequent analysis of the recorded data will lead to more insight into the causes of events. Based on this insight structural actions can be taken to improve the level of patient safety (Bogner, in Bogner, 1994). This level of patient safety determines the quality of care. With regard to Figure 10 the negative relationship (1) can be replaced with the positive loop (2), the Patient Safety Loop. The current situation in health care can be changed in an upward quality spiral due to patient safety initiatives. The quality of care can improve through reporting and the subsequent implementation of patient safety improvement initiatives.

11.2. Protecting Data

"Those who are associated with errors are the most likely people to be able to provide information about what contributes to the errors. There is an impediment to their providing information, however, which is fear of malpractice litigation. Most medical care providers in the United States will not provide error-related information because to do so might be construed as admitting responsibility for any error under consideration. This could lead to litigation."

Bogner, Chapter 17, in Bogner, 1994, pp. 379

Figure 10: Patient Safety Loop

Figure 11: Quality within a Closed Culture
the combined analysis of many events is needed to provide insight into e.g. internal communication. Within a closed culture data might not be available for analysis; due to inadequate reporting and protectionism. This has been depicted in Figure 11.

An important aspect of using data is protecting the data and its reporter. As described in the chapter on HROT blame free reporting is a key characteristic of any reporting system. One way of creating a blame free environment is by anonymizing all event data (Leape, 2002); this guarantees that the person reporting will not personally be penalized for the event. Not only does such an approach prevent this person from reporting again, there is another reason for anonymizing. The approach of ‘blaming the person making an error and training him to prevent him from making the same mistake again’ ignores the possibility of someone else committing the same mistake (Berenholtz, 2007, Pronovost, 2005).
Chapter 12. Conclusion Part III

This part concerned the environment – inside the hospital – that registration has to commence in. The following research question was posed at the beginning of Part III:

*What are the challenges and opportunities for registration created by the hospital environment in which registration should commence?*

To answer this question first the hospital culture and structure have been assessed, after which the stakeholders – present in a hospital – have been described, including their view on registration. This stakeholder analysis was followed by the added value registration can have for these stakeholders. Special attention has been paid to the opposing goals of those working in a hospital.

Patient safety theory is in part based on best practices from other industries, for instance the safety theory of HROT. This theory and its implications for health care have been discussed in the subsequent chapter.

The insights gained have lead to the creation of the Patient Safety Loop. This loop proposes a new way for regarding the relation between errors and quality.

Hospitals are private organizations, yet they provide a public good. This sets them apart from other high risk organizations as they cannot put a maximum on production. They can set a target, but if more patients arrive – in critical condition – hospitals will provide the patients with the care they need.

Even though many parties want insight into the performance of hospitals, hospitals are characterized by their ‘closed culture’. Staff within hospitals finds it difficult to admit to mistakes, often out of fear for blaming. This is a problem with regard to registration systems as the only way to improve the current situation is by gaining insight into current affairs. This does mean that events need to be reported.

Therefore it will be essential for registration of medical errors to instill the goal of registration. Registration is aimed at learning, not at assessing blame (Leape, 1994).

Secondly, the difference between medical errors and organizational errors is not clear. In Part II it was concluded that the added value of registration will be to gain insight into non-medical issues relating to patient safety. Non-medical issues can be apparent in any organization, but are not directly related to the quality of medical care provided. They can, however, improve the quality of care as they define the environment in which medical errors are committed. The goal of registration is to gain insight into these factors.

Nursing staff is employed by the hospital. Physicians on the other hand are grouped in Maatschappen, social partnerships. Staff will record events if registration has more benefits than costs. Feedback and the actual implementation of risk reduction actions will therefore be just as important as a usable and understandable registration system.

The independence of the Maatschappen creates a rather complex organization. In most Dutch hospitals care is governed by two powers, the hospital and the Maatschappen. Not only are they alike, they are dependent upon one another. This dependence is even more critical to the success of patient safety since none of the stakeholders can independently control the own quality.

One of the most prominent factors for health care professionals is this perceived quality of care. In every stakeholder analysis it was concluded that reputation depends on perceived quality. A high quality will attract more patients, which will generate more profit. This
perceived quality might not be the same as the actual quality, due to (sometimes unreliable) commercial rankings. Therefore reputation is even more important than quality; reputation is in the eye of the beholder whereas quality can be assessed based on pre-defined criteria.

The traditional view in health care is that there exists a linear relation between errors and quality. This again is a reason not to report an error; it could damage reputation. This is also one of the reasons why physicians find it hard to admit to a mistake (Bogner, in Bogner, 1994; Carroll, 2002).

This study proposes a more intricate relation between errors and quality. If errors are reported, this can lead to more insight into their causes, especially their non-medical causes. These non-medical causes are detached from the patient, the provided care, and thus the quality of care provided. They do not harm the medical reputation of the reporter as they portray human or organizational error instead of medical error.

Many of these non-medical errors have been discussed in Part I and Part II. They constitute the latent factors and contributory factors. They are detached from the actual incident or adverse event as they can lead to any number of totally different events. Improving upon them therefore can affect the entire organization.

Based on the insight thus gained from analysis, risk reduction actions can be initiated to prevent the failure from presenting itself again. This will have a positive influence on patient safety and thus can improve the perceived quality of care.
PART IV: Patient Safety in the Netherlands

Part III of this report has discussed the position of registration of medical events in hospitals. Patient safety is not an isolated issue that every hospital deals with individually. There are many national initiatives to guide the process of introducing patient safety and registration systems in Dutch health care. Part IV will discuss several of these national initiatives. This part will also focus on the institutional context – as created by the Dutch government – with regard to registration and patient safety.

In Part I & Part II the added value of registration has been discussed. Governmental organizations and regulation create the environment in which this value can be implemented to its full potential.

In Part IV the following questions will be answered:

- What are the challenges and opportunities for registration created by the Dutch government and medical associations?
  - How do national initiatives strive to improve patient safety in the Netherlands?
  - How do national initiatives incorporate the Patient Safety Loop in their assessment of patient safety?
  - How is patient safety dealt with in other countries?
  - What are the implications of the difference in opinion between these countries and the Netherlands?

This part will start with an overview of national initiatives targeted at patient safety, quality of care and registration. Most of these initiatives have been mentioned in other parts of this research. This will lead to a conclusion concerning the reasons for a decentralized system in the Netherlands. Two of these initiatives will be evaluated based on the Patient Safety Loop introduced in Part III.

The Netherlands is not the first country to make patient safety a priority. Therefore the initiatives in several other countries will be discussed as well. This will be followed by a discussion concerning the difference of opinion between the Netherlands and these other countries.
Chapter 13. Health Care in the Netherlands

There are many national bodies that focus on patient safety and registration in the Netherlands. This part will not contain a stakeholder analysis. All national stakeholders have the same goal, improving patient safety. Therefore not the stakeholder is deemed of interest to this research, instead the focus will be on the projects they have started. Important stakeholders that have not taken part in the discussed patient safety initiatives can be found in Appendix 6.

13.1. Government

The government – represented in this subject by the Department of Public Health (Ministerie van Volksgezondheid, Welzijn en Sport, VWS) – is actively involved in initiatives aimed at patient safety. Already in 1993 the first legislation was introduced. The BIG (kaderwet Beroepen in de Individuele Gezondheidszorg) was accepted. The BIG only states general rules concerning the quality of care. In 1996 this act was followed by the Kwaliteitswet Zorginstellingen. This act defined that quality of care is the responsibility of the care providing organization. This is still the opinion in the Netherlands. The quality of care is the responsibility of each individual hospital. Patient safety is regarded as part of quality. Therefore patient safety is also regarded as the responsibility of the hospital.

The quality of care, with a focus on patient safety, has been defined as one of the most important issues for the current Secretary of State of the Department of Health Care (minister Ad Klink, Ministerie van Volksgezondheid, Welzijn, en Sport) (Klink, speech, 2007).

13.1.1. Sneller Beter

One of the first projects aimed at patient safety in the Netherlands is the Sneller Beter project, started in 2003 by VWS together with the representative bodies of physicians, hospitals and nursing staff.

The goal of this project is to provide insight into the quality of health care, catalog and share best practices, and facilitate improvements in safety, logistics and customer-oriented care.

One of the initiatives within this program has been to invite captains of industry from renowned Dutch companies to investigate what the health care industry could learn from their businesses. The goal is to adopt best practices from other sectors. The researchers involved were – alongside the theme of their research:

- Rein Willems, Shell → Safety
- Peter Bakker, TPG (now TNT) → Logistics
- Ad Scheepsbouwer, KPN → ICT
- Johan van der Werf, Aegon → accountability and transparency

For patient safety the investigation done by Shell has been very important. The Hier werk je veilig, of je werkt hier niet report (Willems, 2004) provided several recommendations to the health care sector, all of which have been translated into guidelines for hospitals. The recommendations were (Willems, 2004):

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12 [www.snellerbeter.nl](http://www.snellerbeter.nl) website visited on: 14-04-2008
13 Orde van medisch specialisten, Vereniging van Nederlandse Ziekenhuizen en Verpleegkundigen en Verzorgenden Nederland
All hospitals should have a safety management system by 2008
Safety is the responsibility of the board of directors of a hospital
Insurance companies should use safety and quality in contract reviews
The government has to show decisiveness and take responsibility for safety.

Since January 1st 2008 all Dutch hospitals are required by law to have a certified safety management system (Veiligheids Management Systeem, VMS). This system should at least record events, provide risk surveys and record measures taken to control these risks (Willems, 2004).

The project Sneller Beter is still active. The project for instance contains a database of best practices to be used by other hospitals. They are organized according to specific fields of interest – safety, logistics – and reports all have the same structure, paying attention to the approach, results, usability and contact information for further information. These reports have not been further investigated as they primarily focus on improving the quality of care, not the obtainment of information.

13.1.2. NTA 8009
The report by Willems has lead to the creation of an NTA (Nederlandse Technische Afspraak 8009). The NTA lists the responsibilities of all parties involved, especially the responsibility of the board of directors and the management. The goal of defining responsibilities is to facilitate a change in hospital culture. This includes a constant commitment to this goal and a clear division of responsibility – and mutual acceptance of these responsibilities – between directors and Maatschappen (Willems, 2004). Through a positive change in culture all personnel will feel inclined to report incidents, near misses and complications. As the report Melden van incidenten in de gezondheidszorg from ZonMw states: “culture and professional attitude are much more important for reporting than a more formal arrangement of reporting duty” (translated from Legemaate, 2006).

13.1.3. Veiligheidsprogramma: Voorkom Schade, Werk Veilig in de Nederlandse Ziekenhuizen
In 2007 a national patient safety program for hospitals was presented by:

- Ministerie van Volksgezondheid, Welzijn en Sport
- Inspectie voor de Gezondheidszorg
- Vereniging van Ziekenhuizen (NVZ)
- Nederlandse Federatie van Universitair Medische Centra (NFU)
- Orde van Medisch Specialisten (Orde)
- Landelijk Expertisecentrum Verpleging & Verzorging (LEVV)
- Verpleging & Verzorging Nederland (V&VN)

The goal of this program is to realize a reduction of 50% of preventable events by 2012. To accomplish this goal the program incorporates the NTA for the creation of a VMS (Veiligheids Management Systeem). An important part of this program is the formulation of ten themes that should be the top priority for improving the quality of care. These themes will be addressed in three phases; phase 1 constitutes the first four themes:

- The prevention of hospital acquired Post-Surgery Wound Infections
- The prevention of harm caused to patients with a centraal veneuze lijn (inbrengschade, infecties en sepsis)
- Early recognition of patients with life threatening vital functions
- The prevention of medication errors, especially during handover

For each of these topics specific goals and risk reduction actions have been identified. These will be discussed in Chapter 14.
In Part II it was established that current registration systems do not focus on Contributory Factors. Especially those factors related to staff, organization, or specifically relating to the patient were under-represented. The Veiligheidsprogramma specifically identifies such factors as important points of improvement to reduce the number of preventable events.

"Belangrijke factoren waarmee rekening moet worden gehouden, zijn de menselijke factoren. Ongeveer 65% van de onbedoelde schade, waarvan 61% mogelijk voorkomen had kunnen worden, is gerelateerd aan menselijke factoren als kennis, gedrag en vaardigheden. Daarnaast worden patiëntgerelateerde factoren (39%) benoemd als leeftijd, co-morbiditeit en communicatieve vaardigheden. Ongeveer 30% daarvan zou hoog vermijdbaar zijn. Ook organisatorische factoren (14%) en overtredingen (15%) kwamen voor bij hoog vermijdbare schade." (VMSZorg 2007)

13.2. Inspectie voor de Volksgezondheid

With respect to patient safety the Inspectie voor de Gezondheidszorg is responsible for the quality of care in the Netherlands. They make sure this quality does not drop below certain standards. For this goal they both investigate serious events and review health care based on annual Prestatie Indicators. Care is evaluated in retrospect based on information provided by each health care organization. They also provide an information platform concerning patient safety14.

13.2.1. Incident Investigation

Whenever a severe event happens in a Dutch hospital the IGZ decides whether they will investigate the causes of the event. They decide if a thorough investigation is needed to find out how the event could happen. This often involves an assessment of potential malpractice by physicians and/or hospital. The IGZ can perform their own investigation, but they will first instruct the hospital to carry out an investigation. Normally, the MIP-Commissie will already be working on such an investigation.

There are no guidelines as to what data should be presented to the IGZ. Hospitals can either only hand over the report written by the MIP-Commissie or provide the IGZ with the information from the registration database. Handing information from the registration system over to the IGZ could lead to blame being assessed based on this blame-free reporting system. At this moment, hospitals have to decide for themselves how to handle this issue. And both options are currently in use in the Netherlands.

Minor events – events without lethal or severe harm - are left to the hospital to deal with.

13.2.2. Yearly Evaluation

The IGZ has defined a number of Prestatie Indicatoren (Prestatie Indicators) that provide insight into the quality of care provided by each hospital. Hospitals are required to provide this information annually. Many of the Prestatie Indicators refer to adverse events; events found in the line of work of physicians. Therefore hospitals are dependent on their Maatschappen for their perceived quality.

14 www.igz.nl/dossiers/patientveiligheid/ (11-03-08)
15 This committee, or an equivalent, is present in every hospital to investigate serious events.
The acquired information is used for many purposes. Firstly, it provides an overview of the quality of care in the Netherlands. Secondly, it provides information to the IGZ about ill performing hospitals. By comparing hospitals on a yearly basis, continuous deviations can be assessed.

If the *Prestatie Indicators* suggest a certain hospital to deliver care of low quality, the IGZ takes action. First they will discuss the matter with the hospital; many uncertain factors can influence the outcome measures (the patient mix for instance can deviate). If this does not result in the required improvement of quality the IGZ can issue a warrant. Ultimately the IGZ can take measures; they can prohibit the execution of certain procedures.

Finally, these figures are made public on the website [www.kiesbeter.nl](http://www.kiesbeter.nl). This website has been created to enable patients to assess the quality of care in hospitals. Patients can look for hospitals based on location or certain procedures. The website is not only focused on hospitals, information about any health care related organization can be found here. More on these indicators can be found in Chapter 14.2. The outcome measures are also used for the creation of commercial rankings[^16].

### 13.3. Health Care Sector

#### 13.3.1. Orde: Generiek Datamodel

The Orde (*Orde van Medisch Specialisten*) is the coordinating body for all medical specialists in the Netherlands. Every medical specialism has its own association and these associations are grouped into the Orde. The Orde participates in most national working groups aimed at the quality of health care or patient safety.

Next to these national initiatives the Orde is also working on a *Generiek Datamodel*. This data model will function as a classification for physicians to use when reporting adverse events. Based on this generic list, all specific associations are creating their own specific taxonomy (*Masterclassificaties*) that will list the adverse events that can be found in their line of work[^17]. Several of these classifications are finished, while other associations have not even started the creation of a classification.

#### 13.3.2. NIAZ: Nederlands Instituut voor de Accreditatie van Ziekenhuizen

The NIAZ has been founded by the NVZ and the Orde. The goal of this institute is to assess the structure and process for dealing with quality of care in health care institutions. The NIAZ certification is an individual quality label. Once hospitals have a Safety Management System (VMS), the NIAZ assesses whether this system complies with the developed quality measures; for instance the NTA regulations.

[^16]: http://www.ad.nl/ziekenhuisstop100/ 15-04-2008
[^17]: [www.orde.nl](http://www.orde.nl)
Chapter 14. Patient Safety Loop
Acknowledgement on a National Level in the Netherlands

Part III introduced the Patient Safety Loop as a way to incorporate patient safety in the mindset and evaluation of quality in health care. Quality can be assessed as a derivative of events; this is represented by arrow (1). This research proposes the replacement of arrow (1) with loop (2), the Patient Safety Loop. If quality is assessed through this line of reasoning quality is no longer directly derived from errors. Instead quality is measured based on the actions taken in response to reported errors which in turn heightens the patient safety. This level of patient safety should determine the quality, not the errors made.

This line of reasoning should also be used by national initiatives. These initiatives determine the health care environment and can initiate the change in perspective.

In the previous chapter several national initiatives have been described that focus on the quality of health care in the Netherlands. Here the current inclusion of patient safety principles in the ‘10 thema’s’ and the Prestatie Indicators of the IGZ will be discussed. Both these programs are aimed at improving the quality of health care.

14.1. Patient Safety and the 10 Thema’s

In a letter the Secretary of Health wrote to the parliament in July 2007 (Klink, Letter, July 2007, Appendix 1) the first four of the ‘10 thema’s’ have been explicated. For each theme the goal, the risk reduction actions and the method of impact assessment were described (for more information, see Appendix 8).

<table>
<thead>
<tr>
<th>Goal</th>
<th>Risk Reduction Actions</th>
<th>Impact Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>-50% of Post-Surgery Wound Infections</td>
<td>Four practical actions have been defined. For instance, the proper use of antibiotics.</td>
<td># patients with Post-Surgery Wound Infections.</td>
</tr>
<tr>
<td>- 50% of harm caused through the insertion of centraal veneuze lijnen</td>
<td>Actions include the creation of protocols and adequate training</td>
<td># patients in ICU that die /Total number of patients</td>
</tr>
<tr>
<td>- 25% of events with lethal outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 25% of death of patients with bedreigde vitale functies</td>
<td>Creation of protocols and emergency intervention teams</td>
<td># patients that die / Total number of patients</td>
</tr>
<tr>
<td>To be defined</td>
<td>Creation of risk assessments of the</td>
<td># medication incidents</td>
</tr>
</tbody>
</table>
Several conclusions can be derived from these explications of the first four themes. Firstly, Risk Reduction Actions have been defined. The application of these Actions should lead to the stated outcome.

Secondly, the result of these actions should be an improvement of the quality of health care; thus an improvement of the patient safety. To measure this quality the system is based on the number of patients that do experience a wound infection, the percentage of patient that die, or the percentage of medication errors.

In other words the quality of health care is directly derived from the number of errors. This is in accordance with arrow (1) in Figure 10: Patient Safety Loop.

Counting the number of times a certain event has been reported does not provide real insight into the causes of the event. The number of events can equally be caused by:

- The unwillingness to report certain events,
- A difference in patient mix
- The application of measures.
  - Whether the measures taken were those proposed by the theme or others cannot be assessed.
  - Neither can it be assessed which Actions had a positive effect and which had no effect.

The themes do propose Risk Reduction Actions, which implies that the Patient Safety Loop is applied, but when quality is assessed, the themes rely on the number of errors made. The assessment therefore does not incorporate the level of patient safety. Nor does it acknowledge that there can be a deviation between the total number of occurred events and the total number of reported events. Thirdly, the themes do not acknowledge that new insights might be gained in the course of time due to the reporting of events.

### 14.2. Patient Safety and the Prestatie Indicatoren

The IGZ has defined a number of Prestatie Indicatoren (Prestatie Indicators) to assess the quality of health care in the Netherlands. Every hospital has to provide information about these Prestatie Indicators annually.

Data can be derived from registration systems or other counting mechanisms (depending on the Prestatie Indicator). The source of data is not explicated nor is the completeness of data discussed, therefore it is concluded that the IGZ assumes that: # reported events = # occurred events.
Hospitals are required to provide the *Prestatie Indicators*, but the IGZ performs checks to assess whether the provided data is correct. In this study the provided data for the criterion ‘Adverse Event Registration’ has been examined more extensively. There is a wide variation in data as provided by the hospitals and data as assessed by the IGZ. In many cases the hospital and the IGZ have a difference of opinion with regard to the number of

The Diaconessenhuis in Utrecht, for instance, stated that they have 32 *Maatschappen* of which 12 have a registration system. The IGZ on the other hand concluded that the hospital has 31 *Maatschappen* of which 21 have a registration system.

*Data derived from Prestatie Indicatoren 2006*

*Maatschappen* a hospital has and the number of *Maatschappen* that has an adverse event registration system. This variation is completely random. Sometimes the hospital and sometimes the IGZ counts one *Maatschap* more or less; occasionally the numbers differ more.

On the website, [www.kiesbeter.nl](http://www.kiesbeter.nl), the numbers as concluded by the IGZ are used. No explanation can be provided for this difference of opinion.

Another issue identified with respect to the quality of provided data is the fact that several hospitals state that their *Maatschap Thorax/Cardio chirurgie* uses a national adverse event registration system. *Thorax/Cardio Chirurgie* does not yet have a *complicatienlijst*[^18]. Presumably these hospitals refer to a general registration system – such as the registration system for Post-Surgery Wound Infections – as this answer was given by many hospitals. However, specific information about the used system cannot be found in the *Prestatie Indicators* of the IGZ.

The same analysis has not been carried out for the other issues discussed.

### 14.2.1. Adverse Event Registration

One of the criteria of the IGZ concerns the existence of adverse event registration systems. Hospitals have to state how many of their *Maatschappen* have an adverse event registration system; this figure is presented as a percentage.

On the website [www.kiesbeter.nl](http://www.kiesbeter.nl) this meaning of this number is explained as follows:

*Indicator % complicatieregistratie*

> Hoe hoger het percentage, hoe meer specialismen een complicatieregistratie hebben. Dit zegt iets over het beleid van de specialisten in het ziekenhuis. En de bereidheid om van eigen fouten iets te leren om zo de kwaliteit van de zorg te verbeteren.

Cited from [www.kiesbeter.nl](http://www.kiesbeter.nl) 14-04-08

The last sentence of this explanation states that the existence of a registration system equals the willingness to learn. There are no guidelines in the Netherlands for adverse event registration systems. The consequence of this is that there are potentially many different registration systems – ranging from non-existent, to recording basic medical information, to extensive learning mechanisms. What exactly is reported and whether data is used for learning purposes is not checked by the IGZ.

As discussed in Part II and Part IV the Orde has asked all medical associations to develop an adverse event taxonomy based on the *Masterclassificatie*. This could change the situation as

[^18]: A list of adverse events based on the *Masterclassificatie* created by the Orde
data will be reported based on a structured – and nationally equal – adverse event taxonomy.

For 2008 the IGZ has extended their list of *Prestatie Indicators* with respect to adverse event registration systems. In the *Prestatie Indicatoren 2008* (IGZ, 2007) each *Maatschap* has to state whether they use an adverse event registration system, whether it is based on the national standard, and whether data is discussed in team meetings. It is not expressed how this information will be portrayed on the website. Based on the new *Prestatie Indicators*, no insight can be gained in the thoroughness of team meetings and the resulting actions to improve the quality of care. No question is asked concerning the actual implementation of lessons learned.

Based on the *Prestatie Indicator* formulated by the IGZ for adverse event registration systems it cannot be assessed whether data is used to gain insight – especially into the contributory factors – or to formulate Risk Reduction Actions. The IGZ does ask whether events are discussed in team meetings. However this fact cannot be verified. Secondly, talking about events does not reflect whether data is used for learning purposes or for ‘blaming & shaming’. Neither does it reflect if Risk Reduction Actions have been formulated based on the occurred events.

### 14.2.2. Decubitus

The subject of decubitus has been mentioned several times throughout this study. It is a focus in many hospitals as it can – to a certain extent – be minimized, given staff has insight into the condition of the patient and improvement measures are actively applied. The IGZ regards decubitus as an important indicator for the quality of care (IGZ, 2007).

The website\(^{19}\) only states a number. In the explanation of this number it is explained that the number is the result of a random check done in the specific hospital. Furthermore several examples are given of measures hospitals could take to minimize the occurrence of decubitus.

The website does not explain what the number precisely constitutes. This information can however be found in the complete overview of the criteria of the IGZ. The number represents the percentage of patients that had a certain level of decubitus during a random check. The IGZ requires more insight into this subject than what is given on the website.

In the complete overview of the IGZ they inquire whether the hospital has a registration system for decubitus (IGZ, 2007). The answer to this question can either be YES or NO. The second question asked – with regard to registration – is whether the data is used by management in decisions. The answer again can be either YES or NO. No specifications are asked.

The *Prestatie Indicator* will not provide insight into questions such as:
- What insight has been gained from the data?
- What has been done with the insight gained from the data?
- Has this insight had an effect on the percentage of decubitus cases?

These questions can identify lessons learned and best practices and as such are an essential part of the Patient Safety Loop. These aspects of quality are not recognized in the decubitus quality evaluation of the IGZ.

In the annual report made by the IGZ for 2006 *‘Het resultaat telt 2006’* (IGZ, 2007) the IGZ gave the following conclusions with regard to decubitus:
- All hospitals report incidents relating to decubitus

\(^{19}\) [www.kiesbeter.nl](http://www.kiesbeter.nl) 14-04-08
Most hospitals use the LPOD/LPZ registration method

- There is much deviation in prevention. This can partially be explained:
  - Hospitals measured in different patient mixes
  - Hospitals use different detection methods
  - Hospitals deal with vochtletsel is different ways

In Part II is has been discussed that registration of events is not aimed at finding out what happened in the past, but at how future practice can be improved. Registration is aimed at learning.

The annual report of the IGZ (IGZ, 2007) contains diagrams depicting the percentage of patients with decubitus in hospitals. The conclusions state how Dutch hospitals scored in the year discussed.

The Prestatie Indicators indicate there to be a direct relation between percentage of decubitus and quality of care. The IGZ does not provide any insight into the reasons why some hospitals score better than others. No insight is provided into measures implemented by the better scoring hospitals. The IGZ only provides hospitals with insight into how they are doing compared to other hospitals in the Netherlands. But no mention is made of how they can improve their position or their percentage of decubitus.

### 14.2.3. Post-Surgery Wound Infections

The first theme of the Safety Program (mentioned earlier in Part IV) regards the occurrence of Post-Surgery Wound Infections. Since it is the first of these ten themes it is assumed that this is a very important topic for health care professionals in the Netherlands. As of 2008, this type of adverse event is regarded as part of the Prestatie Indicator ‘Hospital acquired Infections’ (IGZ, 2007).

Questions asked refer to the number of patients that experienced this adverse event, the number of patients that was considered, and how the number of infections was measured. The IGZ also requires information concerning whether interventions have been performed and whether these interventions have had the desired effect.

![Figure 12: Post-Surgery Wound Infections, copied from IGZ, 2007](image)

Figure 12 depicts the conclusions of the IGZ with respect to the interventions after post-surgery wound infections in 2006. In the report of the IGZ no conclusions are made based
on the number of infections, nor is it stated that the IGZ will respond to certain levels of infections. The IGZ does require that hospitals focus on infections, participate in the national registration system and use national registration guidelines. However, the represented data does not provide insight into which interventions have been made, what the desired effect was, or the level of improvement the intervention has lead to. Therefore the *Prestatie Indicator* does not provide insight into lessons learned or best practices.

### 14.2.4. Incident Registration Systems

Every hospital is required by law to have an incident registration system. Therefore no questions are asked as to the availability of this system. Two questions are asked with regard to this registration system:
- Total number of reported incidents
- % that has resulted in actions

No conclusions are drawn with respect to the number of reported incidents. In the WHO report it was concluded that there is inadequate reporting of events in the Netherlands (WHO, 2005). The IGZ does not comment on this (IGZ, 2007). The *Prestatie Indicator* concerning incident registration systems is not mentioned in the annual report of the IGZ about 2006 (IGZ, 2007).

The *Prestatie Indicators* provide no information about the types of incidents that are reported. There are no specific guidelines as to what a registration system should record in the Netherlands, therefore it cannot be assumed that every hospital records the same types of incidents. The more elaborate the registration system, the more events can be reported; thus the higher the ‘total number of reported incidents’.

Another important factor impacting this number is the willingness to report. Some hospitals actively stimulate staff to report incidents. This will lead to a higher level of reported incidents. The impact of this is not acknowledged in the *Prestatie Indicators*.

The IGZ does not specify what is meant with ‘resulted in actions’. No specific information is asked, therefore nothing is known about the types of action taken. For instance, a hospital could refer to ‘event discussed in team meeting’ as a sufficient action, while another hospital could have decided to not qualify this as an action.

No conclusions can be drawn as to whether the actions have lead to an increase in the level of patient safety. No insight into best practices is gained or shared, predominantly because a direct relation between events and quality is assumed.

In the indicator list for 2008 the same questions are asked. No further specification has been made.
Chapter 15. International Event Registration Systems

Patient safety is attracting a lot of attention worldwide. Already in Part I several international taxonomies of patient safety were discussed. Alongside the development of taxonomies, many countries are implementing acts, registration systems, and committees to improve patient safety on a national or local level. This chapter describes several international patient safety registration systems.

There are more systems operational worldwide. These few are chosen because they are the most advanced, most reported about, or because they are often used as blueprints for new systems in other countries. There could be some very interesting systems in use in other countries, but trying to depict all systems worldwide is not an option. Unfortunately, no two systems are alike; this fragmented state of patient safety research has been discussed in Part I.

The focus on patient safety started in the medical specialism of anesthesia. Already in 1983, the first programs aimed at reducing the number of mishaps started. The result of this worldwide focus on standardization of processes has made anesthesia one of the safest medical professions; even one of the safest high-risk businesses (Amalberti, 2005).

The real global interest in patient safety started with a publication by the American Institute of Medicine called To err is Human in 2000 (Kohn, et al., 2000). This report provided insight into the sheer amount of preventable deaths each year in the United States of America alone (44,000 to 98,000 annual deaths). These numbers shocked the medical world and as a result, patient safety became a top priority in many countries.

Most countries with an advanced focus on patient safety have national foundations for the promotion of patient safety initiatives. In some countries reporting is mandatory, but in all countries reporting is safe. Either legislation is in place to protect the reporter, or the registration software guarantees the anonymity of those involved. The situation in four countries – Great Britain, Australia, United States of America, and Denmark – has been described in Appendix 9.

15.1. Registration Systems

The investigated countries all have a centralized patient safety system. Some systems record locally, but data is automatically copied to the national database. The advantage of this is that it allows for trend analysis. Trends can be identified more easily when the body of data is larger.

Another benefit of a nationally deployed system is that best practices can be presented more easily on a national level. In the Dutch system, no sharing of best practices is possible through registration or the IGZ, since every hospital records different data and in a different fashion. Furthermore, the decentralized manner of conduct does not stimulate trust.

The NPSA in Great Britain has provided structured guidelines about what to report to local initiatives, the Dutch government did not create such guidelines. Through the Masterclassificatie, the Orde has created guidelines for adverse events. Since registration systems will be based on this classification, the development is guided as well.
With regard to registration system more general guidelines have been created in the Netherlands. The NTA states who is responsible for patient safety and that hospitals should perform risk assessments (NNI, 2007). Since no definite structure or functional requirements about the VMS have been provided each hospital has to decide for itself what their VMS should record, how to record, who should record and what should be done with the data recorded. Events resulting in severe or lethal harm do have to be reported to a national body – the IGZ. Yet strict reporting guidelines have not been created for severe events, which has lead to the conclusion of the WHO that “the classification and collation of data is not solid and, therefore, may be unreliable” (WHO, 2005).

15.2. Legal Position of Registration Data

The Danish patient safety act states that “a healthcare professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, to supervisory reactions by the National Board of Health or to criminal sanctions by courts”20. In Australia similar legislation can be found. Legislation states that it is a criminal act to use data from quality registration systems in civil courts.

Both this Beleidskader and an official letter written by the Secretary of State (Ad Klink) (Klink, Letter, Appendix 1, July 2007) state that a safe culture is an essential pre-requisite for reporting of events. Yet in the Netherlands no specific legislation has been created for registration data. The opinion of the Dutch government is that “culture and attitude are much more important” (Legemaate, 2006), so protective legislation will not necessarily increase reporting. Secondly, they conclude that there are no evident reasons why legislation would be better than proper guidelines.

This can have adverse effects on the registration of events. As already stated the Dutch system is not used to its full potential; there is inadequate reporting (WHO, 2005). Judging by the effort put into patient safety initiatives by all medical associations (Orde, LEVV, V&VN) this can not be blamed on the unwillingness of medical personnel to learn from events. An important reason could be that staff does not feel safe to report an event. Recently, a judge granted a patient insight into the registration system (Molendijk, et.al, 2008) because the patient file was lacking important information. Such a ruling can lead to a situation in which registration system can get used to assess what exactly happened and who is to blame. Thus a learning system becomes a system for assessing blame.

The effects of protective legislation can be seen in the successes booked by the Onderzoeksraad voor de veiligheid21. Their sources are protected against civil jurisdiction, so their information cannot be used in court. This enables them to find out what happened and give recommendations for future improvement; precisely because they make it very clear that they will never appoint blame.

20 www.npsa.nhs.uk/patientsafety, 14-04-08
21 www.onderzoeksraad.nl 10-04-08
Chapter 16. Conclusion Part IV

The main question posed in Part IV was:

*What are the challenges and opportunities for registration created by the Dutch government and medical associations?*

To answer this question this part has reviewed the national initiatives aimed at patient safety in the Netherlands. Two of these have been evaluated more thoroughly. Secondly, the Dutch situation has been compared to the position of patient safety in several other countries.

16.1. National Initiatives

Based on the active involvement of all representative medical groups in national initiatives it is concluded that patient safety and quality are important subjects in Dutch health care. Although there are many initiatives in the Netherlands there is no structure to combine their focus. Identified focuses include: a focus on best practices (*Sneller Beter*), a focus on responsibilities (*NTA*), a focus on the structure and process of quality management (*NIAZ*), a focus on the development of serious events (*IGZ*), or a focus on the number of events (*IGZ*). No initiative has been identified that primarily focuses on the obtainment of information. This is in line with the conclusion in Part I that there is no Dutch taxonomy of patient safety.

Two national initiatives to improve patient safety are the *Veiligheidsprogramma* and the *Prestatie Indicatoren*. The first one has been created by the government, the *IGZ*, and most associations of medical personnel. The second is defined by the *IGZ*. Both initiatives predominantly focus on the number of events to assess the quality of care. Lessons learned or best practices are hardly incorporated. Based on these two initiatives several constraints for registration are identified.

Firstly, the WHO has concluded that there is under-reporting of events in the Netherlands (WHO, 2005). Yet both initiatives assume that the amount of reported events is equal to the amount of occurred events. Neither initiative – nor any of the other initiatives – emphasizes that all events should be reported to gain insight into the occurrence of events. The improvement of registration is not a focus point, even though every health care organization knows that not everything is reported.22

The assumption that the number of reported events is equal to the number of occurred events can also distort quality assessments. Reporting more events does not mean more events happen; this is not acknowledged in the Netherlands. For some measures the ratio “# events/# procedures” is used, but this ratio is also susceptible to this distortion.

Both initiatives focus predominantly on the number of events (or the ratio) to assess quality. The focus is not on the lessons learned. Neither one promotes the sharing of best practices. The *IGZ* only asks whether improvement measures have been formulated based on events. The exact nature or impact of the improvement measures is not estimated. The *Prestatie Indicatoren* do not take the change in number of events in account. The quality of a hospital is assessed based on the number of events in the previous year.

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22 personal communication with many health care professionals
The Veiligheidsprogramma does list several Actions that can aid in decreasing the number of events, but no insight is gained in the actual improvement each Action constitutes. Currently, this program does not offer the opportunity to share new Actions. The Sneller Beter project does provide a database to share best practices.

The impact contributory factors can have on the quality of care are not acknowledged by either initiative. The Veiligheidsprogramma does refer to non-medical factors – such as culture and fatigue – but these factors are not incorporated in the actual specification of themes; they are not referred to as risk reduction action or as assessment measure. Non-medical factors are not acknowledged by the IGZ. To assess the quality of care the Prestatie Indicatoren only refer to the number of events. The causes of events are not defined. Although the program does refer to improvement measures, no details are asked.

Both the Veiligheidsprogramma as the Prestatie Indicatoren focus predominantly on medical events. The Veiligheidsprogramma does acknowledge Risk Reduction Actions – although none of these refer to changing culture or staff attitudes – but to measure impact they use the amount of events. The IGZ does not acknowledge any Risk Reduction Actions or Contributory Factors. The annual report states the amount of events in the discussed year, without reference to the change with regard to last year; either sector wide or within a single hospital.

Overall the conclusion is that the real meaning of patient safety is not yet acknowledged at the national level in the Netherlands. Single hospitals might focus on patient safety; these initiatives are not acknowledged as such by the IGZ. The IGZ – and other national bodies – still regard quality to be directly derived from events. To assess quality they assume all events are reported.

16.2. International Registration Systems

The position taken by the Dutch government with respect to patient safety is different than that found in several other countries. In the reviewed countries a national registration system is in place. This system can be filed through local registration systems. This homogenizes the data acquired from different hospitals. In the Netherlands there is no national registration system or clear national guidelines for what to report. Some events are to be recorded in national databases, but for the most part patient safety is the responsibility of the hospitals. A result of this decision is that it is not possible to perform national trend analyses into events. Another difference between the Netherlands and other countries is the legal protection of registration data. In the Netherlands data is not protected from legal use. The IGZ does state that they will not use this data and in the Beleidskader Veilig Melden it is acknowledged that using data in legal procedures (even if done only once) will diminish the willingness to report. That this could already be the case is concluded based on discussions with field experts, who state that not everything is reported, yet it is impossible to determine how much is not reported. The WHO also concluded in 2005 that not all events are reported in the Netherlands (WHO, 2005).

In many other countries reporters are legally protected against use of their registration data in court. In Australia it is even a criminal offense to use registration data for legal prosecution. Through such legislation these countries have shown their medical professionals that they value learning – thus improving the future – more than finding out who is to blame. Such fear of shaming & blaming is present in the Netherlands as has been shown in Part III.
PART V: Conclusions

The main research question posed in this study is:

To answer this question this research has been divided into four parts. Each part focuses on a different issue needed to answer the research question.

- The added value of registration
  - Part I: Patient Safety
  - Part II: Registration

- Health care in the Netherlands
  - Part III: Dutch hospitals
  - Part IV: The national context of health care

In this research the following definitions have been used:

**Patient safety:**
1) “Freedom for a patient from unnecessary harm or potential harm associated with health care.” (WHO, 2005)
2) “The absence of the potential for, or the occurrence of, health care associated injury to patients created by avoiding medical errors as well as taking action to prevent errors from causing injury.” (Marx, 2003)

**Registration system:**
“While an individual report may contain important information about a specific incident or event, the notion of a reporting system refers to the processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response, and dissemination of lessons learned from reported events.” (WHO, 2005)
Chapter 17. General Conclusion

17.1. Registration

Patient Safety is a national focus point in Dutch health care. Several national initiatives have been started, like the Sneller Beter project, the Veiligheidsprogramma and the Prestatie Indicatoren of the IGZ. Patient safety is classified as part of the quality of care and thus as a local topic. This means that hospitals are expected to improve their own quality. The IGZ for instance only evaluates whether hospitals meet certain specified quality standards.

As of January 1st 2008 hospitals are required by law to register events by means of an electronic registration system. The goal of registration is to improve patient safety by learning from events. Registration by means of a registration system can be seen as an answer to the mission statement ‘how can patient safety be improved?’, which is the main topic in the Dutch debate on patient safety.

This research poses a different mission statement: the search for improvement measures should be preceded by the following question: ‘what is patient safety?’ This question has not been addressed in the Netherlands yet. The improvement measure has been formulated – registration of events – but which events should be registered in a registration system is unclear.

As there as yet is no taxonomy of patient safety in the Netherlands, three international taxonomies have been evaluated in this research. This evaluation focuses on the usability of these taxonomies for Dutch health care.

Based on an extensive study the conclusion is that the ICPS model provides the most extensive taxonomy of patient safety. This classification of patient safety has been developed by the World Health Organization and is based on four international patient safety taxonomies. The ICPS model addresses the entire patient safety chain. As such it can provide insight to health care organizations into their entire patient safety and quality handling. Another important feature of this model is the inclusion of Contributory Factors.

Contributory Factors are non-medical, can cause every type of incident or adverse event, can be apparent throughout the organization, and will often involve both nursing staff and physicians. Due to the separation of data the full extent of these factors in Dutch health care cannot be assessed.

There is no standardized registration system in the Netherlands. Each hospital is responsible for its own registration system. This has lead to the development of many different registration systems. Since a taxonomy has not been provided to Dutch hospitals, every hospital has the freedom to focus on different issues in their registration system. Therefore it is virtually impossible to gain insight on a national basis into patient safety from patient safety registration systems.

One registration system – used in over twenty Dutch hospitals – has been evaluated to assess whether Dutch hospitals can gain insight into the aspects of the ICPS model through registration. The conclusion is that registration of incidents and adverse events in the Netherlands focuses primarily on the medical causes and the impact of events. Incident Types referring to either organization or staff, the influence of Contributory Factors, or the impact events can have on the organization or staff are not covered to their full extent.
Incidents are the result of multiple causes. Causes can have a medical nature – these often constitute the specific Incident Type – or result from the way the hospital is organized. Miscommunication for instance can be identified as a cause of a wide range of events. Acknowledging the existence of such latent factors is one of the added values of registration. Contributory Factors that are currently not addressed include organizational factors such as culture, environment and distance from service. Staff factors relating to understanding, performance (distraction, fatigue), communication or social issues are not addressed either.

All reviewed patient safety taxonomies explicate the type of human error involved. Human errors can be split into skill based errors, rule based errors and knowledge based errors. Each type of error requires different improvement measures. Yet this explication of human errors has until now not been recognized in Dutch health care. Consequently human errors are considered personal errors and no regard is taken for the difference between errors caused by i.e. a wrong decision or errors caused by habit.

The evaluation of adverse event registration resulted in complementary conclusions. The national association for physicians (the Orde) has created a standardized classification list for adverse events. Each specific medical association will develop an adverse event classification based on the general stated guidelines and classification rules. This improves nationwide standardization of output. This classification however only addresses medical causes and the impact of adverse events. It does not acknowledge latent factors that can lead to an adverse event, nor does it acknowledge the impact events can have on organization or staff.

The conclusion of the first part of the research therefore is that the added value of registration will mostly concern the acceptance and incorporation of non-medical issues. This includes both Contributory Factors, Impact on Staff, Detection Measures, and Risk Reduction Actions. As the focus of this research is on registration, only the Contributory Factors have been further explored.

### 17.2. High Reliability Organization Theory

Many researchers have concluded health care to be a High Reliability Organization (Amalberti, 2005; Weick, 2001, 2007; McFadden, 1999, 2001, 2007; Helmreich, 2000). Similarities and differences between HROs and health care have been discussed. Firstly, health care relies heavily on the Expertise of its staff. Health care is becoming more complex, which has lead to further specialization of personnel. The tacit knowledge staff has in their specific field of work is vital for the execution of their profession. It also makes it more difficult to manage health care institutions as other businesses. This poses a barrier to the introduction of the aspect of human error.

Health care professionals have a tendency to aim for perfection (Willems, 2004). Health care personnel value this position of a craftsman (Amalberti, 2005). Other evidence of this view is the reluctance with which many health care personnel accept standardization tools like checklists or work schedules, tools that form an integrated part of the procedures in i.e. aviation (Leape, 1994).

The organizational structure of most Dutch hospitals differs from that found in other high reliability organizations. In general hospitals physicians are organized in legally separate entities called Maatschappen. Therefore the hospital – ultimately responsible for patient
safety – is dependent on staff that they cannot control for the overall quality of care provided.
The board and the Maatschappen are dependent on each other. The hospital is evaluated on
the basis of the quality of provided care and of the quality of the work performed by the physicians. The physicians need the board to provide them with adequate equipment, nursing staff and work rooms to perform their work as best they can.

This creates an environment in which two equally strong powers have control. From the stakeholder analysis in Part III it is clear that a hospital can be classified as a multi actor system, in which actors often have conflicting interests. This system has two main actors: the board and the Maatschappen. They are alike in power and there is a strong interdependency. Both need and are needed by the other.
This leads to the conclusion that although organizational theories, such as HROT and multi actor analyses, provide some very interesting improvement measures for hospitals, the theories do not acknowledge all characteristics apparent in health care.

17.3. National Initiatives

There are many initiatives aimed at improving patient safety in the Netherlands. From the active participation in patient safety initiatives by medical associations it is concluded that caregivers focus on the improvement of patient safety as well. They want to learn from events to prevent them from happening again. For instance, the goal of the Veiligheidsprogramma is to decrease the mentioned adverse events by 50% in 5 years.
This Veiligheidsprogramma has been created by health care related organizations, including the Orde, the LEVV, the government, and the IGZ. The program explicitly mentions the impact Contributory Factors can have on the care provided, yet when assessing the quality of care the number of events is considered as the main indicator.

In the Netherlands quality is assessed based on indicators defined by the IGZ. The outcome measures of the IGZ strive to provide insight into the quality of care of health care organizations. The information is used for instance to provide patients with quality assessment measures for choosing a hospital. National rankings of hospitals are also based on these Prestatie Indicators.
Several Prestatie Indicators have been analyzed. The IGZ also uses the number of events to determine the quality of care. With respect to several indicators they inquire whether improvement measures have been formulated, but no further explanation is required. This prevents best practices from being shared through the Prestatie Indicatoren and it neither provides insight into the effectiveness of improvement measures.
17.4. **Patient Safety Loop**

It is concluded that quality is regarded as directly related to error in the Netherlands. The more events the lower the quality of care provided; arrow (1). Based on HROT, other safety theories (Bogner, Chapter 17, in Bogner, 1994), and insights gained in this research, a new assessment of quality is introduced: the Patient Safety Loop - loop (2).

Quality is derived from the actions taken to improve the level of patient safety. The level of patient safety is derived from the Risk Reduction Actions taken. Such actions are based on the insights gained from reported events.

The most important part of this cycle is information; information that can be obtained through registration (Bogner, in Bogner, 1994).

To obtain insights from registration systems, information needs to be available for analysis purposes. This is difficult in the Netherlands due to the fear for openness of information. Several reasons have been provided to explain this closed nature of healthcare.

Firstly, in the Netherlands it is assumed that the number of reported events equals the number of occurred events. It is, however, a known fact that not every event is reported, an observation that is supported by WHO-research (WHO, 2005). Providing information can therefore provide a distorted image as hospitals with adequate registration systems might score lower on quality based on the generated data.

Secondly, the assessment criteria and measures on which hospitals or Maatschappen are compared are unclear. Information that potentially could damage a hospital’s reputation will not be shared if it is not clear where information will be used; this inevitably results in a barrier to open communication and thus in a barrier to the sharing of best practices.

Thirdly, the legal protection of data and reporter is unclear. Health care professionals in the Netherlands are stimulated via the various initiatives to report events. Registration data are only to be used for learning purposes, not for assigning blame. Yet the registration data is not legally protected from improper use. In several surrounding countries the use of registration data for legal purposes is considered a crime.

17.5. **Main Research Question**

The goal of this research has been to answer the following research question:

*How can patient safety be aided by registration, within the constraints and requirements formulated by hospitals, the Dutch government and medical associations?*

The most important asset registration provides is insight; insight into the causes of events. To improve patient safety first the causes of the unsafe situation should be known. To gain insight registration should cover all possible causes of events. For that purpose a patient safety taxonomy is needed. Such a taxonomy will also provide healthcare with insight into the non-medical causes of events.
To gain insight from a registration system, events need to be reported. Currently there is under-reporting in the Netherlands (WHO, 2005). This research concludes that the most important reason for this inadequate reporting is fear for misuse of information. The most important requirement for registration systems is that registration should be safe. Information should only be used for learning purposes, not for assigning blame. Currently this is not the case in the Netherlands. There is no legal protection of data; data reported for learning purposes can be used to assign blame.

Another requirement for registration is that it must be clear how data will be assessed and what it will be used for. Reputation is very important, thus health care organizations will not provide data for comparisons based on subjective measures nor insufficiently gathered data (they have to be sure that all events are reported).

Thirdly, the focus in the Netherlands is on the number of events. The IGZ assesses the quality of provided care based on the number of reported events. No insight is gained in improvement or Risk Reduction Actions. Neither is the inadequate reporting addressed as a factor influencing the number of reported events.

Therefore registration can aid patient safety if data is assessed based on objective measures, is only used for learning purposes and if non-medical factors are included as possible causes and impacts of events.
Chapter 18. Recommendations

This research has lead to the following recommendations:

1. The willingness to report must improve
2. A national taxonomy of incidents should be composed to align different initiatives
3. Registration and quality assessment should incorporate contributory factors
4. The possibility of a national registration system – or national guidelines as found in Great Britain – should be investigated
5. Quality assessment should use the Patient Safety Loop to prevent a focus on events and to initiate a focus on Risk Reduction Actions
6. Registration Data should be legally protected.
   a. Registration is aimed at learning, not at assigning blame.
   b. Registration systems must comply with the standards for ‘blame free reporting’

18.1. Willingness to Report

An important issue with regard to data analysis – whether national or locally in a hospital – is proper registration. In the Netherlands not all events are reported in the registration systems. Many reasons have been provided for this; reporters do not receive feedback, there is no adequate feedback thus situations do not change, there is no time for reporting, the registration system is too difficult or time consuming, etc. An important reason mentioned in this study is the fear of misuse of information. Only if data is processed without reference to patient, care takers involved, (and possibly hospital involved) will events be reported.

The current vision in the Netherlands is to deal with patient safety at the lowest level possible. Minor incidents are dealt with by the local managers (department heads). All patient safety documents state that data will only be used for learning, not for assigning blame. Yet personal data concerning the reporter and the patient is attached to the report for categorization purposes. This creates a situation in which superiors do know who made which report.

In the case of a potential national database anonymity is even more important. As already discussed reputation is very important in health care. If reports can be traced back to hospitals or Maatschappen this could pose a threat. As a result events will not be reported, which in turn will hamper learning purposes.

In the event of incidents with lethal or severe outcomes the IGZ can perform an investigation into the causes of the incident. For this they rely in large part on the information provided by the hospital. No guidelines are available in the Netherlands about exactly which information should be provided. Some hospitals provide the information stored in the registration system, others only provide the report made by the MIP-Commissie based on this information. This again can be a reason for hospital staff not to report, as the potentially blame free registration system can turn into a registration system to assign blame (Dekker, 2007).

Another implication of this lack of guidelines is what the WHO in 2005 concluded: “the classification and collation of data is not solid and, therefore, may be unreliable” (WHO, 2005). So far no indications have been found to indicate the IGZ is dealing with this rather serious limitation.
18.2. A National Taxonomy

In the Netherlands patient safety initiatives are focused on the question ‘how can we improve patient safety?’ The preceding question ‘what is patient safety?’ has not been addressed. The first step should therefore be to create a national patient safety taxonomy. If nationwide the same aspects of events are registered, the overall patient safety can be improved. Within a hospital insight into factors such as the distance to a service, the explicitness of tasks and the availability of protocols can improve the overall quality of care, regardless of the underlying incidents. This is in line with the view of safety Experts who warn that Risk Reduction Actions should not be targeted at the prevention of a specific incident or a specific person. Actions should focus on more general issues to prevent a multitude of events (Van Cott, in Bogner, 1994).

The ICPS model only addresses incidents. However the Contributory Factors, Detection Methods, Mitigation Factors, Impact on Patient and Organization, and the Risk Reduction Actions are equal for both incidents and adverse events. Non-medical issues are the same for both types of events. Every event can be the result of miscommunication or distraction and can result in prolonged hospitalization or reputation damages.

This model should be used as the national taxonomy of patient safety on which all registration systems are based. Therefore the Masterclassificatie of the Orde should be extended to include these factors as well. They will provide physicians with improvement measures. Addressing communication deficiencies can prevent a multitude of events from occurring.

The focus on quality in the Netherlands is on the quality of medicine. Causes and impact of events are medical. Non-medical causes and impact receive less focus in registration systems. This is another argument in favor of adopting the ICPS model as the national structure to assess patient safety. The ICPS model incorporates non-medical causes; the contributory factors. Many different incidents can be caused by communication failures distraction, workload, etc. Yet in Dutch health care these factors are not acknowledged as contributing to an incident. Another important part of the Contributory Factors is the acceptance of different types of human error as possible cause of events.

The application of a nationwide patient safety taxonomy will also enhance the uniformity of registration. Currently the government only expects hospitals to record events, without structured guidelines as to what should be recorded and how the recorded data should be processed.

In the introduction of this study health care was depicted as a black box model. Unless guidelines are provided for registration systems health care will remain a black box. Every hospital will focus on different aspects. Where one hospital will develop an extensive registration system to capture all events, other hospitals might only focus on the ‘10 thema’s’ and the Prestatie Indicatoren of the IGZ. This difference in focus is not acknowledged in the Netherlands due to the non-existence of structural national guidelines.

18.3. National Registration System or National Guidelines

Another issue is that the Dutch health care system lacks a more structured approach to patient safety. Many initiatives are undertaken to improve quality and patient safety. As all health care parties participate in these initiatives, it can be concluded that there is an overall understanding about the insufficient level of patient safety. Yet in the current situation a
backbone is missing. All initiatives focus on aspects they deem improvement measures for quality. On some issues they overlap, on others they do not. If Dutch health care would adopt the ICPS model as a classification of patient safety, this could change. The model provides a structured decomposition of all aspects related to patient safety. It provides hospitals with insight into the potential causes of events and the impact they can have. At the same time it provides the sector with improved quality measures to assess the level of patient safety.

On a national level a more standardized registration and classification of incidents provides quality assessment tools. Quality – and thus patient safety – is more than the amount of events. The definition of patient safety by Marx states that patient safety is also “taking action to prevent errors from causing injury” (Marx, 2003). As discussed such actions should also be targeted at the latent factors in an organization as these can contribute to a multitude of events.

The Contributory Factors are non-medical. This means that they can be apparent in any business but also that they provide no insight into the quality of medical care provided. They do however have a huge impact on the general quality of care. Many of the factors apply to incidents and adverse events and to nursing staff and physicians. Insight into these factors therefore can be beneficial to the entire hospital. Secondly, as it is easy to electronically disconnect such factors from events, patients or staff, the system can provide insight into them without blame or loss of reputation. Since these factors are completely disconnected from the medical side of health care they cannot be retraced to specific events. This can be an important argument for more transparency.

Another advantage of standardized registration is the possibility for national data analysis. Currently it is not possible to perform trend analysis in the Netherlands. In the Netherlands limited information is available about the occurrence of incidents on a national scale. There are estimates, but since not every hospital records the same incidents in the same manner data cannot be combined nor compared. Some events have to be reported to national databases, but these initiatives almost always derive from a specific medical sector, and not from the government. The CMR (Centrale Medicatiefouten Registratie) is an initiative of the association of hospital pharmacists to gain insight into their own field of Expertise. Several registration systems incorporate aspects of the CMR in their medication incident registration. As it is, the CMR focuses on the medical side of medication incidents, and not so much on the contributory factors that were involved.

It is still possible for the Dutch government to create a common understanding of patient safety. Registration systems are not yet fully incorporated into organizations, but hospitals have had to invest heavily (Croonen, 2007). Therefore the creation of a national system should also entail a reimbursement of expenses made by hospitals for the development of their own registration systems.

18.4. Patient Safety Loop

The quality of care should not be directly derived from the number of events. Instead quality assessment should focus on the improvement measures taken and the increase in patient safety they have achieved.

It should be less of a focus how a hospital scored in 2006, the focus should be on how it scored compared to 2005. Neither the information provided by the IGZ to the public
Reviewing quality of care based on such a relative frequency has other benefits as well. Currently hospitals are reviewed and ranked based on the absolute number of events. This can lead to a situation in which hospitals that actively encourage reporting incidents are ranked lower, because they acknowledge the appearance of events. Hospitals with a closed culture apparently deliver a higher quality, only because they do not acknowledge the occurrence of events. This is not an incentive to improve the willingness to report. Using the relative frequency would remove this misconception, as hospitals are first compared to their previously achieved quality, thus decreasing the influence of willingness to report. The relative frequency does not incorporate subjective factors – such as culture or willingness to report – and provides a more accurate image of the quality of care in each health care facility. The national comparison is thus based on the personal improvement or decline in quality, instead of on the absolute difference between hospitals. An additional benefit of reviewing quality based on the relative frequency of events would be that the uncertainty created by the patient mix – unique per hospital – also has less of an influence on the equation. The patient mix will not differ that much per year in the same hospital, and therefore the relative frequency is not affected by it. In contrast, the current evaluations – based on actual amount of events – need to be adjusted for the patient mix.

Secondly, using the relative frequency can decrease the fear of openness. Parameters become more transparent as several uncertainties are removed from the evaluation; uncertainties like the willingness to report and the patient mix. Hospitals can become more transparent, because the number of reported events is not a deciding factor anymore. Reporting can truly be aimed at learning.

Ranking and evaluating hospitals based on the actual number of events can be seen as a way of assigning blame, seeing that more reports can equal lesser quality (in the current situation). This is not the intention and national evaluation tools should not propagate this view. Evaluating hospitals based on their effort to decrease the number of events combined with an assessment of their Risk Reduction Actions stimulates the internal openness. Only through openness can insight be gained, actions formulated and the number of events reduced. A ranking based on such insights provides a more accurate image of the current state of affairs.

To truly assess the quality of care provided in the Netherlands, the Dutch health care system has to acknowledge this more intricate relationship between events and quality. The current evaluation made by the IGZ does not take into account the possible change in the amount of events or the actions taken that resulted in this change. Those are important quality measures.

18.5. **Legal Status of Registration Data**

A final important issue with regard to patient safety in the Netherlands is the legal status of registration data; this issue has received much attention in Dutch health care (Molendijk, 2008, Meyst-Michels, 2007, Vesseur, 2007). As discussed previously the willingness to report must improve. The government can accelerate this change by making registration safer. In other countries – Denmark and Australia for instance – legislation has been created to protect registration data. The registration systems are aimed at learning how to perform better in the future. Their goal is not to assess blame. This difference has to be captured in regulations. Reporters
should not fear legal prosecution based on the information they provided for learning purposes (Dekker, 2007).

Unofficially data is protected; the IGZ states that they will not demand this information in case of an investigation (Legemaate, 2007). Yet if summoned by a judge registration data must be provided in the Netherlands. There is no legal protection of registration data. This will prevent health care professionals of trusting the blame free reporting system.

The Dutch government states that a cultural change towards transparency and reporting is more important than legal protection of data (Klink, Letters July 2007 and February 2008). Furthermore, it is argued that the patient ultimately is entitled to information. If physicians or hospitals do not comply with the requests for information of patients, judges must be able to provide patients with the asked documents, even if this means granting them insight into the registration systems (Rechtbank Zwolle, December 2007).

Legal protection of registration data does not entail malpractice cannot be assessed. If health care personnel are to blame for an event they can and should be prosecuted or questioned about this event. Yet for this investigation data needs to be derived from other sources than the registration system. The status of the registration system as blame free is vital for the willingness to report to improve. The other data gathering methods mentioned in the Problem Definition could be useful in such an investigation.
Chapter 19. Reflection

In this research several assumptions have been made with regard to theories, registration systems, and research methodology. In this reflection the accurateness of these assumptions will be discussed.

Secondly, after the completion of this research the Onderzoeksraad published a report that dealt with some of the same patient safety issues. This report will also be discussed in this section.

19.1. Organization Theory

Based on the research described in Part III & Part IV it is concluded that although HROT and more conventional organization theories provide insight into the structure of health care organizations, they are not capable of fully capturing the specific situation found in hospitals. The most important reason for this is that most theories assume an organization to have a certain hierarchical structure. A health care organization is governed by two equal and equally powerful parties; the board of directors and the Maatschappen. Both are dependent on one another to do their jobs and to achieve the desired level of quality. Yet there is no openness of information between the two. They might need each other but they both fear strategic behavior from the other party too.

Therefore it is recommended to perform further research into this relationship by the application of game theory – in particular the prisoner’s dilemma theorem. The most important reason for this suggestion is that these theories are equipped to deal with situations in which two equal powers have opposing goals, yet would both achieve more if they collaborated. What stops them from collaborating is fear of strategic behavior by the other party (Mueller, 2003).

Even though such theories will not provide direct organizational measures to create more openness, they do provide insight into the nature of the barriers preventing openness. Understanding these barriers can provide the tools needed to make HROT or other safety and organizational theories applicable to Dutch hospitals.

More importantly the application of game theory can provide insight into the consequences of strategic behavior in health care. The explication of these consequences might be an incentive for health care professionals and hospitals to address the reasons behind this fear of openness. Thus it can provide the tools needed to improve the willingness to report in Dutch health care.

19.2. The 7 Requirements for Registration Systems

In Part II a number of requirements for proper registration systems of medical events have been defined. Most of these were derived from the work of L.L. Leape. (WHO, 2005, Leape 2002)

Although the description of these requirements states that they concern registration systems, they deal more specifically with the institutional environment in which registration takes place. The system itself is not anonymous, yet the environment can guarantee anonymity of data.

The table presented below depicts the compliance of patient safety registration in the Netherlands with the requirements of Leape.
<table>
<thead>
<tr>
<th>Requirement</th>
<th>True?</th>
<th>Reasoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-punitive</td>
<td>No</td>
<td>Officially registration is to learn, yet registration data can be used by the IGZ and others to assign blame.</td>
</tr>
<tr>
<td>Confidential</td>
<td>No</td>
<td>Although it is stated that reporting is to find system failures, names of both patient and reporter must be filed. This provides the opportunity to review who created the report. This could harm the reporter.</td>
</tr>
<tr>
<td>Independent</td>
<td>No</td>
<td>No national guidelines exist about the providing of registration data to the IGZ, and through court patients can gain access to registration systems.</td>
</tr>
<tr>
<td>Expert Analysis</td>
<td>Yes</td>
<td>All registrations have to be reviewed by the superior of the department involved. This person knows the local situation. In case of severe incidents, a thorough investigation will be carried out by the <em>MIP-Commissie</em>.</td>
</tr>
<tr>
<td>Timely</td>
<td>Partial</td>
<td>For severe incidents deadlines for review have been created, for smaller events no guidelines exist.</td>
</tr>
<tr>
<td>Systems-oriented</td>
<td>No</td>
<td>The registration systems mostly focus on the event. The latent factors and contributory factors present are hardly addressed.</td>
</tr>
<tr>
<td>Responsive</td>
<td>Partial</td>
<td>Based on reports the <em>MIP-Commissie</em> does provide the board with recommendations. Yet what happens with these recommendations is dependent on many other factors.</td>
</tr>
<tr>
<td>Usability</td>
<td>Yes</td>
<td>Systems have been designed according to the preferences of staff. Mistakes in registration are still made, but these issues have been addressed in new versions. It is a focus point.</td>
</tr>
</tbody>
</table>

Table 9: Requirements for a Registration System, based on Leape, 2002

Based on this analysis it can be concluded that most aspects of the registration that are the domain of hospitals – timely, Expert analysis, usability, responsive – are addressed. Yet the institutional aspects that the government should take care of are lacking in the Netherlands. Issues referring to confidential handling of reports are not addressed. Reporters can face liability both internally and externally based on reported events. As long as this issue is not addressed, the level of reporting in the Netherlands will remain suboptimal.

### 19.3. Inadequate Reporting

Both health care professionals in the Netherlands and the WHO state that not every event is reported in the Netherlands. Still this research regarded the potential value of registration for patient safety, while addressing the constraints that partially can explain the inadequate reporting. In the Problem Definition several other data gathering methods have been mentioned. All of these are not as dependent on the willingness to report from personnel, but have not been taken into account.

Inadequate reporting undermines the added value of registration, but after this research this data gathering method is still regarded as the most important means for data gathering. Several reasons can be provided for this.

Firstly, incident specific characteristics should not be taken into account. To analyze data independently of the occurred incidents a large database is needed. Registration systems...
provide the best option to gather such quantities of data since everyone can file a report and reporting can be quick and easy. Secondly, registration systems provide the reporter with a structured way of data input. This not only creates objective information, it also makes it possible to categorize an incident in the same fashion, independent of reporter, department or even hospital.

The other data gathering methods can supplement the information acquired through registration. Interviews can provide insight into the context in which incidents took place. But the data acquired through interviews can be subjective due to the interviewer and interviewee. Secondly, it is difficult to extract the same data in the same fashion from subsequent interviews. Thirdly, interviews can more easily lead to blaming. WalkRounds can provide insight into the current practice but they do provide a limited image. The snapshot view acquired during such a round might not be representative of the complete state of affairs.

19.4. Research Methodology

Two important decisions have been made during this research with respect to the research methodology. Firstly, the research focuses on general aspects of patient safety and quality of care. Secondly, a systems approach has been used in this research. The consequences of both decisions will be discussed in this chapter.

19.4.1. Systems Approach versus Factor Analysis

Patient safety is most of all a culture of safety. A hospital culture is part hospital unique and part nationally determined. The culture is dependent on certain factors, but is created by the system. Although this research identifies many factors that determine patient safety no in-depth analysis of these factors has been performed. It has been established that human factors are causes of events, yet how many events they cause has not been determined. Instead the system that creates these factors – for instance the legal status of registration data that leads to a low willingness to report – has been evaluated.

The research has focused on the current situation of patient safety in the Netherlands. The parameters that create this situation have been identified together with the way in which they could be changed to improve the situation. This has been done without addressing how or to what extent parameters should be adjusted. This leads to less specific recommendations but the recommendations are applicable to all parties involved. Together they create the system and thus the environment in which patient safety has to constitute. Identifying factors often leads to concluding who should have addressed this factor, in other words assessing blame. The goal of this research has not been to determine who is responsible – or to blame – for the current state of patient safety in the Netherlands. The goal has been to provide an overview of the total system of patient safety. This will enable those involved to address patient safety more effectively. Therefore this research has not focused on the identification of specific factors. The following paragraphs explain this decision.

19.4.2. General versus Case Specific Research

Initially the research objective was aimed at the position of registration systems within one specific hospital, yet this objective has changed. The focus has shifted to a general assessment of patient safety in Dutch health care. Reasons for this have been that rules and regulations apply to all hospitals; this makes many issues already of a general nature. The same is true for many patient safety enhancing initiatives that have a national character.
More importantly, a focus on a specific case – a hospital – would have lead to the identification of a number of specific factors apparent in this facility. Patient safety is a national topic; every hospital has to address this issue. This also means that many of the factors found in one hospital could also be found in other hospitals, yet not all or exactly the same. The exact situation is unique per institute, thus a case specific research would not have aided patient safety in a Dutch context.

Secondly, since many of the rules, regulations and initiatives are of a national nature a case specific research could only identify these as steering variables, instead of determinant variables as has been done in this research.

Another important reason for a general research is that reputation is very important in Dutch health care. The goal of the research was not to damage or incriminate the position of a specific research hospital. In the current Dutch health care environment a case specific research could have caused problems for the case subject. Even though the aim would be to find out how to improve patient safety, the focus on blame and liability in the Netherlands could have led to the misuse of research outcomes.

19.4.3. Qualitative versus Quantitative Research

This research has focused on the acknowledgement of certain factors in Dutch health care and on the environment in which patient safety is positioned. This systems approach to patient safety has lead to a qualitative research. The impact of the environment and culture are hard to capture in quantitative measurements. The system has been examined, not the exact impact each identified issue has. A quantitative research would have resulted in the identification of the most important human factor, or the most prominent patient safety enhancing factor. Data to conduct such analyses is not yet available as patient safety is a relative new subject in Dutch health care.

Secondly, no national data on patient safety is available as registration is a local issue. The IGZ does require hospitals to provide Prestatie Indicators annually, but it has been discussed that these measures only focus on the number of events, thus providing little insight into the actual level of patient safety.

Assessing patient safety determinants within a single hospital would be equally difficult. Not only are registration systems not yet used to their full potential – not every event is reported – also Maatschappen do not provide insight into their registration data. This has hampered the quantitative assessment of statements made and would have led to conclusions based on incomplete information of which the quality is hard to assess.

19.4.4. Usability of Research Methodology

This research has not specifically focused on individual factors but on the system in which patient safety must constitute. Secondly, the focus has remained on this general level, not regarding the specific situation in a single hospital. Therefore all conclusions and recommendations are applicable to any hospital, possibly any health care organization.

Thus the research methodology has remained on a (very) high aggregation level. Since the methodology is not dependent on either an institution or a research subject it can be used for other researches as well. In essence the chosen research methodology constitutes a definition of the research subject and an assessment of the context or environment in which the research subject has to function. The same methodology can thus be applied to other health care issues and to safety issues in other industries.
19.5. Onderzoeksraad voor de Veiligheid

After the completion of the research described in this report the Onderzoeksraad voor de Veiligheid (OVV) published a report addressing some of the same topics. In 2005 the cardiology department of the UMC St. Radboud was closed down due to the number of (preventable) deaths. The OVV has investigated the situation in this department of the hospital and how the safety of patients could be jeopardized as such. The researches have been carried out completely separate of each other. Yet both deal (to a certain degree) with the same subjects. Therefore a reflection has been added to this study discussing the differences and similarities between both studies.

One of the main conclusions in this report has been that the first question relating to patient safety – what is patient safety? – has not been addressed in the Netherlands. The main research question of the OVV deals with patient safety, but the report does not address what patient safety is. Many issues are mentioned but all recommendations and conclusions are aimed at patient safety reducing factors and how to improve, without comments about the relation between these different factors.

Both researches acknowledge the importance of contributory factors. The OVV states that: "De kwaliteit van het resultaat van het zorgproces is in hoge mate afhankelijk van meerdere medische professionals met verschillende Expertises. De kwaliteit van samenwerken tussen mensen, informatie-uitwisseling, communicatie, initiatief en leiderschap, en ondersteunend teamgedrag zijn dan ook wezenlijke onderdelen van het zorgproces" (Onderzoeksraad, 2008, p69). These issues are not mentioned in the conclusions or recommendations. Recommendations for medical professionals do include that physicians should be better equipped with safety improvement notions, but no recommendations about active acknowledgement of contributory factors as safety improvement measures are made.

The report of the OVV is critical about the Prestatie Indicatoren of the IGZ. It is stated that these outcome measures are in an early phase of development and only provide the IGZ with retrospective insight into the quality of care. Also the response of the IGZ with regard to severe events – based on the information provided by the hospitals the IGZ decides whether further investigation is needed – constitutes a retrospective attitude towards quality of care. These conclusions are in line with the statements made in this research.

A difference between the two researches is the scope of the research. The OVV has investigated the situation in a single department of a single hospital, whereas this research has not focused on the situation in a particular hospital. Although often the same issues are addressed this difference in scope is apparent. The OVV report contains harsher statements than does the more general research done in this report. The OVV report e.g. states that: "De afdelingen hoefden geen verantwoording af te leggen over de beheersing van risico’s voor patiëntzorg. De raad van bestuur veronderstelde een kwaliteitsbesef bij de medische staf, en nam aan dat professionals (medici) zelf zorg droegen voor kwaliteit en hun werk zelf deskundig inrichten." (Onderzoeksraad, 2008, P76)
"Medici waren niet gemotiveerd voor en voelden zich niet aangesproken door de NIAZaccreditatie en andere kwaliteitsborgingssystemen, zoals de MIP-meldingen.” (idem, p80)
These statements are specifically targeted at a single hospital. They indicate that there was little understanding of creating a safety culture in the organization. The physicians in the UMC St. Radboud did not intend to create an unsafe environment, yet they did. This situation – or parts of it – can be apparent in other hospitals as well, but due to the very
clear statements made about affairs in a specific department of a specific hospital it remains to be seen whether other health care professionals feel addressed by these statements.

The comparison of these two researches thus leads to the acknowledgment of two main differences of opinion. This research starts with the question ‘what is patient safety?’. The OVV research does not acknowledge this question and focuses on patient safety improvement measures. In doing so the OVV research places most responsibility with the hospital and the medical personnel. This research places more responsibility with the government, who should create an environment in which safe care can be provided.
Chapter 20. Further Research

This research has discussed a vast array of issues related to patient safety. Many of these deserve further research before they can be implemented in the Netherlands. In this chapter several interesting subjects for further research will be highlighted.

20.1. Practical Further Research Topics

In the Recommendations several practical further research topics have been mentioned. These topics logically follow upon the issues discussed in this research. They either constitute a more thorough insight into the issues mentioned or they constitute a practical completion of topics. This includes:

- The creation or acceptance of a patient safety taxonomy
- The legal protection of registration data
- The development of feasible patient safety indicators that acknowledge the Patient Safety Loop
- The improvement of the willingness to report
- The acceptance of non-medical causes by medical personnel

However not every subject that would be of interest to the debate on patient safety in the Netherlands has been thoroughly discussed in this report. In this chapter several research topics are described that have not been investigated but that do provide additional insights.

20.2. Quantitative Research

Many qualitative statements and conclusions have been made in this research. These need to be proven using quantitative research methods. At this time this is not possible however, due to the unavailability and quality of registration data. First, a national standard for data needs to be developed. This will enable the national analysis of patient safety data, instead of localized analyses. Secondly, the data needs to improve and more data needs to be gathered. Once a critical mass of data is available the statements made should be checked to see whether the data supports the assumptions made.

20.3. Patient Safety in the Netherlands

Patient safety is a local topic in the Netherlands. Every hospital is responsible for their own level of quality and thus patient safety. The IGZ only makes sure that care is not delivered below certain quality standards.

In the future this could lead to a larger differentiation between hospitals in the Netherlands. Some hospitals will make patient safety an important topic, leading to a very high standard of safety. Other hospitals might not find this such an important topic and might focus on other aspects of care, leading to a less high standard of safety. They could for instance focus more on speed of care delivery or costs of provided care. In a free market system every hospital has the opportunity to make such decisions, given they stay between nationally defined boundaries (minimum level of patient safety, maximum cost of care, etc.).

It would be interesting to see how this system – and the level of patient safety – evolves over the next 5 to 10 years. Further research should be conducted to answer the following question:
Is there a significant difference in level of patient safety between different hospitals in the Netherlands and if so, what are the factors responsible for this difference?

20.4. Patient safety Registration in an International Context

Every country takes a different position with regard to patient safety registration systems. As can be seen in Appendix 9 Australia and Denmark have a national registration system. Great Britain has a national registration system, but reports are made in local systems, but all these local systems are designed according to the same national standards. In the Netherlands hospitals are responsible for their own patient safety registration systems. These local systems make the distance between event and event resolution as small as possible. Local managers can immediately deal with unsafe situations. Further research should be conducted to assess the impact these different attitudes towards patient safety have on the level of patient safety. In 5 to 10 years it can be evaluated whether localized insight or national insight provides the best improvement measures. Such research should answer the following question:

Is there a significant difference in the level of patient safety between countries with different attitudes towards registration systems?

Chapter 21. Personal Reflection

Not all insights gained during this research have a relation to patient safety; I have also gained insights into my own way of working and thinking. Firstly, my graduation project would have been a lot easier had I chosen an industry and a subject of which I already had prior knowledge. At the start of this project I knew nothing about the medical world, other than from my own experience as a patient and from watching soap operas. Neither was I familiar with the safety theories I have decided to use. This has led to a steep learning curve as no prior knowledge was available. I had not expected this, but the medical world is very different from the industries I have encountered in my studies. In fact I still know very little about management and workings of the medical world.

Secondly, it remains challenging to not regard issues from a technical, analytical perspective. Medicine is not organized or structured according to such insights, yet these are the kind of insights I am (due to my study) much more comfortable with. In my research this became evident in the creation of the parts dealing with HROT and Human Error. I find it much easier to write and research a topic such as HROT – which has been created by researchers with a technical, analytical perspective – than the topics mentioned with respect to Human Error. I understand and respect the importance of all these topics, yet their meaning only becomes truly comprehensible to me once they are put into a patient safety taxonomy. Hence, I found it aggravating that there is nothing resembling a structured view on patient safety – such as a taxonomy – in the Netherlands.

Thirdly, my research process would have been easier had I been able to center my thought upon clear structures and goals. Not only was this impossible due to my ignorance with regard to the research matter, I also would have found such a research process much less interesting and challenging. I quite like the fact that even I was surprised by the final conclusions derived in this research. They were not the conclusions I had imagined to reach. Again in part this can be explained by the insufficient and very basic knowledge of the research field. Only after the kick-off meeting was I able to formulate the most important
“why” questions. In my initial research proposal no mention was made of patient safety taxonomies or the institutional environment created by the government. Yet these evolved into the major issues in this report. Even if it would have been easier to have a more structured approach, I do not see this as a problem. Had I performed a research of which the conclusions were obvious from the start I would not have been as motivated as I was for this research. Secondly, such a research would not have complied with the personal research goals I had formulated for my final research project.

I know my research is extensive, many will even say too broad. Yet I still feel all mentioned issues are needed to answer the research question. I think many students and researchers use demarcations too easily. There is a fine line between creating a workable research space and creating an unrealistic perfect world. My research initially focused solely on the registration systems and their similarities. This focus soon evolved into the added value of registration for patient safety. Had I stopped there this research would not have had any practical usability as registration does not commence in a perfect environment. This environment poses some very real restrictions to the research subject. Not acknowledging these restrictions would severely limit the usability of my conclusions. My first requirement for my graduation project was that I wanted to address a real problem. The results needed to matter. This however does mean that the environment of the research subject needs to be taken into account; which has lead to the current size of my research (paper).
Appendix

Appendix 1. References

Amalberti, R., Auroy, Y., Berwick, D., Barach, P., 2005, ‘Five system barriers to achieving ultrasafe health care, Improving Patient Care’, Annual of Internal Medicine, 142: 756-764
Boer, AS, Wille JC, 2003, Complicatierегистraties, Ordenieuws, Nr. 5, pp. 10-11
Bogner, MS, 1994, Human error in Medicine, Lawrence Erlbaum Associates, Hillsdale
Bos, WJ, Borghuis, Th, 2006, Concept Jaarplan 2007 Zorggeenheid Geneeskunde, St. Antonius Ziekenhuis, Nieuwegein
Bosch, W van den, 2006, Beschrijvingen van Patientenzorgprocessen ter ondersteuning van procesverbeteringen, St. Antonius Ziekenhuis, Concept verseii 1.5, januari 2006, Nieuwegein/Utrecht
Chang, A, Schuve, PM, Croteau, RJ, O'Leary, DS, Leob, JM, 2005, ‘The JCAHO patient safety event taxonomy: a standardized terminology and classification
schema for near misses and adverse events', *International Journal for Quality in Health Care*, Vol. 17, nr2, pp.95-105


DPSD, National Board of Health, 2007, *Danish Patient Safety Database*, [www.dpsd.dk](http://www.dpsd.dk)


Klein, D, Motwani, J, Cole, B, 1998, ‘Quality improvement efforts at St Mary’s
Appendix

Hospital: a case study, Managing Service Quality, Vol. 8, No. 4, pp. 235-240

Klink, A, Bussemakers, J (2007), Koers op Kwaliteit, Bijlage 1, Programma veilige zorg deel 1, kenmerk: MC-U-2775877, 6 juli 2007, Ministerie van Volksgezondheid, Welzijn en Sport
Klink, A, Bussemakers, J (2007), Koers op Kwaliteit, kenmerk: MC-U-2775877, 6 juli 2007, Ministerie van Volksgezondheid, Welzijn en Sport
Klink, A, Bussemakers, J (2007), Overzicht en tijdpad patientveiligheid, kenmerk: CZ-TSZ-2768961, Ministerie van Volksgezondheid, Welzijn en Sport

Legemaate, J, 2006, ‘Een open cultuur en goede feedback’, Medisch Contact, Vol. 61, Nr. 43, pp. 1728-1731


Ministerie van Volksgezondheid, Welzijn en Sport, (1996), De Wet BIG, Ministerie van Volksgezondheid, Welzijn en Sport, www.minvws.nl
Schaaf, TW van der, Lucas, DA, Hale, AR (1991), Near Miss Reporting as a Safety Tool, Butterworth-Heineman Ltd, Oxford
Sneller Beter, 2007, Sneller Beter werkt! Een veiliger ziekenhuis voor de patiënt, Den Haag
St. Antonius Ziekenhuis, 2006, Beleidskader 2007, Utrecht/Nieuwegein
St. Antonius Ziekenhuis, 2007, Beleidskader 2008, Utrecht/Nieuwegein
St. Antonius Ziekenhuis, 2007, Jaardocument 2006 St. Antonius Ziekenhuis, Nieuwegein
St. Antonius Ziekenhuis, samenstelling: W. van den Bosch, Discussienota: Patiënnevrijheid; Beleid, organisatie, Actie, “Mensen maken fouten, en leren ervan!”, Maart 2007, Versie 1.7
Weick K, Sutcliffe KM (2001), Managing the unexpected: Assuring high performance in an age of complexity, Jossey-Bass, San Francisco
Willems, R, (2004), Sneller Beter – De veiligheid in de zorg, Hier werk je veilig, of je werkt hier niet, Eindrapportage Shell in opdracht van het Ministerie van VWS, November 2004


Appendix 2. Patient Un-Safety Models

In Chapter 2 several patient safety taxonomies have been described. This appendix will provide a more extensive description and discussion of these models.

2.1. ACM Model

The ACM Model predominantly focuses on the causes of events.

2.1.1. Cause

In the ACM model causes originate on three ‘levels’. Each level builds and exists within the lower level. The basis of each incident lies in the organizational culture (Vincent, 1998). The availability of protocols for instance can be a source of error. These organizational characteristics are called latent factors, because they can be present in an organization for years before leading to an actual event.

The second layer comprises the contributory factors. These factors are neither latent failures, nor active failures. Within the broad spectrum of the organizational culture, they are factors that influence good practice. So they set the conditions under which errors can take place. For instance, in a malfunctioning team the chance of an error is much higher than in a team where advice and feedback can be asked. These contributory factors then produce a playing field for active errors. Errors are not defined based on the type of incident or their impact; they are classified based on the character of the error; it can be an unsafe act, a violation, or an (unintended) error.

The organization can be a teaching hospital; this is a latent factor of the hospital (not necessarily a failure). The effect of this is that not every member of the team has the same level of knowledge or Expertise. This factor could be the cause of certain mistakes, mistakes that a trained professional would not make, but a novice would. When the cause of an event is the lack of experience in a novice, this inexperience is embedded in the latent factor – teaching hospital. Even though the error was not committed actively – the novice did not mean to make a mistake – the latent factors within the hospital combined with certain contributory factors created an (temporary) environment in which the error could be committed. Acknowledging this decomposition provides more insight into the preventable causes of events.

This decomposition acknowledges, among other contributory factors, that medicine is a field where tacit knowledge is very important. The fact that a novice does not possess this tacit knowledge is not an excuse for an event, but it is an important factor in describing the occurrence of the event. It is even more important in identifying prevention measures to minimize the possibility of such incidents reoccurring.

23 See Appendix 4 for more on latent and active failures
2.1.2. **Causal Relation**

There is a causal relation from left to right (Vincent, 1998). Reasoning backwards from the event the first cause identified will be the error made by the care giver. Looking further the investigator might find contributory factors that produced a situation in which it was possible for this care giver to make the mistake. Reasoning even further back to reveal latent factors present in the organizational structure is the most difficult part. Uncovering these factors will require very adequate data analysis. These factors are not always visible to personnel; they are used to them, so they will not list them as influencing factors.

2.1.3. **Defences**

Another important aspect of the ACM model is the explicit depiction of system defences. Not every error committed leads to an incident or adverse event. Many mistakes are prevented from causing real harm. This can be attributed to the barriers that are in place throughout the organization.

Barriers can range from a nurse spotting the mix up of medicines before distribution, to a patient calling attention to unfamiliar medicine, to a team in the operating theater working together so seamlessly that an error committed by one of them is simultaneously fixed by the others without them even noticing.

Any such barrier prevents an error from escalating into an event. The error becomes a so-called ‘near miss’. Near misses and events have the same causes; the only difference is that a near miss was prevented in time. This makes near misses equally important for identifying causes (Reason, 2000); especially with respect to contributory factors and latent factors.

2.2. **PSET Model**

The PSET Model depicts the entire patient safety cycle.

2.2.1. **Impact**

In the PSET model impact is not broken down into medical impacts, like extra treatment, prolonged stay. Instead a classification based on severity of impact is made. This makes it possible to classify incidents based on the severity of their impact.
2.2.2. Type

The PSET model does not define the event as such. In the Type block not the event itself is described but the “clinical or management processes that are associated with events without any judgments about root causes within those processes” (Chang, 2005). Failures in communication, failures involving handling of the patient and failures in clinical performance are defined – in broad terms. Failures in clinical performance can for instance be defined as ‘pre-intervention – inaccurate diagnosis’ (Chang, 2005). This does not provide insight into the actual event that has taken place. The demarcation of clinical performance aims to create a ranking, not providing insight into how the event could occur. It provides a good structure for classifying purposes, but it does not provide the insights needed to better future performance.

A problem with using this classification within a hospital or nation is determining the ranking. Can the reporter of an event correctly assess the appearance of (in)correct diagnoses or interventions? In order to identify the real causes of an event, the report should be as objective as possible. The proposed demarcation does not adhere to this goal of “correct” reporting. The proposed breakdown leaves much room for personal interpretation of the processes leading to the event.

Patient management and communication both describe performed or neglected processes that have led to the event. They do not represent the event; they represent the processes leading up to the event. This means that the event itself does not feature anywhere in the PSET model. Only impact and causes are explicated.

2.2.3. Cause

The division of causes contains roughly the same factors as does the ACM model, but they are grouped differently. The PSET model makes a distinction between system failures (organizational and technical) and human failure. Where the ACM model positions factors in a sequential way, the PSET model positions them all on an equal level. This suggests that all happen simultaneously. Furthermore the treelike structure - in line with the root cause analysis basis of the PSET model – suggests that any event only has a very limited number of causes. Both models do recognize the importance of near misses. In the PSET model they are explicitly featured; human error constitutes of “Actual & Near Misses” (Chang, 2005).

Human failure is divided into three categories. Failures committed by practitioners are classified in the same way as does the ACM model. Another part of human failures are patient factors, including patient characteristics and patient actions.

The other type of causes deals with system failures. These constitute both organizational causes (called latent factors in the ACM model) and technical failures. Technical failures are a very diverse category. The design of equipment, its use, and its availability can be causes of an event.

2.2.4. Domain

The goal of the Domain block is to describe the environment in which the event took place. The domain classification is more detailed than many other parts of the PSET model. The
model is designed to provide insight on a national level. Therefore most parts have a high aggregation level, higher than usually found in a single hospital. The classification of staff – 22 different types of staff can be identified – or the ‘target of patient admittance in the hospital’ are very detailed.

This does not provide immediate insight into the causes leading up to the event. It does depict the situation in which the event took place. This can provide useful information when reviewing the overall performance of a division or the hospital as a whole. It does not provide insight into the actual team situation at the time of the event; it only depict who were present, at what time the event took place, and to which patient.

Target aims to describe why the patient was admitted to the hospital. This information can be found in the patient files. Patient specific facts that play a part in the occurred event are depicted in the patient specific part of the Causes. This information is not part of the hospital environment.

2.2.5. Prevention and Mitigation

There are two important notions for prevention and mitigation measures. Firstly, prevention should not be targeted too specifically at the occurred event. No two events are alike; therefore measures should be robust enough to tackle the causes of various similar events (Reason, 2000). Prevention has to be targeted at all incidents, including incidents imbedded much deeper in the organization, instead of being restricted to the most obvious causes, like human errors (Reason, 2000; Carroll, 2002; Leape, 2002). Secondly, before prevention and mitigation can commence a critical mass of event data needs to be available (Stock, 2007). Only then useful measures can be taken. The major threat to prevention measures is that every event gives rise to another measure (Carroll, 2002), in due time this will have an adverse effect. The sheer number of measures will then make working efficiently impossible and furthermore too many measures make it more difficult to determine latent causes (Perrow, 1984).

Therefore it is vital to recognize that prevention measures can be very diverse. It cannot be estimated which prevention measures will be needed in a specific organization, as the events have not occurred yet, or have not been recognized as such.

The PSET model groups prevention and mitigation measures into one category. The model has pre-defined prevention methods. They are in part based on the National Patient Safety Goals as created by the JCAHO (Chang, 2005). By specifying prevention methods, the model implies that the causes are already known. General issues can already be identified (by medical personnel). These general issues can be determined on pragmatic grounds and can be implemented alongside further investigation into the occurrence of different events.

2.3. ICPS Model

The ICPS has been created by the Drafting Group for the World Health Organization, World Alliance for Patient Safety, Project to Develop an International Patient Safety Event Classification (WHO, 2006), hereafter referred to as the Drafting Group. In this Drafting Group many internationally recognized Experts on patient safety take seating.

2.3.1. Incident Type

Events can be categorized into fifteen different Incident Types. This typology was not present in either ACM or PSET model. Incidents can be classified as:

- Medication
- Documentation
The ICPS includes two specific Incident Types relating to Patients. The first is Patient Behavior. This class is explicated into Behavior – obstructive, prejudice, wandering, etc – and Aggression/Assault – verbal aggression, physical assault, etc. The second is Patient Accidents. This class is explicated into several specific categories, ranging from blunt force created by crushing or contact with another person, to scratching, to exposure to excessive heat, and exposure to chemicals.

An important notion is that the Incident Types are non-exclusive. This means that an incident can be part of several categories (WHO, 2007).

### 2.3.2. Patient and Incident Characteristics

Both Patient and Incident Characteristics mostly serve to describe part of the environment in which incidents occur. There are a lot of similarities between this decomposition and the Domain part of the PSET model. The patient is categorized according to Demographics, Procedure and Primary Diagnosis.

The Incident is categorized based on Care Settings, Disciplines Involved, Person Reporting, and Time and Date of Incident.
2.3.3. Contributory Factors/Hazards

This part of the ICPS seems heavily based on the ACM, AIMS and PRISMA model. These models are constructed using the theoretical notions of Rasmussen and Reason24. This class represents several aspects of incidents. As explained in the ACM model these factors create a situation in which incidents can happen. The ICPS model does not provide opportunity for the depiction of relations between certain contributory factors. The classification of contributory factors is quite extensive. The model explicitly lists factors such as Distraction or Fatigue, factors that research has shown are present in many events (Rhodes, 2003; Helmreich, 2000). An addition to the ACM model is the inclusion of Emotional and Social Factors relating to the staff. Another addition to the Contributory Factors is the Remote/Long Distance from Service. A factor that is not explicitly listed in the list of Contributory Factors or in any other incident factor is the malfunctioning of equipment. The factors after an incident do list the possibility of equipment failure, but it cannot be ticked as one of the factors leading up to an event.

2.3.4. Detection and Mitigation

Detection measures are alike to the barriers in the ACM model, although the definition is slightly different. In the ACM model barriers stopped the error from developing into an incident, after the error had been committed. The same goes for Detection in the ICPS. Through detection the initial error can be prevented before it harms a patient. Detection is defined at the process by which an incident is discovered combined with the person who discovered it. After an event is detected Mitigation Factors prevent it from causing more harm. A Mitigating Factor is “an action or circumstance which prevents or moderates the progression of an incident towards harming the patient” (WHO, 2007). Mitigation Factors already point to certain solutions. The mitigation factors directed at staff and organization list factors such as Good Team Work, Good Supervision, Effective Protocol Available, and Documentation Error Corrected. Another noteworthy mitigation factor is the explicit inclusion of Apologizing to the patient after an error. Research suggests that care givers find it hard to admit they made a mistake. Even though most patients would not press charges on their physicians if apologies were made and lessons learned to prevent the error from happening again to another patient (Willems, 2004).

24 More on these theories can be found in Appendix 4.
2.3.5. Patient Outcomes

Patient Outcomes mostly serve categorization purposes in the ICPS. Precise information about the effect of an error on the patient is vital for patient recovery and therefore should be documented in the patient files. Patient Outcomes is defined into Type of Harm and into Degree of Harm. The degree of harm is represented on a five point scale: None – Mild – Moderate – Severe – Death

2.3.6. Organizational Outcomes

Errors do not only have an effect on the patient involved. Errors also have an effect on the hospital. Not only do errors generate extra costs (patients have to stay longer, which insurance companies do not compensate for), even more importantly they have a negative effect on the reputation of the hospital. And health care is an industry where reputation is very important. The effects events can have on the organization are classified in both Increase in Required Resource Allocation for Patient, meaning an increased length of stay, additional treatments, or additional staff required. Other effects include Media Attention, Damaged Reputation and Formal Complaints.

2.3.7. Ameliorating Actions and Actions to Reduce Risk

After an error the consequences – the outcomes – are established. The different ways of dealing with these outcomes are positioned in the Ameliorating Actions. These actions all serve to minimize the (long term) effects of an error. This includes taking care of the patient and possible injury inflicted upon him, as well as taking care of the organization. This class ranges from taking care of the media, to staff counseling, to complaint management.

After an event one of the important questions is whether the event could have been prevented and if yes, how? “Actions taken to reduce risk are defined as actions taken to reduce, manage or control the harm, or probability of harm, associated with an incident. An action can relate directly to incidents and contributing factors, detection, mitigating factors or ameliorating actions and can be pro-active or reactive” (WHO, 2007). The actions focus on learning from what happened and can be targeted at care, the organization, or staff.

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25 This has all been discussed in Part III & Part IV
Appendix 3.  Multi Criteria Analysis – Criteria

The criteria for the MCA have been derived from the following sources:

A. Chapter 2.4.2. In order to compare data, data must be assessed consistently. This means that data must be assessed based on objective criteria, not subjective evaluations.
B. Chapter 1. To provide insight into the use of data the entire patient safety cycle should be gathered. Only gathering data does not improve patient safety.
C. Appendix 4. Possible causes of events include organizational factors or personal factors. Therefore these should be included in the model.
D. Appendix 4. Active failures are committed in the situation created by the latent factors of the system.
E. Appendix 4. Patient safety is a local topic in the Netherlands. Hospital staff also want insight into the specific incidents in relation to the causes. The number of falling accidents is important to staff to assign priority to certain incidents or causes.
F. Chapter 13 and Appendix 4. Events do not just happen due to human error. The system in which staff works creates the opportunities for making an error.
G. Chapter 10 and Chapter 6. Reporters must feel safe to report. No personal blame should be assigned. Registration is aimed at learning, not at assessing blame.
H. Appendix 4. In the Netherlands a difference is made between incidents and adverse events. The specific events might be different, their non-medical causes and impacts can be the same. Therefore the same taxonomy is applicable.
I. Appendix 4. Near misses originate in the same causes as do other events, the only difference is that they do not evolve into an event and thus have no direct consequences. They do, however, provide the same lessons.
J. Chapter 11. Sometimes events happen even though the care provided was excellent. Such events do have consequences and thus can provide insight.
K. Just knowing that the event occurred and its general outcomes does not aid patient safety. In order to improve the current situation staff needs more detailed insight into the causes and outcomes. Therefore taxonomies should also provide the insight needed at a decentralized level.
Appendix 4. Human Error

Health care is a very complex and dynamic industry. It will never be error free. Several factors can be distinguished that contribute to this situation. First, health care is a people business. The majority of work is and will be carried out by humans. Humans are not infallible; they can try to be so to a certain extent, but everyone makes errors now and then. The key for a hospital therefore is to minimize the effect of errors made by personnel. Secondly, health care has to deal with a great number of uncertainties in their day to day operation (Amalberti, 2005). The biggest uncertainty found in health care is the product: the patient. Every patient is unique. Allergies cannot be predicted, therefore medical personnel always has to be on the lookout for possible unexpected complications. Several of the different types of errors as can be found in the ICPS model are not explicitly acknowledged in Dutch Health Care. This chapter provides insight into the meaning of different error types and provides arguments why they should be acknowledged.

4.1. Human Error in Medicine

"Hospitals need to rethink the manner in which they deal with human mistakes. Hundreds of mistakes occur every day in a major hospital. Too often in the past emphasis has been placed on identifying who made the error rather than on why the error occurred and how it can be prevented in the future."

(Leape, Chapter 2, in Bogner, 1994, p. 23)

A hospital is a decentralized environment. This has its consequences for the way errors are dealt with. Many errors occurring in a hospital are human errors. Dealing with an error is not the same as making sure this person does not make the error again; especially not in a decentralized organization as a hospital is. Blaming one person for an error might prevent him from making it again, but it does not prevent the next person from committing exactly the same error (Van Cott, Chapter 4, in Bogner, 1994). That is one of the reasons why it is vital – especially in an environment such as a hospital – to search for root causes; those causes or factors that created a situation in which someone could commit a certain error. Another reason for this is that not every event that happens is the result of an error; many events are simply undesirable outcomes, in which the person involved did do nothing wrong (Moray, Chapter 5, in Bogner, 1994).

Factors can either be extrinsic or intrinsic (Van Cott, Chapter 4, in Bogner, 1994). Extrinsic factors create an environment for error and include factors such as legal and regulatory rules, social factors, or even equipment design. These factors facilitate the intrinsic factors (carelessness, inattention) that in the end lead to the error. In most situations it is more beneficial to target the extrinsic factors as this will present beneficial results throughout the organization (Van Cott, Chapter 4, in Bogner, 1994). If staff tends to register incidents in the wrong sheet of the registration system, it might be easier and more profitable to change the registration system than to change the behavior of the entire staff. This is one of the key points of human factors engineering.

4.2. Active versus Latent Error

"Latent errors or system failures pose the greatest threat to safety in a complex system because they lead to operator errors. They are failures built into the system and are present long before the active error. Latent errors are difficult for the people working in the system to see since they mainly are hidden in
computers or layers of management and people become accustomed to working around the problem.”

(WHO, 2005)

An active failure is an “unsafe act committed by the sharp end of the system: humans” (Reason, 2000). These active failures happen at the human-system interface and the results of the failure are usually quickly apparent.

Latent conditions on the other hand are much harder to assess as they can be present in an organization for years before all the odds line up so they can manifest themselves. “They arise from strategic and other top-level decisions made by governments, regulators, and organizational managers” (Reason, 2000). They can be the same as the extrinsic factors described before, and they cannot be prevented. They are an “inevitable part of organizational life” (Reason, 2000). Latent factors often result in defensive weaknesses, for instance the malfunctioning of an alarm.

In the ICPS model all these factors are presented as being equal. Therefore in Figure 21 the differentiation made in the ACM model is depicted again. This model clearly shows the causal relation between latent factors and active failures. Within the domain of the latent factors, opportunity is created for the active error to manifest itself or be committed.

When latent factors line up with active failures and local triggers they create an opportunity for accidents (Reason, 2000). This has often been depicted as a piece of Swiss cheese (Willems, 2004). Within each system an abundance of barriers has been erected to prevent a near miss from developing into an incident. These barriers exist throughout the organization. Latent factors can create holes into barriers though, as do active failures. When all these ‘holes’ line up an event can occur.

After an event the active failures can be relatively accurately be assessed. Finding the latent conditions is much more difficult. That is the reason why the existence of such conditions is highlighted in this research. Only by identifying and dealing with these underlying conditions can the entire system be made safer, thus creating a safer hospital.

### 4.3. Level of Human Error

Most research into human error regards errors on a high aggregation level. A useful distinction has been made by Reason (Reason, 2000). He states that human errors can stem from two sources. Either “the plan is adequate, but the actions fail to go as planned”, or “the actions may conform exactly to the plan, but the plan is inadequate to achieve its intended outcome” (Reason, 2000). Which type of error is committed largely depends on whether exceptional situations are expected to occur during the performance of a task and whether a solution to a situation can be found. If the situation itself is ill-understood, chances are that the person involved makes a wrong assessment of the situation.

**Skill based error** (Reason, 1990) are errors most likely to occur during routine tasks. This can stem from “overattention” (Rason, 1990) or “inattention”.

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**Figure 21: Causes in ACM Model**
The other extreme is inattention in which a task is performed without any conscious attention; it has been done so many times before that habit takes over. This can be very dangerous in such a complex environment as a hospital where every patient is unique. Automatic performance should not be trusted as every situation can and will be different from the last.

Several causes for skill based errors have been identified. The most common is the above mentioned habit where someone fails to make the appropriated checks or accepts rough input and thus relies on “the actions most usually performed in such a case” (Reason, 1990). A medical example of this behavior would be the prescription of medicine by a physician (to a nurse) over the phone.

Other common causes are disruptions. If someone is interrupted during the execution of a task chances are that they either forget the task they were doing or mix up the old and new tasks. An example would be interrupting a nurse busy with medication preparation. This happens frequently in hospitals and it can result in forgetting a patient’s medication. Or if a new prescription is added to the workload the nurse might mix up the doses or patient labels or both.

Skill based errors are frequently referred to as “slips and lapses” (Reason, 2000, Carroll, 2002). These kinds of errors are to be avoided as they do not have to occur. By training and gaining experience people can be better prepared to handle unpredictable cases (Carroll, 2002) and move up the performance ladder.

Rule based errors (Reason, 1990) also stem from routine but with the difference that automatic performance does not take over. After having encountered a certain situation several times a person develops an understanding for the matter. Rules and protocols are learned, tacit knowledge is gained, and training has perfected the understanding of the situation; yet the person stays alert to signs that the situation could be different from expected. Based on signals certain rules come to mind and people act accordingly. The risk in such a situation is that the more closely a rule resembles a situation, the more likely a person is to apply it; this is called similarity matching (Moray, Chapter 5, in Bogner, 1994). And the more often a certain rule is applied, the more likely it will be used again in the next (slightly) similar situation. Even if this application is wrong because the situation is in fact not similar. Thus errors become skill based errors.

Knowledge based errors (Reason, 1990) happen if no pre-defined solution for an encountered situation is available. This implies that the chosen solution can be right or wrong. Solving a problem on the knowledge based level is therefore much more time consuming and laborious. A medical example of such error can be found in new interns. They do not have any tacit knowledge yet, and might not know all protocols. Therefore they have to think about every situation they encounter. In due time, they will develop more insight, but there is a heightened chance of error when they begin.

4.4. Active Failure

"People are the nodes that link the components of health care; they are critical to its reliability and safety. Unlike other systems in which technology is the center of the system and humans serve as equipment monitors and supervisors, the health care system is people centered and people driven."

(Van Cott, Chapter 4, in Bogner, 1994, p. 56)

Throughout this report it is stated that health care is a very complex industry. Cook and Woods identify another characteristic of this complex system. The percentage of critical
incidents that are caused by human error is about 70% to 75% (Cook and Woods, Chapter 13, in Bogner, 1994). Most active failures include some form of human error. As stated before this does not imply that the person in question can be blamed for the error. Often the person could not have acted otherwise given the contributory factors present in the system.

This study uses the Dutch definitions (Wagner, 2005) as much as possible, because the research focuses on patient safety in the Netherlands. A difference is made though with regard to adverse events. Outcomes of the process of care are internationally referred to as ‘adverse events’. In the Netherlands the English term ‘calculated risk’ is proposed for such events (Wagner, 2005). Instead Wagner proposes to use the term ‘adverse event’ to refer to vermijdbare complicaties (Everdingen, et al 2006). This new use of terminology can cause unnecessary confusion, especially as this study had made extensive use of international literature.

This study will use the following terminology:

- **Incident**: event occurring during the execution of work
  - Consistent with both in the international and Dutch terminology

- **Adverse event**: unwanted outcome of the process of care
  - Consistent with international terminology

- **Preventable Adverse event**: event that could have been prevented
  - Consistent with international terminology

- **Near miss**: event prevented before it could harm a patient
  - Consistent with both international and Dutch terminology

### 4.4.1. Incidents

An incident is an event occurring during the execution of work. This can range from malfunctioning equipment, to the administration of wrong drugs, to patients falling out of their beds.

The majority of reported events are incidents. Less than 1% of reported incidents have a lethal outcome. The vast majority (75%) has none to a small impact on the state of the patient or his treatment (St. Antonius Ziekenhuis, 2007).

A distinction should be made here between the occurrence of incidents and the resources consumed by incidents. Minor incidents make up the bulk of reported incidents, yet they receive the least attention of regulatory agencies. Their combined impact on patient’s safety is however far greater than that of the lethal incidents that take place (Runciman, 2002).

### 4.4.2. Adverse Events

The Orde defines an adverse event (complicatie) as: "een onbedoelde en ongewenste gebeurtenis of toestand tijdens of volgend op medisch specialistisch handelen, die voor de gezondheid van de patiënt zodanig nadelig is dat aanpassing van het medisch (be)handelen noodzakelijk is dan wel dat er sprake is van onherstelbare schade” (www.orde.nl, 21-04-08).

An adverse event is an undesired outcome of a medical process. Since adverse events are outcomes of a medical process they mostly are found in the line of work of physicians. Since they are related to the given treatment – a patient receiving chemotherapy cannot develop an inflammation of a wound – their diversity is far greater than that of incidents. Not much is known about the occurrence of adverse events as physicians register them in their private files. They are present in the patient files, but they cannot be recovered from the general registration systems.

Incidents and adverse events can be related. There can be a cause-effect relationship between the two. A falling accident can cause an inflammation of the operation wound.
4.4.3. **Preventable Adverse Events**

Sometimes the adverse event could have been prevented though. This is especially the case when an incident leads to the complication. For instance, using non-sterile equipment can lead to an infection of the wound (unwanted outcome).

4.4.4. **Near Misses**

“Because a greater understanding of the types of injuries and their causes is essential for the development of more effective methods of prevention, it seems evident that improved reporting of accidents and serious errors that do not cause harm (close calls/near misses) must be an essential part of any strategy to reduce injuries. Yet physicians have been reluctant partners in reporting.”

(Leape, 2002)

The last category of active errors constitutes near misses.

A near miss is can be described as:

A near miss is an event that failed to materialize

Or

Any event is a near miss that was intercepted too late.

Near misses and events share the same causes, this means that the ICPS model is applicable to both cases.

In Dutch health care reporting and learning has focused predominantly on occurred events. There is no insight into the occurrence of near misses. Identifying near misses can be very difficult. Because “how can one measure the accidents that could have occurred but did not?” (Gaba, 2000). Events that are successfully prevented from turning into events are very difficult to identify. The difference between a near miss – caught in time by a watchful person - and a team effort where members work seamlessly together – thus preventing the occurrence of an adverse event – can be a fine line.

Even though it might be difficult the following quote makes it very clear why more attention has to be paid to the occurrence of near misses. "Although people learn from close calls in everyday life, most organizations do not incorporate such learning as a standard operating procedure. This is extremely short sighted and verges on irresponsible, as the organization that ignores lessons from close calls is essentially declaring that they will wait for a tragedy to occur before making changes" (Bagain, 2006).

There are several reasons why reporting of near misses is so important, equally important as reporting of adverse events (Bagain, 2006; Chang, 2005; Barach, 2000). In many cases, near misses happen with greater frequency than adverse events, making them very useful for quantitative analyses. To extract insight from gathered data a large database is needed. The more data is available, the less causes are linked to specific events. This enables data analysis to find latent factors that are difficult to assess in single cases. Secondly, near misses happen more frequently – estimates into the occurrence of near misses range from 7-100 times more often than incidents or adverse events (WHO, Drafting Group, 2006).

A near miss should be regarded as an adverse event that failed to materialize (Chang, 2005). Since no one got injured as a result of a near miss, the barriers to data sharing are much lower (Barach, 2000). There is no fear of litigation (Bagain, 2006) so discussing a near miss is easier and presumably more honest.

Three important barriers to the reporting of near misses have been identified by van der Schaaf et al (Schaaf, van der, et al, 1991). Investigations are targeted towards “incidents with serious consequences (idem), registration systems are event focused, and registration systems focus on actions instead of on causes (idem0.
4.5. Latent Factors

"Latent errors pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors"

( WHO, 2007)

In the previous part the difference between active failure and latent factors has been explained. Latent factors are difficult to perceive at a local level (Carroll, 2002) and easily forgotten in a search for causes as they are much more difficult to assess. Especially since front line personnel are so used to them that they do not notice the factor anymore, they just work around it.

Any latent factor can be at the source of a multitude of events, just as any event can have a multitude of latent factors that created the situation in which an active failure could occur and lead to the unwanted situation. Only by tracing back the chain of events that caused the event can the latent factors be found, in order to prevent the same error from occurring anywhere else in the hospital (McFadden et al, 2006).

Latent conditions that create unsafe situations are often called contributory factors as they contribute to the happening of an event; they produce the conditions in which an event can take place. The WHO describes contributing factors as: “a circumstance, action or influence (such as poor scheduling or task allocation) which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident. (WHO, 2007)”

This category of factors comprises everything from equipment problems (Tucker, 2004, McFadden, 2006), miscommunications (Tucker, 2004), organizational, political and cultural issues (Carroll, 2002), staff factors such as stress (Amalberti, 2005), inertia (McCafferty, 2007), fatigue (Rhodes, 2003) or workload, but also patient characteristics, such as age, personality, behavior, communication (dealing with a patient who does not understand your language).

4.5.1. Organizational Factors

One of the most important factors influencing the occurrence of events is the organizational culture (Stock, 2007). In any organization that has a so-called “shame&blame” culture towards error instead of a “blame free reporting” (Willems, 2004; Van Cott, Chapter 4, in Bogner, 1994; Stock, 2007; Reason, 2000) culture, there will be a very low number of reported errors. It is known that active failures happen, not much can be done about them when there is no real proof of their appearance. So the underlying culture in an organization is very important, as it is the basis for a patient safe hospital.

Another important asset of the organization in creating a safe environment is the use and availability of protocols and standards. Protocols provide guidelines for personnel, so personnel does not have to device solutions themselves for every problem encountered. Implementing standards and protocols, however, does present problems at the organizational level. Personnel in the health care sector are used to much freedom of choice. Central policy decisions do limit the behavior of teams or individuals (Moray, Chapter 5, in Bogner, 1994). Especially physicians are very skeptical towards such measures at the organizational level as they feel this is an infringement on their professional standing (Carroll, 2002).

Another mechanism is standardization of practices (Amalberti, 2005) and equipment (Leape, 1994). In every hospital various systems and procedures are in use that perform exactly the same function, but work differently. This is a remnant from the decentralized structure hospitals used to have; every department bought the system they thought best.
Standardization of equipment can prevent active failure as using the same system decreases the chances of misinterpretation of the equipment.

The last important organizational factor discussed here is the level of production. Hospitals cannot refuse patients, so there is no maximum on production. Hospitals are production driven, but public demand restricts them from applying “common-sense safety-enhancing solutions, such as limiting the flow and choice of incoming patients” (Amalberti, 2005). This inability of putting a maximum on production is also a threat to the medical performance of physicians as it can push the workload up to an irresponsible level. Many researchers (Helmreich, 2000, Amalberti, 2005, Rhodes, 2003) have reported on the impact of workload on physician’s performance. One research (Rhodes, 2003) even stated that in 16% of the incidents fatigue was a factor and in 22% of incidents excessive workload was found to be a contributing factor.

### 4.5.2. Staff Factors

“Practitioners need to eat, drink, sleep and have bathroom breaks. They also have personal lives and stresses that may alter their focus or influence their attention while they are caring for patients. These ‘human factors’ are important considerations when mapping patient safety problems.”

(Marx, 2003)

Another group of contributory factors can be grouped as staff factors. This category consists of factors that can influence the performance of medical staff. Most of these factors are not intentional of causing active failures.

One of factors that can influence the possibility of active failure is the level of experience of medical personnel. Unlike other industries that operate in a dynamic and complex environment, health care is supported by many novices; both students and volunteers (Amalberti, 2005). Next to that junior trained staff does not have all the Expertise as they do not yet have the tacit knowledge of their superiors, while they do have to perform at a high level. As McCafferty states: "even the less experienced surgeon can be challenged by the novelty and complexity of the situation, which may lead to poor decision and technical errors” (McCafferty, 2007).

Health care is very dynamic, not in the least because every patient is unique. It has already been stated how dangerous routine can be in such an environment. A junior surgeon might miss the tacit knowledge, the danger for senior staff is that they are "more likely to be prone to complacency arising from years of success in performing operations in a routine fashion” (McCafferty, 2007).

Another frequently cited factor is communication, both verbally and paper based (WHO, Drafting Group, 2007). Not only communication problems with patients are common, internal communication can be equally problematic. For instance, many prescription errors are caused by misreading the prescription or by misunderstanding caused by look-alike sound-alike drug names. “Many of these errors can be attributed to physicians' not writing clearly” (Roberts, 2001).

Physicians expect themselves to work flawless, active failures can be caused by ordinary human characteristics. The systematic working of overtime can cause fatigue among staff (Moray, Chapter 5, in Bogner, 1994; Rhodes, 2003); combined with a shortage of staff this can lead to situations of stress (Amalberti, 2005).
Appendix 5. Registration Systems

In Part II several registration systems have been evaluated. This appendix provides a more detailed decomposition of these registration systems.

5.1. VMOS

VMOS® is the term used by PMC Advies to refer to their electronic registration systems. In this research version 2.8nn has been evaluated. The term VMOS should not be confused with VMS, which is the name of the total patient safety program within hospitals.

The goal of the registration systems is to gain insight into medical events – general insight and case specific – and their causes. So the system has to perform three tasks at once. It has to:

1. provide insight into the specific event
   a. causes
   b. the actual incident
   c. impact
   d. recommendations to prevent the adverse event from happening again
2. provide insight into risks hospital wide (patient safety), critical issues
3. predict risks, trend analyses

Next to that the total VMOS will also provide evaluation tools for event analysis purposes.

Reporting cannot be done anonymously. Data about the reporter is used to make it possible to track incidents to departments or certain ‘patient paths’, it is not used to follow up on certain employees.

Currently three different registration systems are under development or are already operational.

- Patient Risico-analyse (PAR)
- Meldingen Incidenten Patientenzorg (MIP)
- Complicatie Registratie (CR)

5.2. Pro-active Patient Risk Assessment (PAR)

Many incidents and adverse events originate in the patient (‘s condition). In order to reduce these kinds of incidents, patients are reviewed before admittance. This registration focuses on the following issues:

- Decubitus
- Delier
- Kwetsbare oudere
- Ondervoeding
- Vallen

Identifying the potential risk of a patient gives the hospital the option to provide extra care to those patients that are most likely to need it.

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26 All basic information about the registration systems has been provided by PMC Advies, some information may concern newer versions of the systems than are currently operational in hospitals. [www.pmc-advies.nl](http://www.pmc-advies.nl) (27-03-2008)
Initially the system will only be used during the intake of clinical patients, simultaneously with the *verpleegkundige anamneses*. As the two intake forms have so much in common, they are going to be combined. There is also much overlap with the data needed for the EPD (*elektronisch patiënten dossier*). To relief nursing staff solutions are sought to copy data from one system into others.

Once the forms have been filled out, the system automatically calculates certain – pre-identified – risks. If risks are identified, a message is sent to responsible staff. Information gathered in the PAR is available to all staff concerned with the medical proceedings of the patient. The system provides insight and is equipped with tools to enable staff to incorporate the needed extra care into their daily duties. Thus it can relieve workload for staff by accurately predicting which patients will most likely need extra care. This will allow staff to focus their attention more appropriately and relieves them of (unnecessary) duties.

Because patients are screened at admittance the system can also provide insight into the progression of patients’ physical condition during the hospital stay. This provides opportunities for enhancing the quality of care in general. It can also assist in preventing long term harm to patients, such as decubitus or the decline in mobility of elderly patients.

### 21.1. Melding Incidenten Patientenzorg (MIP)

This reporting system is designed to register all incidents that occur in the hospital. An incident is an error in the process of care. It contains errors associated with decubitus, nutrition, patients falling, wrong use or administration of medication, mistakes associated with technical equipment, and incidents involving blood products.

#### 5.2.1. Quality

The new version of the MIP Expert incorporates available national guidelines or quality checks. This is another reason why the system has been used as a surrogate for a national registration system. The level of harm to a patient has been based on the risk matrix created by VMS Zorg (VMS Zorg, 2007), a national program targeted at patient safety. All sheets of the MIP Expert have been created in cooperation with ten VMS pilot hospitals in the Netherlands.

#### 5.2.2. Decomposition

The MIP does not aim to appoint blame. As with the ICPS the goal is to record incidents as objectively as possible, focusing on system failures, not human error. To accomplish this goal causes and impact of the incident are defined in general terms. Any specific information should be listed in the patient files as it only concerns this single patient. For convenience, users only have to review two sheets. Reports can be saved in between registration, to enable staff to finish registration at different times.

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27 personal communication with PMC Advies
The MIP-Expert starts with a general sheet. Next the reporter can choose between five different sheets, all aimed at a different type of incident. Each of these sheets starts with an incident type specific section. The lower part of each sheet refers to the causes and impact of the incident, as well as measures implemented. This part is (almost) the same for each different incident type. Not only is this convenient for staff as they can easily familiarize themselves with the layout of the questionnaire. It also makes it possible to evaluate causes regardless of the incident they caused. As discussed in previous chapters, latent and contributory factors can result in very diverse incidents. For instance, a communication deficiency can result in any of the incident types present in the MIP-Expert.

5.2.3. Causes and Impact of the Incident
Each sheet contains the same cause and impact questions. Possible causes are split up into three categories: Equipment, Human Error, and Internal Organization. When the event is related to equipment the device registration number and room number have to be provided as well. This will enable the technical department to retrieve the defect piece and check its condition.

Impact is divided into impact on the patient and impact on the treatment. The fact that additional information can be added at a later time is especially useful for the impact on treatment. Impact such as prolonged stay cannot be determined when the incident happens, only afterwards will it be clear how much impact the incident has had on the treatment. Impact on the patient is – equal to the ICPS model – divided into a five point scale. Explanation is available to assist staff in determining the severity of harm. Yet again, it remains a subjective decision. The system does provide opportunity for superiors to change the degree of harm. Through this measure, an attempt is made to make the subjective scale more objective.

The sheets also contain questions concerning the measures taken after the incident. Each sheet ends with two open question boxes. Here staff can give a more specific description of the incident – for instance the setting in which the incident took place – and any suggestions they have to prevent the event from happening in the future.

5.2.4. The sheets
5.2.4.1. General Sheet
The MIP Expert starts with a general sheet. In this sheet facts concerning the patient, the time and location of the incident, those informed, and details about the reporting party have to be provided. The system will not proceed to the next sheets if not all items are filed correctly. The sheet explicitly states that it can be used for incidents and near misses.

5.2.4.2. Treatment Related Incidents
This class focuses on three different incident types. The first type is patient identification. Incidents can happen as a result of proper care delivered to the wrong patient. No figures are available about the number of times this happens on a yearly basis. An issue concerning
this incident type is the impact wrong identification can have. It can be expected that other incidents happen as a result of a wrong identification, for instance administering the wrong drugs. These two cannot be filed in the same incident report. They have to be recorded separately; except when the follow-up incident involves nutrition or decubitus; because these are located on the same sheet.

The second incident type is concerned with nutrition. Both the specific incident as the type of nutrition involved can be listed. The third incident type is decubitus. This is one of the focal points in Dutch health care. The specification possible for this kind of incident is therefore greater than for many other incident types. Not only can sixteen different locations of decubitus be identified, but also the level of injury can be specified.

5.2.4.3. Blood Products

Only 2% of filed incidents at the St. Antonius Ziekenhuis in 2007 concerned blood products (St. Antonius Ziekenhuis, 2007). This is however a very specific category and recognized as such by both the MIP Expert and the ICPS model. This type of incident is further explicated into four different types. Incidents can happen as a result of administrative errors (missing patient information), execution errors, delivery problems associated with the laboratory, and administration errors by medical personnel.

5.2.4.4. Medication

Many incidents involve medication problems. To gain more insight into the nature of these incidents this sheet is more elaborate. The sheet is based on the Centrale Medicatie Registratie. The CMR is a national registration system for medication errors created by the association of hospital pharmacists (the NVZA).

The prescribed drugs as well as the wrongfully administered drugs have to be listed. Next to that six different kinds of medication errors are defined. Each of these is further explicated, to gain maximum insight. Errors can be related to prescription, transfer, delivery, preparation (distinguishing between errors committed by the pharmacy or by nursing staff in the ward), administration, and errors committed outside the direct vicinity (this includes errors in medication prior or after hospitalization).

As many medication errors are discovered prior to administration to the patient, the impact of the incident category is slightly different in this sheet. This differentiation makes it possible to acknowledge that a near miss was spotted in time, and if not what the impact on the patient was. The five levels of impact are further explicated as well, to allow for more precise insights.

5.2.4.5. Falling

Falling incidents can originate in the patient’s condition. Therefore this sheet starts with questions concerning the patient’s initial risk of falling (valrisicoscore). In the future this risk will be estimated during patient intake, as it is one of the items in the PAR.

The nature of the incident can be explicated into location, activity during which the patient fell, and how the patient fell (for nursing staff it is of interest whether the patient fell out of bed or out of a chair or just stumbled.). Specific questions regarding falling accidents constitute whether the patient has experienced falling accidents prior to this accident and whether the patient was alone or if other people were present in the room.

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28 decubitus is commonly known in Dutch language as ‘doorligwonden’.

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5.2.4.6. Using Registration Data

Every reported incident is stored in a database. Before the report can be closed several people are required to review it. Several trajectories are possible, depending on the nature of the incident.

Once an incident is reported the system automatically sends – when needed – an e-mail to a sleutelfunctionaris (key staff member). Every medication incident is automatically reported to the pharmacy, they are then obliged to check, comment on and approve of the report. Only then can the report be closed. The same procedure is followed for incidents involving blood products or technical equipment.

After registration the afdelingsverantwoordelijke – and when applicable the sleutelfunctionaris – determine the level of severity of the incident. They can change the level assigned by the reporter. Minor incidents are dealt with by the de-central VIM committees; every department has created such a committee. Incidents in which a patient died or which resulted in very serious harm to the patient have to be handled by a special committee, the MIP-Commissie. Any minor incident – considered by the reporter to be of interest to the entire hospital or of such proportion that it should receive extra attention – can also be submitted to the MIP-Commissie directly.

The MIP-Commissie leads the internal investigation into the causes of the incident. To assess what happened they use the incident report, accompanied by subsequent investigations; such as interviews with those involved, examinations of the equipment involved by the technical department of the hospital, etc.

Minor incidents are not all investigated with such rigor. The MIP-Commissie does not literally take action upon reported incidents. They review all minor incidents they receive to provide the board of directors with advice. Since they do not personally know every department they cannot give tailored advice. Action should really be taken by department heads as they know what, where and whom they are dealing with. The board of directors can pressure them to take action, the MIP-Commissie can advice the board to do so when needed.

So the MIP-Commissie needs very specific information to be able to deal with severe incidents, but much more general insight regarding all minor incidents.

5.3. Complication Registration (CR)

Complications or adverse events are reported by physicians. A complication is an adverse outcome of the process of care.

Adverse events are very specific per field of care. Therefore the Association of Medical Specialists (Orde van Medisch Specialisten, hereafter referred to as Orde) created a ‘master classification’ and asked all specific associations to develop their own classification of adverse events likely to happen in their field of Expertise. Many associations have developed such a classification. Some are very elaborate, maybe too elaborate to be of practical use. Not all specialisms have developed a national classification.

![Figure 24: CR]
Many *Maatschappen* have developed their own adverse event registration systems. These systems – and the data recorded in them – are the property of the *Maatschap* and are not automatically accessible to hospital personnel. The *Maatschappen* just provide certain figures to the board of directors; other than that the systems are closed. This will not change once the new registration systems are operational.

Registration systems developed by *Maatschappen* are not taken into account in this research as they will be replaced by the new CR. Also *Maatschappen* do not easily provide insight into these personal systems. No insight has been acquired into whether these registration systems address causes of adverse events and what *Maatschappen* do with generated data. More information can be found in Part III & Part IV.

An important issue is that the CR-Expert® uses national guidelines as much as possible. This makes future sharing of information – after thorough anonymization – within the national specialist associations possible. The system will also provide ample analysis tools, to enable each *Maatschap* to assess the causes and impact of the reported adverse events.

### 5.3.1. Generiek Datamodel

As mentioned the Orde has created a Generic Datamodel (Orde, 2006) as a basis for adverse event classifications designed per specialism. In this model the key classes of an adverse event are specified, and numbered. The identified classes of the *Generiek Datamodel* are:

- **Compulsory Classes:**
  - Adverse Event
  - Pathology (Adverse Event Type)*
  - External Factors (Contributory Factors)*
  - Patient
  - Physician – patient period of responsibility
  - Physician – patient interaction (face to face contact)

- **Non-compulsory Classes:**
  - Medication*
  - Intake (date, reason, urgency)
  - OK stay (duration, urgency)
  - Operation/Procedure
  - Anesthesiology

The classes marked with an * have been explicated in the *Masterclassificatie*. This classification provides a structured decomposition of these classes. It should be the basis for any classification created by the associations. Each specialism has to construct its own classification based on the coding system provided by the Orde. This makes it possible to compare data derived from different *Maatschappen*.

As the registration system for adverse events does not exist yet and the system will use national standards, it can be expected that the CR will comply with these classes. Therefore this classification will be used as a substitute for the breakdown of the registration system in the analysis.

As an additional check conclusions derived from this *Masterclassificatie* have been checked by means of the adverse events classification lists as compiled by several specialist associations. Several of these associations have completed their adverse events classification lists29. These lists provide insight into the actual acknowledgment of all concepts defined by the Orde.

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29 [http://orde.artsennet.nl/content/resources/AMGATE_6059_397_TICH_L8917839/AMGATE_6059_397_TICH_R14316686222897/#complicatielijsten](http://orde.artsennet.nl/content/resources/AMGATE_6059_397_TICH_L8917839/AMGATE_6059_397_TICH_R14316686222897/#complicatielijsten) (08-04-08) only the *bevroren versies* have been used as these have been checked and verified.
5.4. Additional Systems Relevant to Registration of Events

The VMOS has been specifically designed to record all events that happen in a hospital. But hospitals have been improving the quality and continuity of care for years. Many of these other initiatives are equally important to the enhancement of patient safety. Therefore they will be included in the analysis as well.

5.4.1. Electronic Patient Files

Hospitals are moving from paper based patient files to an electronic filing system. This system is called the *Elektronisch Patiënten dossier (EPD)*. The EPD is important in the scope of this research because much data can be retrieved from the patient files. For instance patient name, date of birth, and current medication do not need to be entered twice. After filing the patient identification number, such data could be retrieved from the EPD.

5.4.2. Protocols and Guidelines

Since care is a very complicated industry protocols have been developed to standardize the execution of procedures and actions. Protocols have been developed addressing topics ranging from ‘dealing with aggressive patients’ to ‘assessing whether a patient is confused’ to ‘dealing with leaking medication containers’.

Use of these protocols is compulsory and is monitored extensively. The goal of protocols is to create an environment in which certain errors – that are considered a risk to the safety of patients – scarcely occur.

Protocols are created after certain events have taken place. Therefore they are considered ‘Risk Reduction Actions’ in the ICPS model classification. In Figure 6: ICPS model, cited from (WHO, 2007) it can be seen that Risk Reduction Actions influence both the Contributory Factors as the Detection of incidents.

Even though they do not explain the causes of an event, they do provide insight into these two classes. There are for instance protocols that discuss how to evaluate the condition of the patient. They do not serve as replacements of Contributory Factors or Incident Types, but their existence can be seen as proof of the acknowledgement of the factor in question by health care organization. For instance, incidents involving oxygen cannot be reported, but there are protocols in place for handling oxygen. So the issue has been recognized, but is for (not discussed) reasons not included in the registration systems.

5.4.3. Other Systems

There are other registration systems and reporting mechanisms besides the VMOS. All medication incidents must be reported in a national database, *Centrale Medicatier Registratie*30. The MIP sheet concerning medication incidents therefore is based on the data required for CMR.

PREZIES is a national registration system designed for hospital acquired infections31. The PREZIES not only collects data on hospital acquired infections, it also keeps a specific database of post-surgical wound infections (*post-operatieve wondinfecties*) (POWI)31.

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30 [www.nvza.nl](http://www.nvza.nl), 05-04-08
31 [www.prezies.nl](http://www.prezies.nl), 05-04-08
Appendix 6. Case Study: A possible Hospital Structure

At the St. Antonius Hospital several departments – nursing wings, clinics – are grouped together in a division (zorg eenheid). Divisions combine all departments addressing the same sort of patients, so divisions are for instance ‘mother & child’ or ‘heart-lung’. Divisions are run by the zorg manager together with the medisch manager.

Physicians do not belong to a department or division; they do work together with them though. Physicians are grouped in Maatschappen.

The hospital facilitates their work by providing training facilities for students, work space, nursing, and equipment but other than that the Maatschappen are independent.

This structure can be classified as a divisional structure, which has been described as follows: “quasi-autonomous divisions perform the work” and “co-ordination is achieved...through the standardization of outputs” while “each division serves its own market” (Buchanan, 2004).

6.1. Management

The structure described below is based on the case study (Appendix 6, structure of the St. Antonius Ziekenhuis in Nieuwegein). Other hospitals can have different management decompositions.

6.1.1. Department

At the lowest organization level the hospital is divided into departments. Each department has its own department head (afdelingshoofd). This manager has about the same need for information as the nurses that work in the department, so specific information about the care and type of events and errors that take place in the department.

Based on the events reported in the department the department head should look into the causes and possible solutions to problems encountered. By providing this feedback and thus creating a safer environment the department head will give a positive incentive for nursing staff to put report events.

6.1.2. Division

Several departments are grouped into one division. The division head is further removed from the actual nursing tasks and therefore needs less specific insight into the care and causes of occurred events. For the division head it’s necessary to have insight into the number of falling incidents, not necessarily into the footwear of the patient. So the division head needs more general information about care and the types of events and errors.
occurred. The division head has more contact with the medical staff, at least with the medical manager of the division. This is a vital role for patient safety as many unsafe situations involve both nursing staff and physicians. The division head can discuss incident data more easily with the medical staff than a nurse could. This type of feedback will create more overall understanding about the causes of an unsafe situation.

6.1.3. Medical Staff
The medical staff management does not fall under the direction of the board. As discussed the medical staff is an equal partner to the board. They only need general insight into the medical work in the hospital. For this the medical staff management needs to have a good relationship with all Maatschappen, but also with the division heads and the board.

6.1.4. Quality Management
Patient safety is part of quality management. This falls directly under the board and is thus separated from the medical activities in the hospital. Although most quality measures need to be implemented on ‘the floor’, general overview of the safety state of the hospital is centralized in one department. With regard to patient safety quality management needs general information about the occurrence and severity of events and of initiated and proposed improvement measures. Since quality management is detached from any department or division it can regard all that is happening and lift local initiatives to hospital wide implementation.

6.1.5. MIP-Commissie
All minor incidents are dealt with by the department heads. Incidents in which a patient died or which resulted in very serious harm to the patient have to be handled by a special committee, the MIP-commissie. Any minor incident – considered by the reporter to be of interest to the entire hospital or of such proportion that it should receive extra attention – can also be submitted to the MIP-commissie directly. The MIP-commissie does not literally take action upon reported incidents. They review all minor incidents they receive to provide the board of directors with advice. The board of directors can pressure department heads to take action, the MIP-Commissie can advice the board to do so when needed.
Appendix 7. National stakeholders

In Chapter 13 national stakeholders have been discussed. There are other important stakeholders as well, that have not been assessed as thoroughly. These can be found in this appendix.

The position of national societal parties with respect to patient safety is reviewed from the perspective of hospitals. The stakeholders mentioned can impact the position of hospitals and therefore health care should acknowledge their potential influence.

Patients have been excluded from this research in Part III, but society as a whole can play a part. In Part III the influence of commercially created rankings has been discussed. These rankings are produced by the media; therefore it is important for health care organizations to acknowledge the media as a party they have to be able to deal with.

7.1. Society

Society as a whole also has an interest in the quality of medical care. But this interest is very general. As long as care is provided locally, for reasonable prices, and of high quality society’s demands are covered.

7.1.1. Insurance Companies

Insurance companies are gaining power in the health care industry. They pay for care and will eventually only want to pay for quality. Insurance companies will start to evaluate care based on its quality (Willems, 2004). The most profitable agreements will be made with hospitals that can prove their quality, e.g. their level of patient safety.

Insurance companies can gain insight into the quality of care through registration systems and the Prestatie Indicators of the IGZ. Therefore hospitals need to assess carefully what information insurance companies want and what the hospital will give them.

Private insurance by patients is not taken into account here. The registration system is not targeted at specific patient developments. Patients should be able to find all data relevant to their progress in the patient files, the same goes for their personal insurance companies.

7.1.2. Media

The other external party that should be mentioned here is the media. Although the media cannot be considered a premier actor in the registration of patient safety, they can have an influence on the reputation of hospitals. The media has two objectives with information about the quality of health care. They either want very general information – to create before mentioned rankings or general information providing to the public – or they want very specific information – for articles about a specific event32.

In a competitive market any hospital needs to know how to deal with this media attention. On the one hand, the media can be used for positive attention; the St. Antonius Ziekenhuis has recently been visited by several television crews from programs differing from specific medical programs to children’s television.

32 www.volkskrant.nl/binnenland/article503462.ece/Patient_overlijdt_na_foute_bloedtransfusie (accessed 14-04-2008) is an example of such specifically targeted articles. The article deals with a single patient who died of a wrong blood transfusion.
At the same time a hospital should have press protocols ready just in case a severe event occurs. This is recognized in the ICPS model which lists ‘Media Management’ as an Ameliorating Action (WHO, 2007). The influence of bad publicity should not be underestimated.

### 7.2. Other Stakeholders

As the subject in this research is ‘the reporting of medical events’ only actors directly involved with medical events are taken into account. The pharmaceutical industry, equipment manufacturers or registration system manufacturers are not included in the analysis. They are involved in the occurrence, prevention and registration of medical events but only indirectly. The assumption is made that all these secondary actors provide the hospital with the best product they can offer. They do not intentionally provide service that could harm a patient.

Medical schools are also not taken into account. They should incorporate safe practice in their curriculum but this education takes place before their students enter the hospital. Medical students working in the hospital are taken into account; they are grouped together with either the physicians or the nursing staff, depending on their education.
## Appendix 8. The 10 thema’s

<table>
<thead>
<tr>
<th>Goal</th>
<th>Risk Reduction Actions</th>
<th>Impact Assessment</th>
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| Halveren van het aantal postoperatieve wondinfecties (POWI). | - Het adequate gebruik van de profylactische antibiotica.  
- Stoppen met preoperatief scheren van de te opereren plaats.  
- Het gebruik overige bekende perioperatieve maatregelen, zoals het monitoren van het bloedsuikergehalte  
- Het gebruik van hygiënevoorschriften van de Werkgroep Infectie Preventie (WIP) | Het aantal patiënten met een postoperatieve wondinfectie wordt geregistreerd. |
| Voorkomen van schade bij patiënten met een centraal veneuze lijn - Terugdringen van de inbrengschade met 50%. - Aansluiten op Nederlands initiatief voor ‘surviving sepsis’ met als doelstelling om in vijf jaar de sterfte aan ernstige sepsis met 25% te reduceren. | - Om de inbrengschade te beperken zal in alle ziekenhuis zorg gedragen moeten worden voor de juiste toepassing van de inbrengtechniek, door gebruik te maken van een protocol inclusief training.  
- Voor de vermindering van schade en sterfte door sepsis is een bundel van maatregelen beschikbaar die gebaseerd is op evidence-based ervaringen. Deze maatregelen zijn gericht op het snel behandelen van patiënten bij wie sepsis of een septische shock is geconstateerd. De maatregelen worden in protocollen vastgelegd. | Elke patiënt die overlijdt door sepsis op een IC wordt geregistreerd. Dit aantal wordt gelegd naast het aantal patiënten op de IC. |
| De sterfte bij patiënten met bedreigde vitale functies wordt teruggebracht met 25% in vijf jaar. | Opstellen van een protocol met bandbreedtes voor de vitale functies.  
- Opstellen interventie-protocol: wie waarschuwt wie.  
- Instellen spoed-interventie-team. | De sterfte van patiënten met bedreigde vitale functies wordt geregistreerd en vergeleken met het totaal aantal patiënten met bedreigde vitale functies. |
| De doelstelling voor medicatieoverdracht wordt vastgesteld als de richtlijn medicatieoverdracht formeel is vastgesteld en is bepaald waar de aandacht komt te liggen binnen het thema medicatieoverdracht. | - Het invoeren van een risico-inventarisatie met betrekking tot het voorschrijven en toedienen van risico medicatie zoals slaap- en kalmeringsmiddelen.  
- Het invoeren van standaardgesprekken met de patiënt over het actuele medicatiegebruik, het geneesmiddelenbeleid binnen het ziekenhuis en het gebruik van geneesmiddelen (en eventueel geconstateerde bijwerkingen) na ontslag. Zulke gesprekken en het terugkoppelen te openbare apotheker en huisarts dragen bij aan het terugdringen van medicatiefouten.  
- Het gebruik van meldingsystemen op het terrein van medicatieveiligheid. | Het aantal keer dat er met medicatie iets fout gaat (klinisch, dagbehandeling en poliklinisch: daarna door overdracht medicatie vanuit ziekenhuis) door onvolledige anamnese bij opname of onvolledige overdracht bij ontslag. Dit wordt vergeleken met het totaal aantal klinische en dagbehandelingen zoals ontslagen én polikliniek bezoeken. |
Appendix 9. International Patient Safety Regulation

In Chapter 15 Dutch patient safety regulation has been compared to international patient safety regulations. In this appendix the position of patient safety in four countries will be described. All these countries have an advance patient safety registration system.

9.1. Denmark

Denmark was the first country to implement a mandatory reporting system for adverse events. As of January 1st 2004 reporting is mandatory in the DPSD system (WHO, 2005). Data is only used to improve health care. The regulations state that personnel must report adverse events in the national registration system, hospitals must act on reports, and the National Board of Health must communicate lessons nationally (Danish Society for Patient Safety33).

The Danish reporting system is backed up by laws and regulations. The Danish Act on Patient Safety became active as of January 1st 2007 and states that “A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts”33.

9.2. Great Britain

Another country with a national database for adverse events is Great Britain. The National Patient Safety Agency34 (NPCA) operates a voluntary national reporting system, the National Reporting and Learning System. The goal of this system is to learn from incidents in an open reporting culture (WHO, 2005).

The NPSA has defined the type of incidents and the type of data that should be reported. These specifications have been provided to local registration system developers. The result is that incidents are dealt with locally, but the electronic system automatically sends a copy to the national database, so reporters never have to file data twice.

In case a trust (hospital that is part of the National Health Service) does not have a (compatible) electronic system the practitioner can report directly to the NRLS. Collected data is made anonymous before use. The goal of the NPSA is to identify trends nationally and provide solutions to affiliated health care organizations.

9.3. Australia

In Australia the Australian Patient Safety Foundation35 is an important force in improving patient safety. This non-profit organization is partly funded by the government and develops a software tool for incident reporting. This software tool – the Australian Incident Monitoring Tool – registers incidents based on a generic classification system (WHO, 2005). This classification scheme is very detailed and dissects the event into underlying, often not easily

33 www.patientsikkerhed.dk, 14-04-08
34 www.npsa.nhs.uk/patientsafety, 14-04-08
35 www.apsf.com.au
identified, causes (Runciman, 2006). The subjects in and the structure of this classification scheme can to a large extent be compared to the ICPS model\textsuperscript{36} (Part I).

Reports can be made by anyone connected to the health care system, including patients and their families.

The system has been designed by the APSF, but is heavily protected by the government (Toyne, 2005). The government has granted the AIMS databases the status of “formal quality assurance activity” (WHO, 2005). This means that “revealing or disseminating individually-identifying information that becomes known solely as a result of safety and quality activities is a criminal offense” (WHO, 2005). The location of the databases is equally heavy protected.

\textsuperscript{36} Professor Runciman is the main person responsible for the GRM classification on which AIMS is designed and he is also chairman of the Working Group of the WHO