Safety does not happen by accident

Improving patient safety using risk management systems and formulating measures for improvement

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Author: M.A. Schraa BSc.
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Supervisor UMCG: Dr. E.C.M. ten Have

Supervisors University of Twente: Dr. Ir. A.A.M. Spil
Dr. J.G. van Manen

University Medical Center Groningen

UNIVERSITY OF TWENTE.

Samenvatting

In 2008 werd landelijk besloten dat het aantal medische fouten in Nederland drastisch moet worden verminderd. 50% van de vermijdbare schade moet worden gereduceerd. Dit landelijke besluit leidt tot verschillende maatregelen in het Nederlandse zorglandschap. Een van deze maatregelen is het invoeren van een incidenten registratie systeem in alle ziekenhuizen om zo inzicht te krijgen in de frequentie en aard van medische incidenten.

Het UMCG gebruikt sinds 2008 een ziekenhuisbreed incidenten registratie systeem. Dit systeem zou er aan bij moeten dragen dat er van incidenten geleerd kan worden, met als doel om de patiëntveiligheid te verbeteren. Het systeem is opgezet op basis van ervaring, logisch nadenken en landelijk opgestelde eisen. De veiligheidscultuurladder van Parker & Hudson wordt gebruikt als inspiratie om aan te geven dat het UMCG hoger op deze ladder wil komen en integraal wil werken aan een verbeterde patiëntveiligheid. De vraag is of de inspanningen van de afgelopen jaren al vruchten afwerpen, of het model van Parker & Hudson de beste inspiratiebron is en wat de volgende verbeterstappen voor het UMCG zijn.

Een uitgebreid literatuuronderzoek laat zien dat veiligheidsprincipes die gebruikt kunnen worden in het ziekenhuis veelal afkomstig zijn uit de vliegtuigindustrie. Wanneer de bestaande literatuur vergeleken wordt met de ziekenhuispraktijk, zoals in het UMCG, blijken er hiaten te bestaan. Deze hiaten worden met name gekenmerkt door een gebrek aan concrete handvatten en verbetermogelijkheden in de ziekenhuiscontext. De belangrijkste overeenkomst tussen de bevindingen uit het literatuuronderzoek enerzijds en de veiligheidsladder anderzijds, is de noodzaak van een constructief model ter verbetering van patiëntveiligheid. De vijf verschillende niveaus van de veiligheidscultuurladder worden door Parker&Hudson *pathalogisch – reactief – calculatief – proactief – generatief* genoemd. De niveaus van deze veiligheidscultuurladder liggen nog te ver uit elkaar. Er dienen tussenstappen gemaakt te worden, waarbij het erkennen van een probleem altijd de eerste stap is. In totaal zijn er vijf tussenstappen per niveau noodzakelijk: *erkenning – geen verwijten en schaamte - incidenten melden – incidenten analyseren – verbetervoorstellen*.

Resultaten uit het literatuuronderzoek zijn gebruikt om de veiligheidscultuurladder operationaliseerbaar te maken voor het UMCG. Hiervoor is gebruik gemaakt van interviews met 3 afdelingen binnen het UMCG en met 5 andere, Nederlandse UMC's. Deze interviews zijn gebaseerd op het theoretische raamwerk volgend uit het literatuuronderzoek. Verschillende stakeholders zijn geïnterviewd: artsen, verpleegkundigen, managers en leden van de Decentrale Incidenten Meldingscommissie van de afdelingen chirurgie, kindergeneeskunde en interne geneeskunde. Ook is de organisatiestructuur van het UMCG vergeleken met andere UMC's in Nederland. Zo wordt er niet alleen op afdelingsniveau naar het UMCG gekeken maar ook op organisatieniveau.

Uit de interviews is gebleken dat alle 3 de geïnterviewde afdelingen in de fase van reactief naar calculatief gaan. Samenwerking binnen de afdeling, tussen afdelingen onderling en tussen verschillende ziekenhuizen kan en moet worden verbeterd. Een begin hiervan is het decentraliseren van incident analyse en het implementeren van een nieuw incident meldingssysteem. Dit nieuwe meldsysteem moet het vergelijken en delen van incidenten gemakkelijker maken. Ook kan het nieuwe meldsysteem bijdragen aan automatische trendanalyse. Verder is gebleken dat er veel verbetervoorstellen worden bedacht, maar dat de uitvoering hiervan sterk achterblijft. Er zal dus duidelijker een verantwoordelijke voor de uitvoering moeten worden aangewezen op de werkvloer. De algemene verantwoordelijkheid voor verbetermaatregelen blijft wel bij het afdelingshoofd. Bijna-incidenten worden nog nauwelijks gemeld binnen het UMCG. Van bijna-incidenten valt veel te leren, dus is het belangrijk dat dit extra onder de aandacht wordt gebracht.

Abstract

A national white decision in 2008 in the Netherland was the starting point of new measurements in the field of patient safety. The target contains a 50% decrease in medical errors.. This national decision was accompanied by several improvement measurements. One of these measurements is the introduction of a mandatory incident reporting system in every hospital. This reporting system may lead to more insight in the number and origin of medical errors.

The University Medical Center in Groningen (UMCG) introduced a hospital wide incident reporting system in 2008. This system helped learning from incidents and increased patient safety. The system was based on experience, common sense and national requirements. De safety culture ladder of Parker & Hudson was used as inspiration. The UMCG is striving to increase on higher levels of the ladder aimed to improve patient safety. The questions are 1) whether all the measurements during the past years lead to a improved patient safety, 2) whether the model of Parker&Hudson was the right inspiration model and 3) what further improvement measurements for the UMCG may be.

An extensive literature review shows safety principles from aviation industry which are also used in healthcare. Comparing literature with daily practice in the UMCG, shows an important gap. In literature no practical or specific instrument is described for assessing current state of patient safety or improving patient safety in hospitals; only end terms are described. The most important similarity between literature and practice is the need of a constructive model for improving patient safety. The five different levels of the safety culture ladder are described by Parker&Hudson as *pathological – reactive –calculative – proactive – generative.* The steps between the levels of this safety culture ladder not specific enough , therefore extra steps are introduced. For each level five extra steps are added: *acknowledgement – no blaming and shaming – incident reporting – incident analysis – improvement measurements.*

Results following literature review and the case description of UMCG are combined in order to make the safety culture ladder useful in daily practice in the the UMCG. Three departments within the UMCG are interviewed, as well as 5 other, Dutch, UMCs. These interviews are based on the theoretical framework following the literature review and are checked by an expert panel. Different stakeholders are interviewed in the departments surgery, pediatrics and internal medicine covering the following functions: doctors, nurses, managers and DIM (Decentralized Incident reporting Commission)-members. Also the organizational structure of the UMCG is compared to other Dutch UMCs. Not only at department level patient safety is reviewed, also on organizational level.

Surgery, Pediatrics and Internal Medicine are located between reactive moving up to calculative at the patient safety ladder. Collaboration within the department and with other departments should be improved. Important aspects are decentralizing of incident analysis at larger departments and introducing a new hospital wide incident reporting system. This new reporting system should support easy sharing of incidents and comparing with other departments. Also trend analysis should be one of the features.
Improvement measurements are proposed, but not carried out well enough. This means that responsibility should be divided to nurses or doctors. The head of the department should monitor the general progress of the implementation. Near-incidents are hardly reported. Because of the learning aspect of near-incidents, this should be explained, promoted and more stimulated at the departments.

Table of contents

Abbreviations

UMC University Medical Center

UMCG University Medical Center Groningen

IMS Incident Meldingsysteem
IRS Incident Reporting System

CIM Centrale Incidenten Meldingscommissie;
Central Incident Management-commission

DIM Decentrale Incidenten Meldingscommissie;
Decentralized Incident Management-commission

SAQ Safety Attitude Questionnaire

CQ Consumer Quality (Index)

NIVEL Nederlands instituut voor Onderzoek van de Gezondheidszorg;
Dutch institute for health care research

1 Introduction

1.1 Context of the research

From 2008 onwards, Dutch hospitals have been prioritizing the reduction of medical errors, with the aim to reduce all avoidable damage by 50% in five years. The national attention on this subject triggered extra focus and studies on organizing patient safety in the Netherlands. A national report with guidelines for patient safety was published. Medical specialists, nurses and other healthcare workers also introduced improvement measures in their own hospitals. (Langelaan et al., 2013)

Patient safety is seen as an important contribution to the quality of care. The definition of patient safety is 'the absence of (the chance of) possible harm (both physical and mental) which is caused by not following the professional standards by health care providers and/or a lacking health care system' (Smits, Christiaans-Dingelhoff, Wagner, Wal, & Groenewegen, 2007).
The publication of 'To Err is Human' in 2000 created a worldwide increased focus on patient safety (Kohn, Corrigan, & Donaldson, 2000). This report was based on preventable medical errors that every year lead to almost 100,000 deaths in hospitals in the United States. These preventable medical errors are not only a hot issue in the US, all over the world the report 'To Err is Human' has led to new insights and campaigns aimed at increasing safety.

One of the steps towards higher patient safety is reporting and learning from incidents (Mahajan, 2010). Incident Reporting Systems (IRS) originate from high risk industries such as railways and aviation. The systems are used to report, analyze and learn from incidents in order to increase safety (Mahajan, 2010). Flanagan describes the first IRS developed in the 1940s which was used as a technique for improving the safety of military pilots (Flanagan, 1954). In 1978 the first IRS for health care issues was reviewed by Cooper et al., it focused on preventing incidents by anesthetists (J. B. Cooper, Newbower, Long, & McPeek, 1978).

An evaluation of the impact of 'To Err is Human' after five years showed slow improvements and an enormous increase of new reporting systems (Leape & Berwick, 2005). The developed systems varied significantly; from national centralized systems to local decentralized systems, and from mandatory to voluntary systems. With improving safety as a primary goal, voluntary systems are recommended (Wu, Pronovost, & Morlock, 2002). For effectively increasing patient safety also reporting near-misses appears relevant (Rivard, Rosen, & Carroll, 2006), because the underlying cause of the near-misses can in future lead to serious injuries (Wu et al., 2002).

This report will describe a literature review about patient safety, safety principles and risk management in health care. The literature review is the base for further research in the field of patient safety in university medical centers in the Netherlands. This research is performed at the University Medical Center (UMC) Groningen, one of the eight university medical centers in the Netherlands. The UMCG introduced a voluntary Incident Reporting System (IRS) in 2008. Many initiatives for improving patient safety are introduced. During the past five years, the number of reports increased from 1042 (in 2008) to 4971 (2013).

1.2 Problem description

In daily practice, the UMCG complies with legal requirements and recommendations from the IGZ and Dutch authorities concerning incident reporting and patient safety.
In the current situation several systems in the UMCG are keeping track of information; incidents are reported and recorded in the IRS, the safety attitude of the employees (Safety Attitude Questionnaire) is measured just like the safety perception of the patients (Consumer Quality index).
There is input available for determining the current state of the safety performance, but due to absence of a good method for measuring this is not done yet.

1.3 Research objective

The objective of this research is to guide the departments of the UMCG to a higher safety performance level, by developing a safety evaluation instrument that helps university medical centers in the Netherlands to keep track of safety performance. The instrument will be developed by using a combination of quantitative and qualitative data.

1.4 Research scope

With the UMCG as problem owner, the research is focused on situations and departments within the UMC. This means an extensive study of data from the UMCG has been made, with interviews complementing the available data.
The model and improvement measures following from this research will at least be relevant for the UMCG, but involving other UMCs should expand the utility of the model.

1.5 Research questions

1.5.1 Central question

How can risk management systems be used in order to improve patient safety?

1.5.2 Sub questions

Literature review: What is patient safety, what is risk management in health care and which safety models are available?

Case research: How is the UMCG organized concerning incident reporting and patient safety, and how is the safety culture ladder used? What is the meaning of the available data (IRS, SAQ and CQ)?

Analysis: Which conclusion can be drawn by comparing the literature review and case research?

Interviews: What do the different stakeholders in the UMCG think about patient safety and risk management? How do other UMCs organize a safe patient environment?

1.6 Outline

The first part of the study describes the differences between lessons learned from literature, based on safety principles of other industries and patient safety in the UMCG. The only model that is used by the UMCG (safety culture level - (Hudson, 2007)) needs better scientific support that will follow from the literature review.

For a better understanding of patient safety in the UMCG, different interviews will be performed. The interviews complement the theoretical framework of the first part of this research.

The research result is a clear model for determining the status of patient safety culture for general use, with practical implications for the UMCG. The recommendations consist of steps towards higher patient safety.

2 Methodology

For the literature review PubMed is used as database. Fields of safety models, quality assurance and risk management are studied, resulting in 23 useful articles. The UMCG is described as the case study for this research and relevant available information - incident reporting rates, safety attitude questionnaire, and consumer quality index - is reviewed. The case description will be combined with the literature review results in order to create a well supported safety evaluation instrument for guiding and analyzing patient safety improvements.

2.1 Literature search

A literature review is performed in order to create the theoretical framework around patient safety, safety models, risk management and incident reporting.

PubMed is used for the literature review, because PubMed contains articles from all medical journals. Important domains for searching literature are:

1. Patient safety
    - Safety model
    - Quality assurance
2. Risk management
    - Incident reporting

Mesh-terms (Medical Subject Headings) are used to expand the search terms. Mesh terms were useful for 'patient safety' and 'risk management'.

Inclusion of the articles was based on the following criteria:

3. Text availability: Abstract available
4. Publication date: >2000
5. Languages: English
6. Species: Humans

The first search resulted in 1713 articles.

The second selection was based on evaluating the titles. Articles focused on improving a specific treatment, identification of risk factors of new medical devices, analyzing specific hazardous situations such as medication errors or fall incidents, improving curricula of medical education, improving contribution of patients in reporting incidents or research focused on other areas than hospitals (for example: dental practice or home care) were excluded. Based on the abstract, 226 articles remained for further research.

These 226 abstracts were read with a focus on 'improving safety', 'measuring safety', 'safety models', 'comparable industry' and 'review of relevant literature'. This resulted in 17 useful articles (go to Chapter 2 - Literature study for an overview).

Web of Science was also consulted for data about risk management and safety management in other industries. The articles found were sorted based on the number of citations; the first 50 titles were reviewed. Many articles focused on industries were not comparable with

PubMed: ("Patient Safety"[Mesh] OR patient safety[tw] OR safety model*[tw] OR quality assurance[tw]) AND ("Risk Management"[Mesh] OR risk management[tw] OR incident* AND report*[tw])

Figure 1: Literature search query PubMed

healthcare. Although the main part was not useful, a few articles could have been selected for an extension of the theory about safety management.

Snowball sampling is used within the UMCG. This technique allows the researcher to ask respondents for literature about the subject, in this study 'organization of patient safety and risk management'. The result of this snowball sampling technique was the article by (Hudson, 2007) about the safety culture model. *Chapter 3.1 gives an overview of all literature used for this study.*

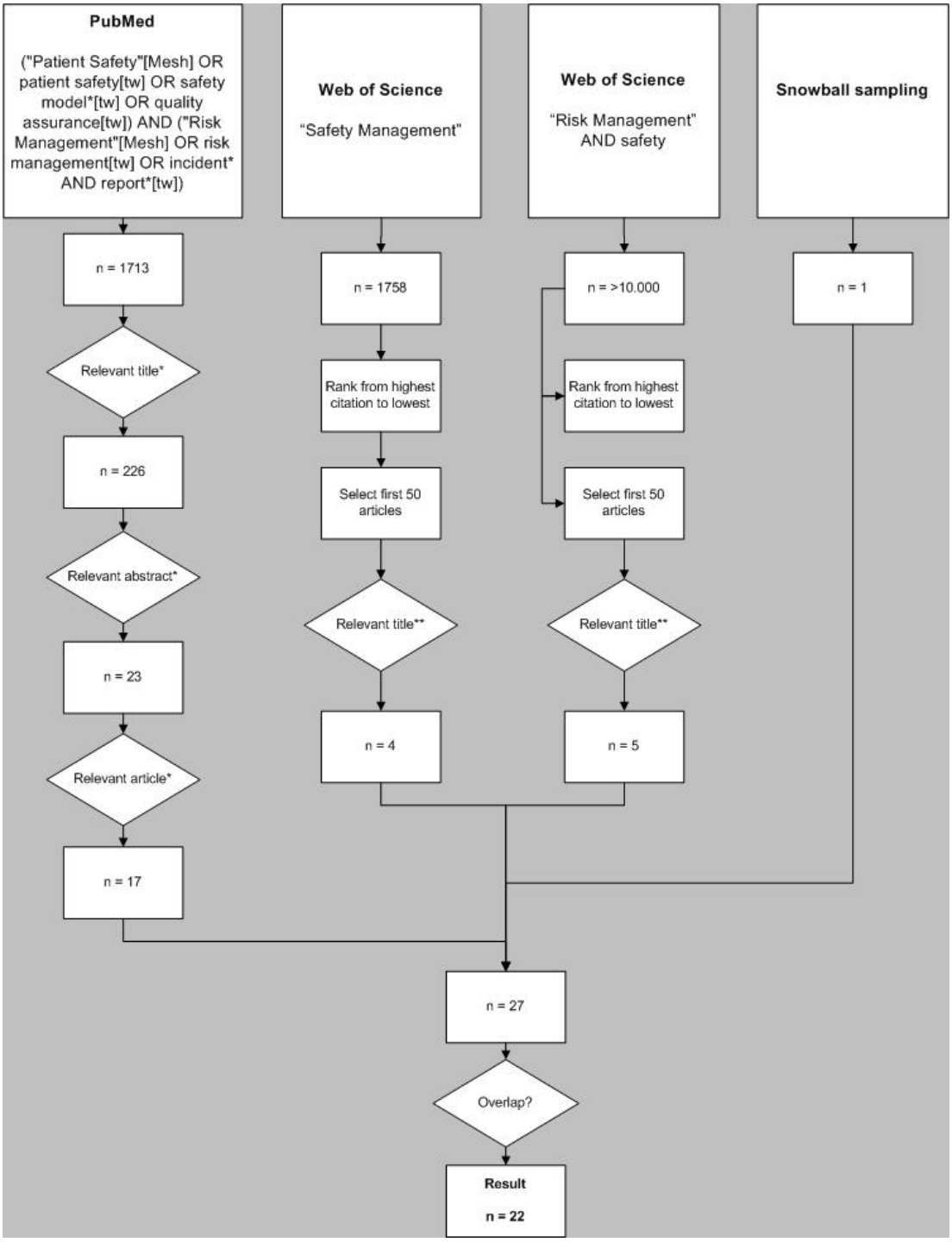


Figure 2: Overview of literature search

2.2 Case research

Methodology: Currently the UMCG is using the safety culture ladder (Hudson, 2007) as an inspirational method for assessing patient safety. The objective of this research is to extend this model in order to make it useful and applicable for the UMCG. Instead of an inspirational model it should be a guideline to measure patient safety and stimulate measures for improvement. The extension of a model with existing literature, followed by interviews, is called theory building and therefore case research is a suitable design (Bhattacherjee, 2012) .

An important step of case research is to decide on the appropriate unit of analysis (Bhattacherjee, 2012). This research is focused on patient safety, risk management and safety models. Therefore relevant information is needed to get insight into UMCG practices. General information about the organization of risk management and patient safety is gathered from the annual reports of the CIM (Central Incident Management commission) (Centrale Incident Meldings-commissie, 2012; Centrale Incident Meldings-commissie, 2013).

- IRS data: (The Patient Safety Company, 2014)
  The Incident Reporting System provides data about the number of incidents reported, by who (function) and risk number. This can be reviewed for the UMCG as a whole and for every department or DIM. Incident reporting is organized in the CIM-DIM structure, therefore incident reports will be reviewed per DIM (as defined in the system).
- SAQ: (Effectory, 2012)
  The employee survey in 2009 and 2012 contain parts about safety. These parts reflect the perception of the UMCG employees on safety; these numbers will be reviewed (both for 2009 and 2012). The research was performed by an external company and the results were presented to and published for the UMCG.
- CQ index: (NFU, 2013)
  Patients that stayed at least one night at the UMCG were asked about their perception of safety. The research was performed by the Dutch Federation of UMCs and a report was published for the UMCG. The results for the UMCG are reviewed.

In a multiple case analysis, a combination of qualitative and quantitative data will be used (Bhattacherjee, 2012). The quantitative data as described above (IRS, SAQ and CQ) is complemented with qualitative data from interviews with the relevant stakeholders of three different departments. Three different departments within the UMCG will be reviewed with interviews. The departments of Internal Medicine, Surgery and Pediatrics were chosen because of the availability of all three types of quantitative data. Also the size and organization (wards as well as policlinics; same type of employees/functions) are comparable. The comparison will be on the departmental (internal) level: how is incident reporting organized and how is patient safety improved? UMCG as a case will also be compared to other reviewed UMCs on the organizational (external) level.
The relevant stakeholders for the interviews are determined based on their function. For every department five interviews will be organized, Table 1.

Stakeholders for interviews	
Internal	***External***
2 Nurses	CIM responsible
Clinical manager[1]	
DIM member	
CIM responsible	

Table 1: Stakeholders for interviews
DIM = Decentralized Incident Management-commission
CIM = Centralized Incident Management-commission

The stakeholders are representative of the involved employees. Table 2 gives an overview of the different tasks and associated functions. The total 20 interviews can be found in Table 3.

	Patient care and/or treatment	**Incident reporting**	**Incident analysis**	**Encourage reporting**	**Implementing measurements**	**Measurement evaluation**
Nurse	x	x				
Doctor	x	x				
Management				x		X
DIM			x	x	x	x

Table 2: Overview stakeholder and responsibilities
DIM = Decentralized Incident Management-commission
CIM = Centralized Incident Management-commission

		# DIM	**# Clinical manager**	**# Nurse**	**# CIM**	***Total***
Intern	Internal medicine	1	1	2	1	5
	Surgery	1	1	2	1	5
	Pediatrics	1	1	2	1	5
Extern	UMC 1					1
	UMC 2				1	1
	UMC 3				1	1
	UMC 4				1	1
	UMC 5				1	1
Total		*3*	*3*	*6*	*7*	*20*

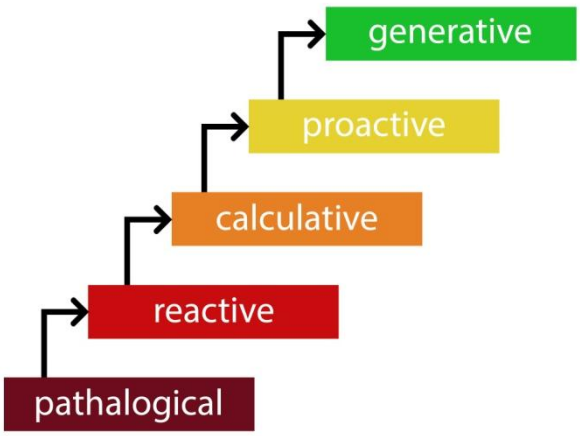
Table 3: Overview of interviews
DIM = Decentralized Incident Management-commission
CIM = Centralized Incident Management-commission
UMC = University Medical Center

[1] In several functions at the departments, healthcare givers (nurses as well as doctors) combine their care giving tasks with management tasks. For the privacy and anonymity of this person, the exact profession is only known by the researcher and supervisors.

2.3 Safety evaluation instrument

This paragraph describes the instrument that is used in this study and provides a preview of the literature study. Literature is used to give the instrument a substantial support and interviews will be performed in order to give insight into the characteristics of the different levels of the safety culture ladder.

The model that is used in the UMCG is the safety culture ladder of Parker and Hudson, Figure



3Figure 3.

Figure 3: Original safety culture ladder - one step between each level (Parker & Hudson)

As stated in literature (see: Chapter 3) levels of the safety culture ladder are a chain of the same continuous processes. The same characteristics should be evaluated for every level. The characteristics are (Wilf-Miron, Lewenhoff, Benyamini, & Aviram, 2003):

1. Acknowledgement
2. No blaming and shaming with incidents
3. Incident reporting
4. Analysis of incident reports and near-miss reports
5. Prevention/improvement measures

Every characteristic will be called a different stage between two different levels. That means that when you want to climb up from 'pathological' to 'reactive', you need to fulfill the five steps mentioned above. This can be seen as a small ladder within the ladder. The figures below demonstrate the changes in the safety culture ladder.

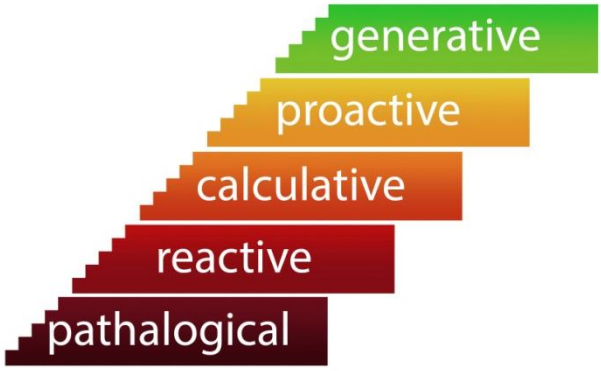


Figure 4: Adjusted safety culture ladder - five steps in every level

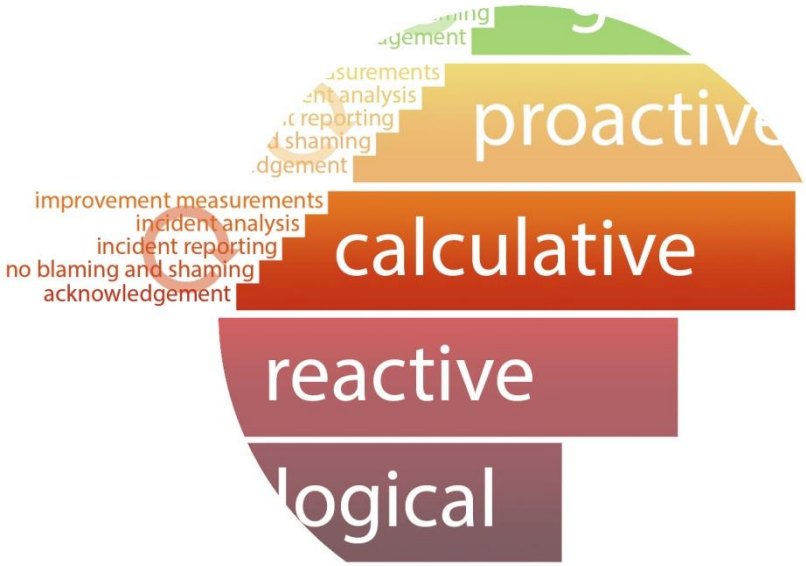


Figure 5: Adjusted safety culture ladder – details.

The continuity process that is needed for successful safety improvement has to be implemented in every single step of the ladder. Figure 6: Adjusted safety culture ladder - PDCA cycle shows this for the improvement measurements step. After a cycle of plan-do-check-act, the next plan-step can be the beginning of a higher step on the ladder.

For example, after finishing the PDCA cycle of 'improvement measurements' on the level 'calculative', the beginning of the next step is planning the 'acknowledgement' of level 'proactive'.

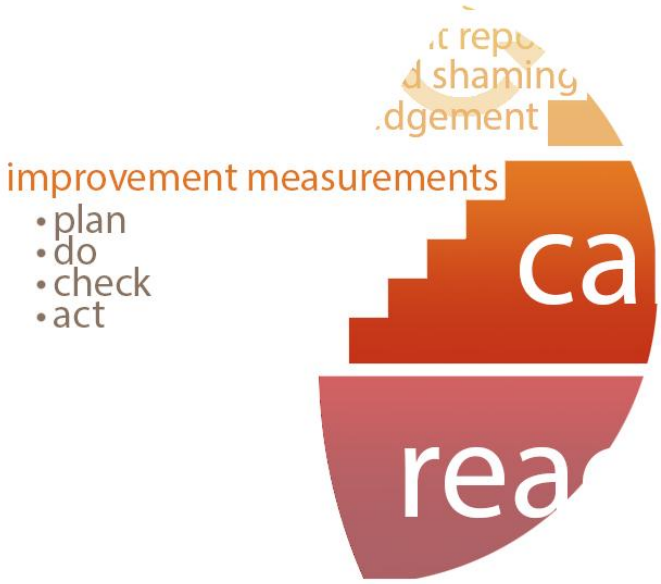


Figure 6: Adjusted safety culture ladder - PDCA cycle

2.4 Analysis

The literature review will be combined with the case research in order to adjust the safety culture ladder (Hudson, 2007); this is the theory building part. To make the theory applicable for the specific situation in the UMCG, interviews are needed; this chapter will form the framework for the interview questions based on both the literature review and case research.

According to (Bhattacherjee, 2012) data from interviews are best analyzed using grounded theory, which was originally developed by Glaser and Straus in 1967. The analysis consists of three phases: Open, Axial and Selective coding.

The goal of open coding is: "a process aimed at identifying concepts or key ideas that are hidden within textual data, which are potentially related to the phenomenon of interest (Bhattacherjee, 2012)". Interviews are recorded and the textual transcriptions will be coded, with reference to the different categories that will be identified at the end of Chapter 3. Constructs found in literature are used to name the categories (Bhattacherjee, 2012). Below the categories are named, they will be further explained in Chapter three:

- Composition of DIM
- Collaboration with (other) department(s)
- Incident reporting
- Incident analysis
- Improvement measurements
- Relationship to patients
- Data about safety

The results from the interviews will help theory building. For every category, characteristics and dimensions will be identified, patterns will be found within the categories (Bhattacherjee, 2012).

Axial coding is the next phase, which is needed to form causal relationships or hypotheses about patient safety (Bhattacherjee, 2012) , the subject of this research. This type of coding will be performed simultaneously with open coding. This phase will lead to the start of theoretical

propositions (Bhattacherjee, 2012), explaining what conditions are needed for the best possible organization of patient safety. The last phase of the grounded theory is selective coding, where a link between the categories should be created (Bhattacherjee, 2012). If necessary new data can be sampled and added, but for this research that was not necessary.
Data analysis is finished when theoretical saturations have been reached (Bhattacherjee, 2012), in this research the chapters Conclusion and Recommendation will describe the conclusions from theory, practice and interviews and recommendations in the field of theory building as well practical recommendations for the UMCG.

3 Literature study

Table 4 gives an overview of the 21 articles that have been reviewed. The first ten articles are all about safety improvement, two articles display relevant overviews of different articles, five articles are focused on measuring safety, one article is interesting for defining the term of error, and three articles give insight into comparing healthcare with other high risk industries.

	Author	*Title*	*Publication year*	*Reason for selecting*	*Subject*
1	Allen S, Chiarella M, Homer CS	Lessons learned from measuring safety culture: an Australian case study.	2010	Safety improvement	Combining qualitative and quantitative data give advantages when measuring safety culture.
2	Anderson JE, Kodate N, Walters R, Dodds A	Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting.	2013	Safety improvement	The importance of voluntary and anonymous reporting systems is described. Higher contribution of clinicians lead to higher levels of knwoledge and owner-ship of the incident reportign system.
3	Anderson JG, Ramanujam R, Hensel D, Anderson MM, Sirio CA	The need for organizational change in patient safety initiatives.	2006	Safety improvement	Improvement is always a continous process.
4	Berwick BW	A user's manual for the IOM's 'Quality Chasm' report.	2002	Safety improvement	Four different levels in healthcare need to be changed in America: experience of patients, functioning of

					microsystems, functioning of organizations, environment of policy.
5	Cooper MD	Towards a model of safety culture.	2000	Safety improvement	Safety culture is defined as a sub-facet of organizational culture.
6	Helmreich, R.L.	On error management: lessons from aviation.	2012	Safety improvement	Safety principles described in aviation indurstry
7	Hogan H, Olsen S, Scobie S, Chapman E, Sachs R, McKee M, Vincent C, Thomson R	What can we learn about patient safety from information sources within an acute hospital: a step on the ladder of integrated risk management?	2007	Safety improvement	Collaboration between departments increases the usability of data collected in the hospital.
8	Isaac T, Jha AK	Are patient safety indicators related to widely used measures of hospital quality?	2007	Safety improvement	Different safety indicators are not related to measures of hospital quality. The measures of hospital quality are more focused on medical causes in stead of organizational processes.

9	Mahajan RP	Critical incident reporting.	2010	Safety improvement	Incident reporting is one of the keys in improving safety; under-reporting is one of the biggest threats.
10	Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM	Promoting a culture of safety as a patient safety strategy: a systematic review.	2013	Safety improvement	As a patient safety strategy a culture of safety should be promoted.
11	Clarke S	The relationship between safety climate and safety performance: a meta-analytic review.	2006	Review of relevant literature	Safety climate surveys for assessing organizational safety performance are very useful.
12	Stelfox HT, Palmisani S, Scurlock C, Orav EJ, Bates DW	The 'To Err is Human' report and the patient safety literature.	2006	Review of relevant literature	After 2000 the number of articles about increasing patient safety increased; a stron focus on prevention of mistakes and errors
13	Colla JB, Bracken AC, Kinney LM, Weeks WB	Measuring patient safety climate: a review of surveys.	2005	Measuring safety	Different models vor safety climate are proposed.
14	Jackson J, Sarac C, Flin R	Hospital safety climate surveys: measurement issues.	2010	Measuring safety	Safety climate surveys are integrated in several management systems of hospitals.

15	Miller MR, Elixhauser A, Zhan C, Meyer GS	Patient Safety Indicators: using administrative data to identify potential patient safety concerns.	2001	Measuring safety	Patient Safety Indicators are developed for quality improvement. Besides incident reporting systems, this is also useful for determining medical errors.
16	Noble DJ, Pronovost PJ	Underreporting of patient safety incidents reduces health care's ability to quantify and accurately measure harm reduction.	2010	Measuring safety	Under-reporting causes are divided over structure, process, outcome, attituteds, fears-public and fears-medical.
17	Wakefield JG, Jorm CM	Patient safety - a balanced measurement framework.	2009	Measuring safety	Five different components of patient safety exist: safety learning, safety action, safety performance, patient experience and staff attituted and behaviour.
18	Hofer TP, Kerr EA, Hayward RA	What is an error?	2000	Definition	A medical error is a failed process that has rigorously demonstrated to cause an adverse outcome
19	Bagian JP	Patient safety: lessons learned.	2006	Comparison with other industry	Healthcare is a high-reliability organization.

20	Mearns K, Whitaker SM, Flin R	Safety climate, safety management practice and safety performance in offshore environments.	2003	Comparison with other industry	The importance of safety climate, explained in offshorre indudstry
21	Wilf-Miron R, Lewenhoff I, Benyamini Z, Aviram A	From aviation to medicine: applying concepts of aviation safety to risk management in ambulatory care.	2003	Comparison with other industry	Concepts of risk management from aviation are translated to healthcare.
22	Hudson, P	Implementing a safety culture in a major multi-national .	2007	Safety culture	Explaining the five steps of safety culture ladder

Table 4: Literature review

3.1 Patient safety

What is patient safety?

The famous report 'To Err is Human' by the Institute of Medicine in the United States was published in 2000. This report was the beginning of a changing attitude towards healthcare and patient safety. The report described the high number of medical errors that lead to death, which was shocking for many patients and healthcare professionals. The report focused on building a safer health system, instead of blaming the healthcare professionals for committing mistakes.

After the year 2000 the number of articles intending to increase patient safety increased. Articles published after 2000 differ in subject compared to articles published before 2000. Before 2000 the main subject of patient safety literature was 'malpractice', which means it had a strong focus on mistakes and errors. After 2000 the focus went from 'malpractice' to 'organizational culture', meaning that the feeling of blaming and shaming disappeared over time. This shift in literature subjects again emphasizes the impact of the 'To Err is Human' report. The year 2000 can be seen as the turning point in health care all over the world, from then on attention was paid to improving patient safety, learning from and reducing errors instead of speaking about malpractice. (Stelfox, 2006)(Stelfox, Palmisani, Scurlock, Orav, & Bates, 2006)

Shortly after the publication of 'To Err is Human', a report about definitions of errors was published. The definition of the IOM (publisher of 'To Err is Human') was: *'the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)'*.

The article by (Hofer, Kerr, & Hayward, 2000) suggests this definition might be too broad. Therefore it reviewed different medical and non-medical literature to create a new definition of errors in healthcare: '*medical error should be defined in terms of failed processes that have been rigorously demonstrated to cause adverse outcomes'*. (Hofer et al., 2000)

A medical error is a failed process that has rigorously demonstrated to cause an adverse outcome (Hofer et al., 2000)***.***

3.2 Risk management

What is risk management in healthcare?

(Bagian, 2006) describes healthcare as a high-reliability organization. 'High-reliability organizations are those that operate in an environment of high hazard but, from a statistical point of view, do not have mishaps where these hazards cause a tragedy. High-reliability organizations are those where lines of communication remain open so that whoever has a critical piece of information is expected to communicate it to whoever needs this information, unfettered by barriers of hierarchy, seniority, title, pay grade, gender or ethnic background.'

Another well known example of a high-reliability organization is the aviation industry. Aviation started risk management programs around 1950, health care followed almost 50 years later. Due to the similarities of both high-reliability organizations, healthcare can learn much from aviation.

'The primary objective of designing safe systems is to make it difficult for the individual to err' is the first sentence of the article by (Wilf-Miron et al., 2003), which describes the concepts of a risk management system in healthcare. Using the principles from aviation, the leading industry in risk management, healthcare can develop a risk management system that eliminates errors.

Key safety principles are:

1. Errors inevitably occur and usually derive from faulty system design, not from negligence;
2. Accident prevention should be an ongoing process based on open and full reporting;
3. Major accidents are only the 'tip of the iceberg' of processes that indicate possibilities for organizational learning.

Table 5 gives an overview of the safety principles that can be transformed from aviation to healthcare. The principles applied to healthcare give clear ideas of a risk management system. (Wilf-Miron et al., 2003)

(Helmreich, 2000) has the same ideas about the application of lessons learned from aviation to healthcare. He also underlines the similarities between aviation and healthcare. For managing safety three kinds of data are required: (1) confidential surveys to gain insight into organizational commitment to safety, appropriate teamwork and leadership; (2) non-punitive incident reporting systems; (3) an observational methodology that records threats to safety, errors and their management, and behaviors identified as critical in preventing accidents.

Application of aviation safety principles to medicine	
Aviation safety principle	**Application to medicine**
Error-free environments do not exist	Design of systems to absorb errors through redundancy, standardization and checklists
In most cases, errors do not result from negligence or discipline related problems but from faulty system design. "Pilot error is not all pilot"	Movement from placing blame to designing safe processes and procedures, i.e. applying a systems approach
Mishap reporting is aimed to encourage open and full reporting	Assurance of full immunity while implementing a non-punitive approach
Adverse event definition is a leading factor in organizational learning: major accidents are viewed as the "tip of the iceberg"	Debriefing of all events, including near misses, that have learning potential. Focus on the severity of the potential risk rather than on the severity of the event's final outcome is more conducive to establishing effective prevention programs
The prevention of accidents is a long-term ongoing process rather than an episodic effort	Institutionalization of a permanent program for risk identification, analysis, and dissemination of the lessons learnt throughout the professional community

Table 5: (Wilf-Miron et al., 2003)**- Application of aviation safety principles.**

A risk management system should be a strategy focused on reducing errors, in order to minimize the development of adverse outcomes (Wilf-Miron et al., 2003)***.***

In the overview of aviation safety principles by (Wilf-Miron et al., 2003) and (Helmreich, 2000) you can see the constructive structure. The safety principles start with acknowledgement and end with a long- term mission for improvement.

1. Acknowledgement
2. No blaming and shaming with incidents
3. Incident reporting
4. Analysis of incident reports and near-miss reports
5. Prevention/improvement measurements

Other results from the literature review are related to the safety principles acknowledgement, no blaming and shaming with incidents and incident reporting. They will be described below.

Ad. 1: Acknowledgement

The main reason why safety programs in aviation are successful is the acknowledgement of the safety issues. For healthcare, the first step to higher patient safety is therefore acknowledging that this problem exists (Bagian, 2006).

Ad. 2: No blaming and shaming with incidents

As a patient safety strategy, (Weaver et al., 2013) suggest promotion of the safety culture, based on a literature review. (M. D. Cooper, 2000) defines safety culture defined as a sub-facet of organizational culture. Safety culture is the attitudes and behavior towards safety in an organization, the concept of safety culture is characterized by shared thoughts and behaviors.

Weaver researched common strategies for improving safety culture and found that bundling multiple types of interventions (such as team training, communication initiatives, executive walkrounds, etc) gives the best result. All interventions can be directed back to leadership,

teamwork or behavior change, instead of a specific process, team or technology. (Weaver et al., 2013)
(Clarke, 2006) again underlines the popularity of using safety climate surveys for assessing organizational safety performance. Industries such as the chemical, nuclear processing, manufacturing and service industries show positive results when it comes to reducing accidents.

An Australian article studies the use of interviews and surveys for understanding the safety culture, because they believe that full understanding of the safety culture of an organization is necessary for improving patient safety. Safety culture consists of five different domains: safety climate, teamwork, job satisfaction, perception of management and stress recognition. All these domains are studied, using the Safety Attitude Questionnaire (SAQ), semi-structured interviews and a policy audit and mapping of the key policies influencing safety culture. The main finding of this study was the advantage of combining qualitative and quantitative data when measuring safety culture. (Allen, Chiarella, & Homer, 2010)
Following the article by (Hogan et al., 2008), the usability of data collected in the hospital increases through collaboration between departments and triangulation of systems. Information sharing should be stimulated, and therefore leadership by senior managers is vital to promote a stimulating culture instead of shaming and blaming. “Incident reporting systems alone can never be relied upon to provide a comprehensive picture of patient safety” (National Patient Safety Agency, UK) .

Ad. 3: Incident reporting
(J. E. Anderson, Kodate, Walters, & Dodds, 2013) study the influence of incident reporting on safety improvement by examining the vision of different health care professionals. Their study describes the characteristics of incident reporting systems and underlines the importance of voluntary and anonymous systems. The study found that incident reporting was perceived by most staff as having a positive effect on safety, not only by leading to changes in care processes, but by changing staff attitudes and knowledge. Although there is a perceived positive effect, the researchers found that improving safety in healthcare by using incident reporting is difficult. Incident reporting is described as a process of several steps: report, investigation, implementation of actions, evaluation of actions and feedback to staff. The third important finding is that the organization of the incident reporting systems should be focused on implementing clinicians in reviewing teams. Higher contributions by clinicians lead to higher levels of knowledge and ownership of the incident reporting system. (J. E. Anderson et al., 2013)

(Mahajan, 2010) sees incident reporting as one of the keys to improving safety, but the system is under-utilized in health care systems. Under-reporting is one of the biggest threats to the incident reporting system, and different reasons for this are mentioned. The attitude of doctors results in lower incident reporting rates. Also the lack of feedback discourages users of incident reporting systems. This feedback is most important when it is desired to learn from incidents. “Any effort to improve incident reporting and learning should begin with assessment of prevailing safety culture within an organization, and long-term, sustained program of improving it". (Mahajan, 2010)
Noble underlines the importance of reporting again by researching the influence of under-reporting. Under-reporting causes a lack of quantifiable and accurate data, which makes improvement monitoring almost impossible. This under-reporting can be caused by several factors, which can be seen in Figure 7.

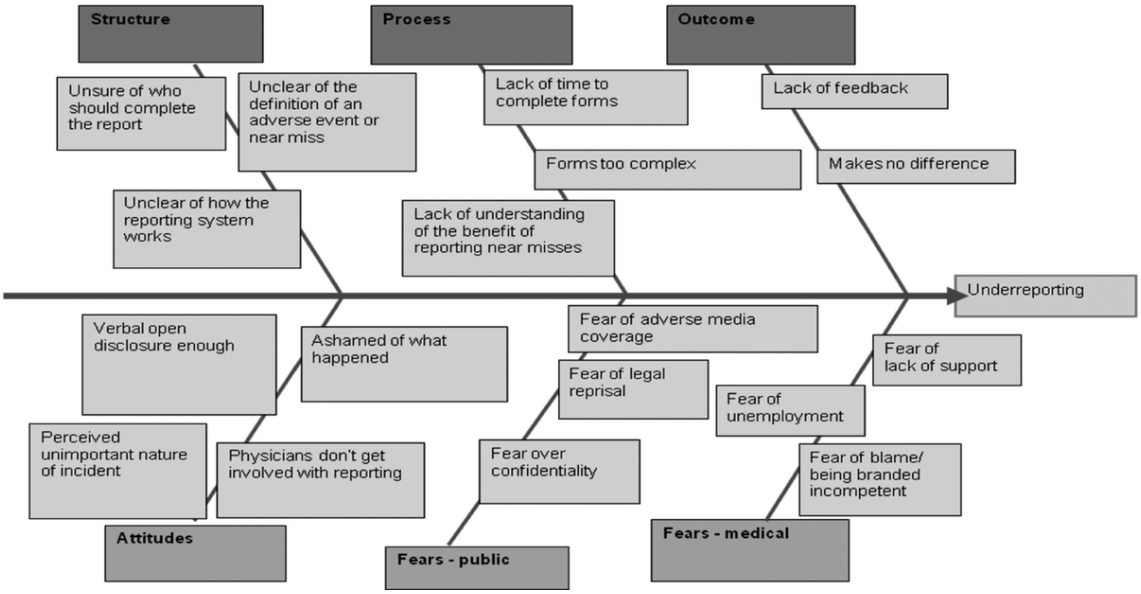


Figure 7: (Noble & Pronovost, 2010) **- Factors for under-reporting**

All the different sources that might lead to under-reporting are threats to the optimal system for patient safety; attitude-threats influence step 1-3 from Wilf-Miron et al., (2003), fears-threats influence step 3, structure-threats influence step 1 and 2, process-threats influence step 3 and outcome-threats influence step 4 and 5.
The different threats (Noble & Pronovost, 2010) combined with the safety principles (Wilf-Miron et al., 2003) give a good overview of aspects that should be minimized.
For the analysis of incident reports, near-incident reports and prevention/improvement measurements, there was no extra information found within this literature review.

Ad 4. Analysis of incident reports and near-miss reports
PRISMA is the abbreviation of Prevention and Recovery Information System for Monitoring and Analysis. PRISMA as a risk management tool that is used in steel industry, energy production and also healthcare. The focus of this incident analysis tool is on safety consequences. Important is that almost never only one flaw causes an incident, usual it is a chain of flaws that causes the incident. (Schaaf, 1996) This PRISMA method is recommended by the Dutch government for incident analysis.

Ad 5. Prevention/improvement measures
A good analysis technique such as PRISMA, should lead to improvement opportunities. (Schaaf, 1996) The improvement measures are the key to learning from incidents. (Mahajan, 2010)

3.3 Measuring patient safety

How is patient safety measured?
According to (Wakefield & Jorm, 2009), five different components of patient safety exist: safety learning, safety action, safety performance, patient experience and staff attitudes and behavior. The different components have different measuring opportunities. Figure 8 gives an overview of the different measurement domains and the corresponding measures.

2 Balanced Patient Safety Measurement Framework

Measurement domain	What this measure is best for	Measurement source	What this measure cannot do	Use of this measure in Australia
Safety learning	Understanding *why* incidents occur	Incident reports Incident analysis findings Claims data	Determine safety performance (reported incidents actual incidents)	Well established
Safety action	Determination of whether the *corrective action* is being performed	Compliance audits of specific patient safety initiatives (eg, observation audit of handwashing)	Determine whether the action has led to improved safety (implementing a strategy does not guarantee improved safety)	Poorly established
Safety performance	Determination of true adverse event or injury *rate*	Coded medical record data for hospital acquired injury Trigger tools Standardised mortality data and variable life adjusted displays (VLADs)	Determine the underlying causes for incidents (merely knowing adverse event rate does not contribute to improved safety)	Variable
Patient experience	Understanding whether patients *feel safe* and trust health care staff and health care system and measuring patient reported harm	Patient surveys Complaints and compliments Online patient rating systems	Determine safety performance (feeling safe is important but is not necessarily equated with low rates of harm)	Variable
Staff attitudes and behaviour	Understanding organisational safety culture	Staff safety culture measurement tools (eg, Safety Attitude Questionnaire [SAQ]; Manchester Patient Safety Framework [MaPSaF])	Determine safety performance	Variable

Figure 8: (Wakefield & Jorm, 2009) **- Balanced Patient Safety Measurement Framework**

This model shows different steps that were already identified by (Wilf-Miron et al., 2003) and (Helmreich, 2000), from safety performance to safety learning and safety action. Staff attitudes and behavior reflect the safety culture part and thus the 'no blaming and shaming' step. A new element in this overview, and not a part of the literature reviewed before, is the patient experience. This has been ignored in all previous models. Everything was focused on the process within the hospital, but none of the articles focused on the patients' feelings of safety.

Safety performance – Safety learning – safety action

(Berwick, 2002) describes four different levels that need to be changed in American health care. This follows the reports published by the IOM with the call for improved patient care. The four levels are:

1. The experience of patients;
2. The functioning of small units of care delivery ("microsystems");
3. The functioning of the organizations that house or otherwise support microsystems;
4. The environment of policy, payment, regulation, accreditation, and other such factors.

The levels 2, 3 and 4 directly influence the outcome of level 1, therefore the first level is always the most important level to measure the outcome. All efforts put into improving healthcare should be reflected on level 1, the patient's experience. (Berwick, 2002)

(J. G. Anderson, Ramanujam, Hensel, Anderson, & Sirio, 2006) emphasize that improvement is always a continuous process. The steps in the overview model of Anderson correspond to the steps 3, 4 and 5 of the safety principles of (Wilf-Miron et al., 2003).
(J. G. Anderson et al., 2006) acknowledge the importance of organizational change when hospitals want to achieve a higher level of patient safety. Figure 9 shows the continuous patient safety improvement chain that is suggested. Solutions focused on individuals are often proposed, but only organizational changes will help to improve patient safety. This is concluded because individual mistakes are not the only cause of medication errors (the field studied in this article), the organizational context seemed much more important.
The article also suggests a mismatch between patient safety goals and hospital actions to reduce the risk of future medication errors. A growing number of voluntary incident reporting systems are being introduced, while organizational change focused on increasing patient safety is often neglected.

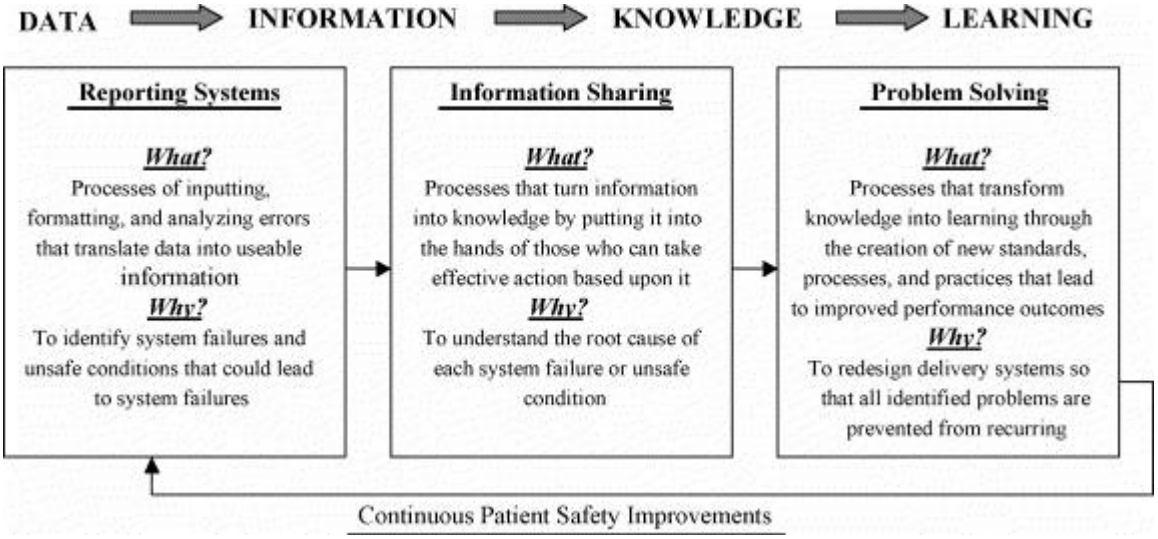


Figure 9: (J. G. Anderson et al., 2006) **- Continuous Patient Safety Improvements**

3.4 Conclusions from literature review

Increasing patient safety needs a decrease of medical errors; risk management can be a tool in order to enhance the safety system and thus reduce errors.

Different models and theories about patient safety define different steps that should lead to better patient safety. There is no one single step to reach optimal patient safety, but this is as expected. The different steps that should lead to the patient safety environment are based on (Wilf-Miron et al., 2003):

1. Acknowledgement
2. No blaming and shaming with incidents
3. Incident reporting
4. Analysis of incident reports and near-miss reports
5. Prevention/improvement measurements

As mentioned by (Berwick, 2002), the patients' experience should be top priority for hospitals when effort is put into improving healthcare. Patients' experiences should be an outcome measurement.

Both (Wilf-Miron et al., 2003) and (J. G. Anderson, Ramanujam, Hensel, Anderson, & Sirio, 2006) emphasize the importance of a continuous cycle when it comes to improvement measures: data -> information -> knowledge -> learning.

When applying this continuous improvement cycle to the three principles of (Wakefield & Jorm, 2009), it is clear that this is also a circular process;

Safety performance - Safety learning - safety action - *safety performance (again)*

This means that a continuous process is needed to achieve every single step in improving patient safety.

4 UMCG

In addition to the literature reviewed in the last chapter, the current situation in the UCMG is also important. Different information sources in the UMCG are used to describe the current state of the hospital. The reporting system will be described, as well as the organizational structure and methods of analysis. Data from the Safety Attitude Questionnaire, the Consumer Quality index and Incident Reporting rates is reviewed to describe the situation. The description and data review together will form an extensive report about the UMCG.

4.1 Reporting system and structure

Although incident reporting was not entirely new to Dutch hospitals, the number of incident reporting systems increased since the beginning of an patient safety campaign in 2007 (NVZ, NFU, OMS, & VVN, 2013). Incident reporting in the Netherlands is based on a voluntary, decentralized system. This means that every hospital has its own system and procedures, mostly based on the criteria recommended in a report published following the safety campaign (NVZ, NFU, OMS, & VVN, 2011). The only mandatory reporting to the national inspection for healthcare relates to calamities (Inspection for Healthcare, 2013). A calamity is defined by the Dutch law as an "unexpected or non-intended event that influences the quality of care and results in death or serious injury of the patient" (Dutch law, 18-01-1996).

The University Medical Center in Groningen (UMCG) is one of the eight university medical centers (UMCs) in the Netherlands. The UMCG introduced a hospital-wide Incident Reporting System (IRS) in 2008. The number of reported incidents and near-misses increased from 1042 (in 2008) to 4971 (in 2013), Figure 10. Every department of the UMCG has its own Decentralized Incident Management-commission (DIM), which is responsible for analyzing the reported incidents and proposing measures if necessary. There is one Central Incident Management commission (CIM) that also is the link to the Board of Directors. This CIM can be consulted by DIMs, the Board of Directors or heads of medical departments for varied reasons. Although the 58 DIMs are supervised by the heads of the medical departments, the CIM has also a coordinating and supervising function, Figure 11.

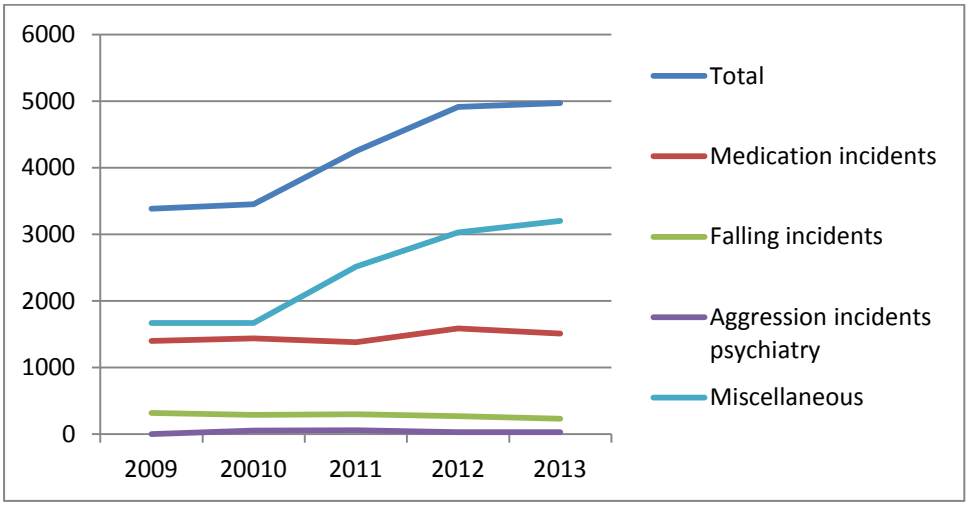


Figure 10: Number of incidents per year

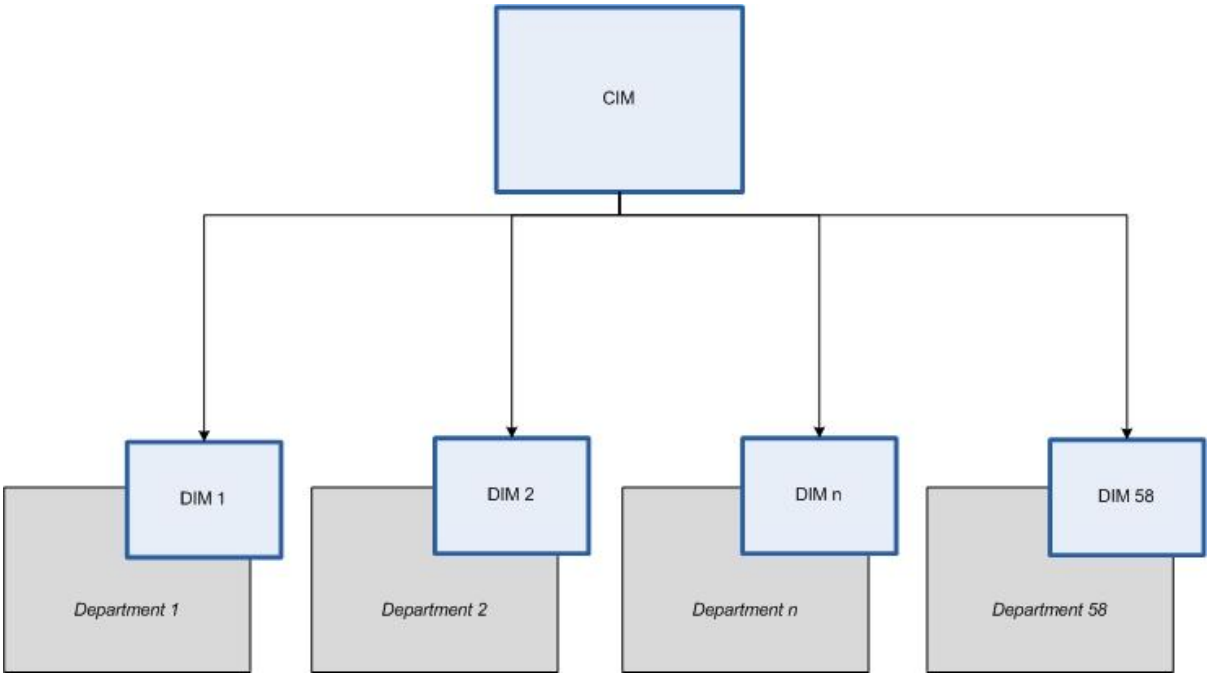


Figure 11: Overview structure CIM-DIM

4.2 Reporting

Incidents can be reported by all medical employees. Access to the general reporting system is easy; every computer has access to the online system. The intranet page shows a button to 'Incidenten melden Patiëntenzorg', which guides you to the page for reporting the incident. The procedure exists of different steps for identifying the incident and the underlying causes. A notable drawback is the slowness of the system, the different steps in the procedure might take several minutes mainly due to the slow database. This causes irritation and might lead to less willingness to report incidents. The UMCG is developing a new incident reporting system, which will be implemented at the end of 2014. This system is based on the same reporting principle, but will provide more tools for data analysis and also the database should work better and therefore faster.

4.3 Analyzing

DIMs are responsible for the analysis of the reported incidents. The DIMs are trained in analyzing incidents systematically; by means of a two-day training to provide insight into analyzing techniques (PRISMA method), and conversation strategies for interviewing involved people. Depending on the risk rate of an incident, an analysis is performed. The risk is determined based on the possible frequency and the severity of the situation. Only high risk situations are subjected to extensive study.

4.4 Calamities

The incident reporting system makes an important distinction between incidents and calamities. Only calamities are mandatory to report to the national inspection for healthcare (Inspection for Healthcare, 2013). A calamity is defined by the Dutch law as an "unexpected or non-intended event that influences the quality of care and results in death or serious injury of the patient" (Dutch law, 18-01-1996). The analysis of calamities is performed by employees who are specially trained for this. It is more extensive than incident analysis and, in addition to the safety principles of the UMCG, also answers to the inspection for healthcare.

The reporting of calamities can be done through the incident reporting system, but also by reporting to the head of the department. This system makes it possible to pass the DIM and also the data of the incident registration system. This is an important drawback for the data analysis, because not all calamities and associated information is available in the incident reporting system. *Because of the differences between (near-)incidents and calamities, calamities are disregarded within this study.*

4.5 Method

The working method for the CIM as well as for the DIMs is the PDCA cycle (Deming, 1994). This means that there is a continuous cycle: plan-do-check-act and then plan again, Figure 12. For incident reporting the PDCA cycle means the following:

- Plan: collect the incident reports, analyze the data
- Do: try to resolve the incident and implement improvement measurements
- Check: confirm if the measurement has the expected result
- Act: learn from the result and/or standardize the improvement measurement

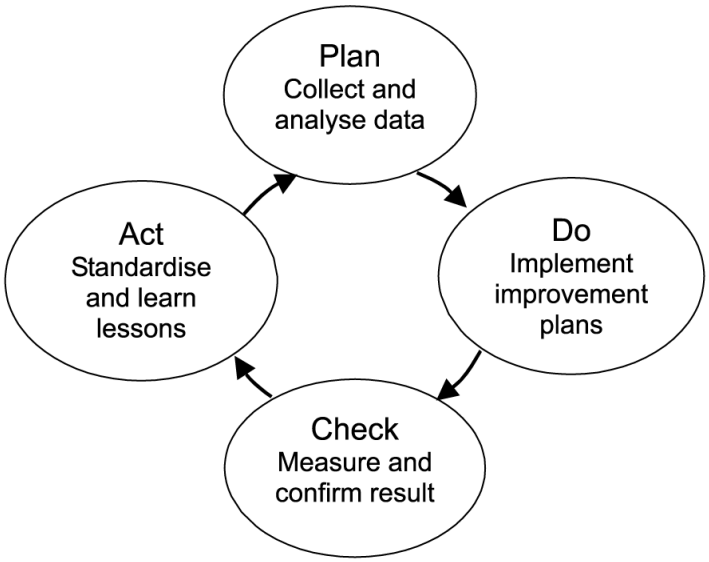


Figure 12: (Deming, 1994) **- PDCA-cycle**

The safety culture ladder (Parker, Lawrie, & Hudson, 2006), Figure 13, is used as inspiration in the UMCG, not as a scientific or well-grounded document. This means that most of the departments are aware of the existence of this model, but there is no methodology to score the departments on the different levels of the ladder. It is used as an inspiration, because departments are encouraged to climb up to a higher level, but there is no specific description on how to climb or even to know where the current position on the ladder is.

Figure 13: (Hudson, 2007) **- Safety Culture Ladder**

An article about the Manchester Patient Safety Framework (NHS, 2006) describes several properties of the different levels of the safety culture ladder. The Manchester Patient Safety Framework does not outline clear questions or improvement measures, but only minor and distinctive characteristics of the different levels. This is useful of course, but intended for self-assessment. An equivalent of the Manchester Patient Safety Model exists in the Netherlands, but this has also been developed with self-assessment in mind. The problem with self-assessment in the hospital is that not much attention is paid to it and that the motivation should be very high before using it.

4.6 Safety Attitude Questionnaire

The Safety Attitude Questionnaire is part of the employee satisfaction investigation, which is outsourced to a company that also studies other (academic) hospitals in the Netherlands in order to benchmark all hospitals and data. Safety Attitude Questionnaires were validated in a study by (Huang et al., 2007). They are validated questionnaires to determine safety attitudes and the safety climate at different departments of hospitals.

The questions relevant for this research are the ones from the 'safety climate' part. Translated, the different questions are based on the following principles:

1. Feeling safe as a patient
2. Correct handling of medical incidents
3. Appropriate channels for asking questions
4. Adequate feedback
5. Speaking freely about incidents
6. Encouragement for incident reporting
7. Safety culture to learn from incident

Retrospective to the literature found in Chapter 3, the statements of the SAQ are in line with the constructs found. The SAQ covers acknowledgement (question 7), no blaming and shaming (question 3, question 5), incident reporting (question 2, question 6) and analysis of incident reporting (question 4). The construct prevention/improvement measurements found in Chapter 3 is not reflected in this questionnaire. The first question, about whether the healthcare worker would feel

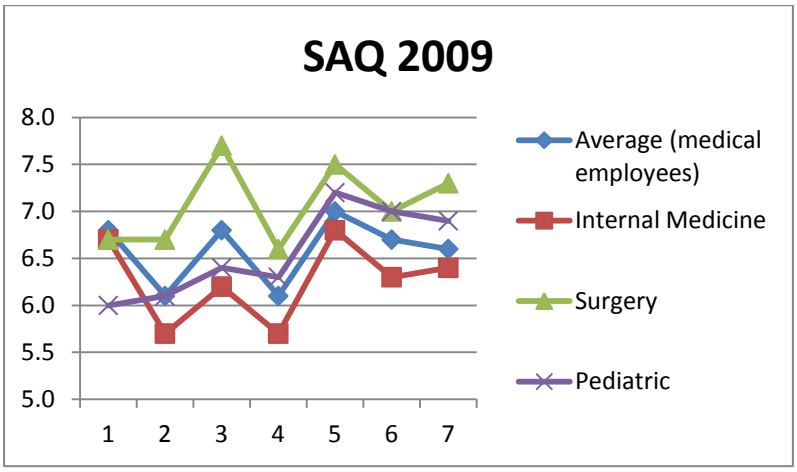
safe as a patient in his or her own department, is a good reflection of the importance of patients' awareness, as mentioned earlier (Berwick, 2002).

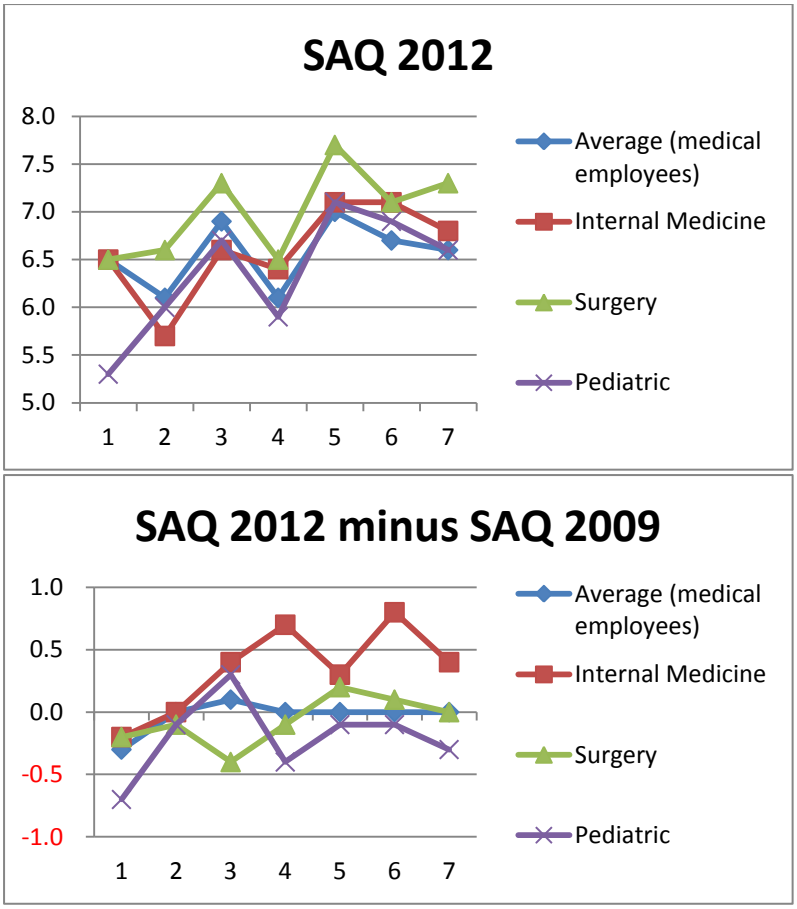
The employee survey took place in 2009 and 2012. The two data sets make it possible to analyze the differences over the years. A comparison shows us that the number of respondents is substantially equal (n_{2009} = 2995 and n_{2012} = 3070). For the different departments Internal Medicine, Surgery and Pediatrics the number of respondents is also substantially equal, Table 6.

	Total	Internal Medicine	Surgery	Pediatric
2009	2995	208	133	311
2012	3070	179	134	313

Table 6: SAQ - number of respondents
SAQ = Safety Attitude Questionnaire

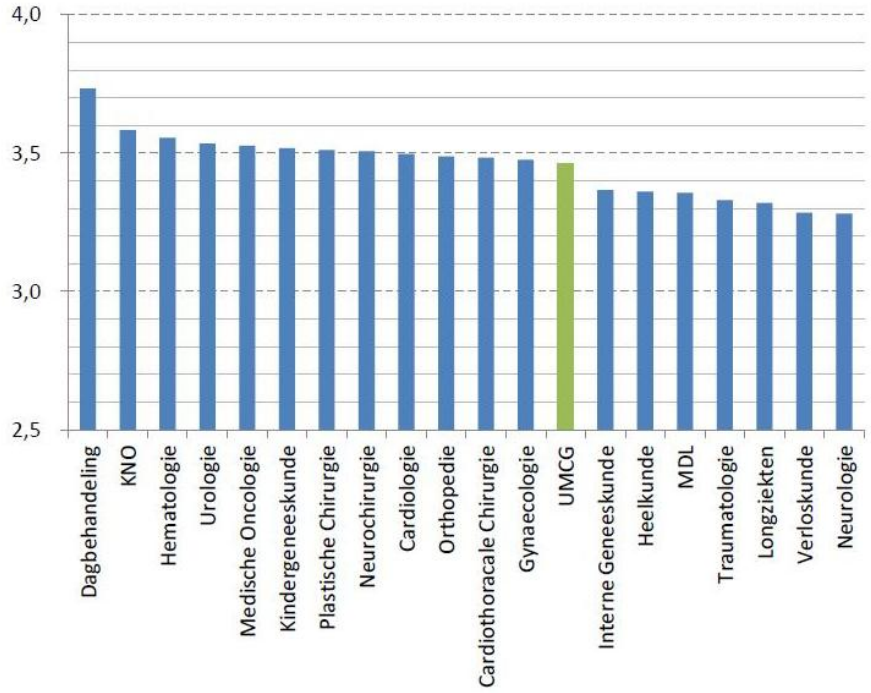
Different graphs show the results for the questions of the SAQ. In 2009 Surgery scored the best compared with the average and the other two departments (Internal Medicine and Pediatrics). Internal Medicine had the worst average score, and Pediatrics scored partly above and party below average.
In the results three years later, you can see that Internal Medicine had made the greatest improvement. The average score of the medical employees did not fluctuate on all questions, except on question 1 (feeling safe as a patient), that score was 0.3 lower in 2012 than in 2009. Question 3 (appropriate channels for asking questions) improved by 0.1 compared with the results of 2009.
For the individual departments there are more differences visible. Internal Medicine improved the most, the scores on all questions except for question 1 improved or remained the same (question 2). Surgery made improvements as well as downturns. Pediatrics deteriorated in all questions, except for question 3.
When you only look at the results from 2012, Surgery is still the best scoring department. Internal Medicine and Pediatrics both score some points above and some points below the average.



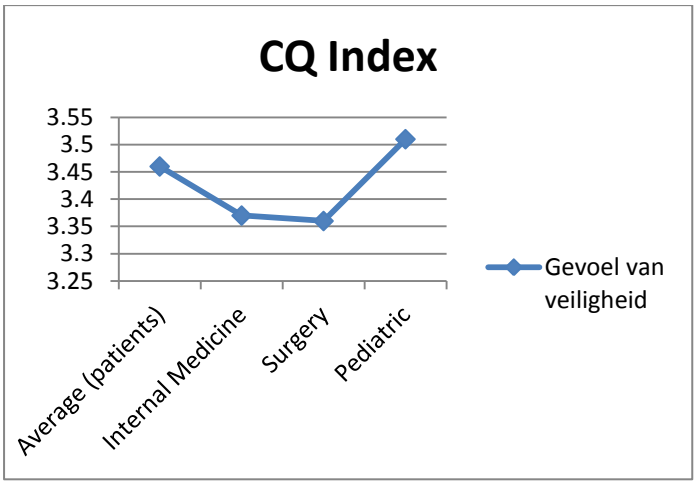


4.7 Consumer Quality index

In 2013 a questionnaire was distributed to consumers of healthcare in hospitals, also called patients. This questionnaire consisted of multiple questions about the care received in the hospital; one of these issues was safety.



Internal Medicine and Surgery ('heelkunde') score below average ('UMCG'), Pediatrics score above average. The differences between the departments are relatively small.



4.8 Incident reporting system

The four figures below show the development of incidents over the years. Figure 14 shows the development of the number of incidents over the years from 2009 to 2013. The total number of incidents reported increased; only for Surgery and Pediatrics the increase is rather moderate. Figure 15 shows that many different types of incidents are reported, although there are different categories, miscellaneous is still the largest category in 2013. Figure 16 shows the development in risk factor over the years. For Internal Medicine there are no figures available because they do not register this. Pediatrics shows a decrease in the 'very serious' category whereas Surgery shows an increase in this category. Figure 17 shows that nurses still have the biggest share of all incidents reported; the share of doctors has slightly increased over the years.

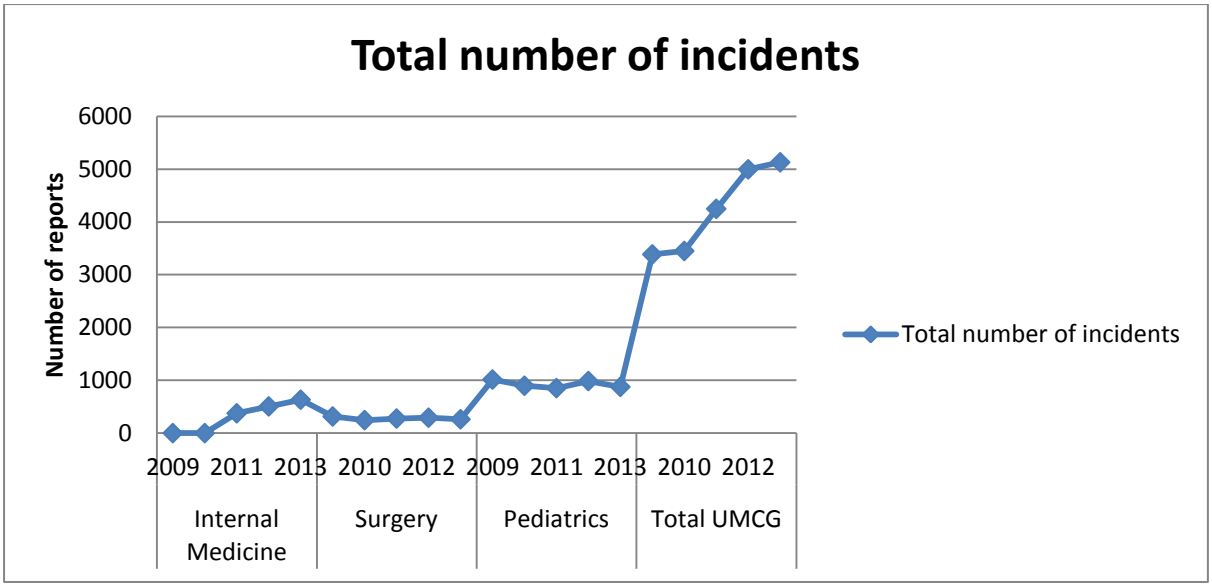


Figure 14: Total number of incidents

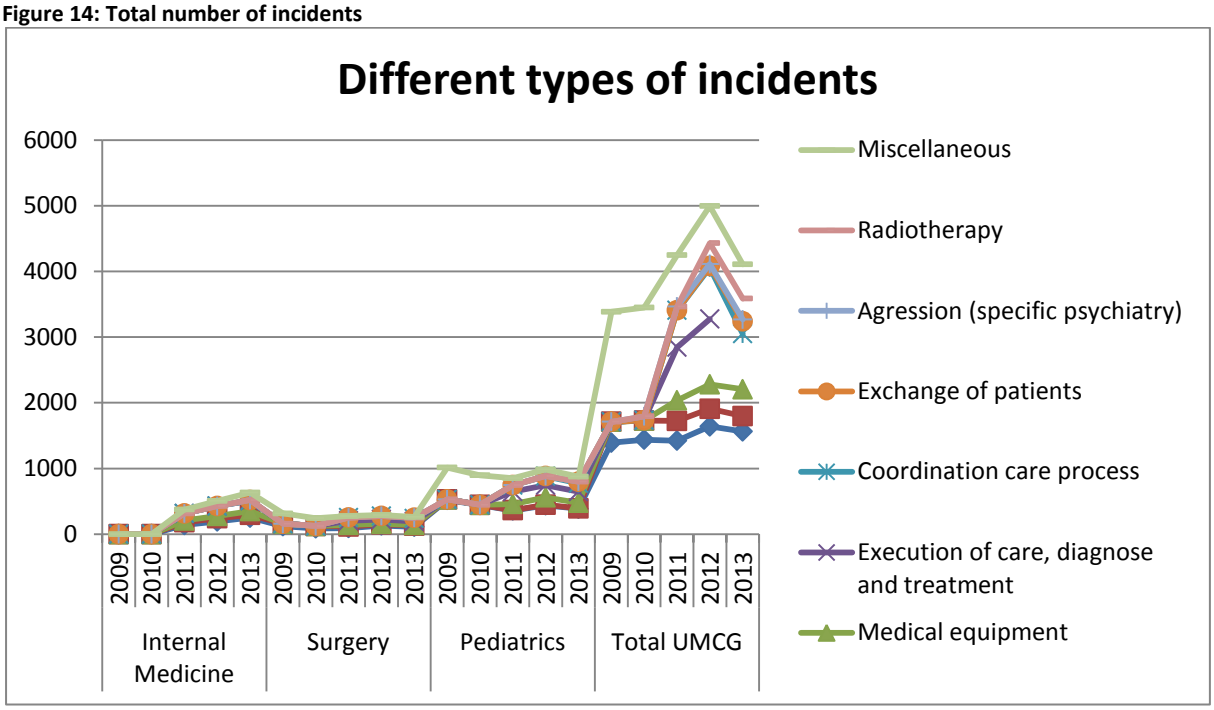


Figure 15: Different types of incidents

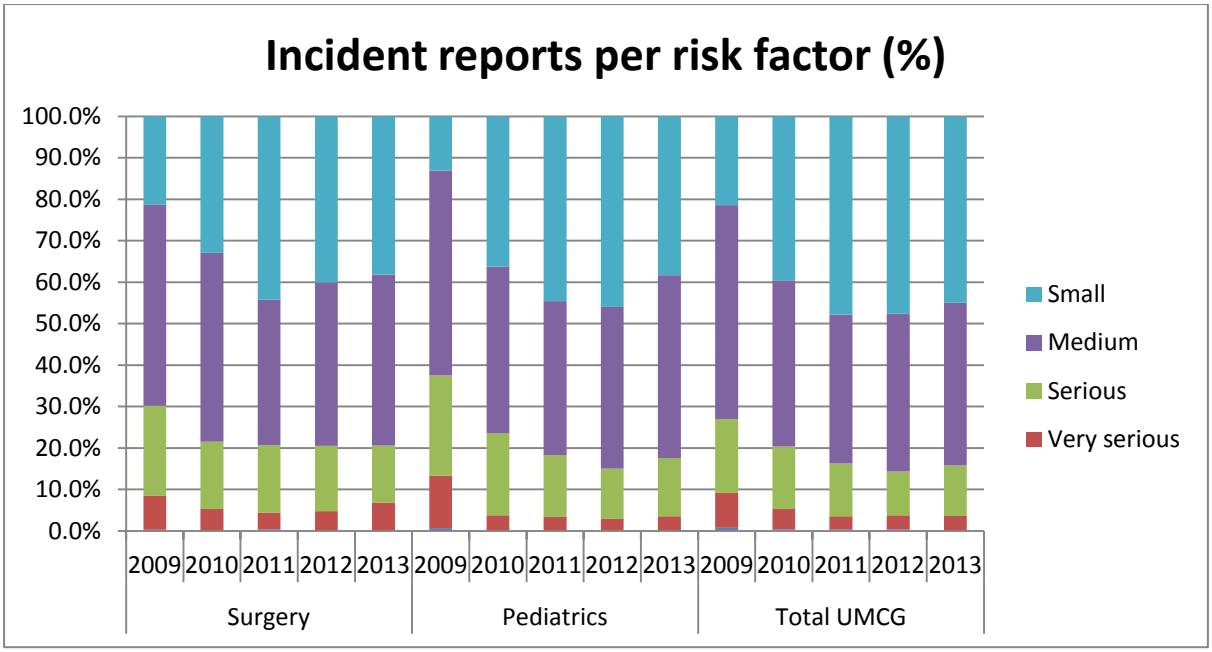


Figure 16: Incident reports per risk factor (%)

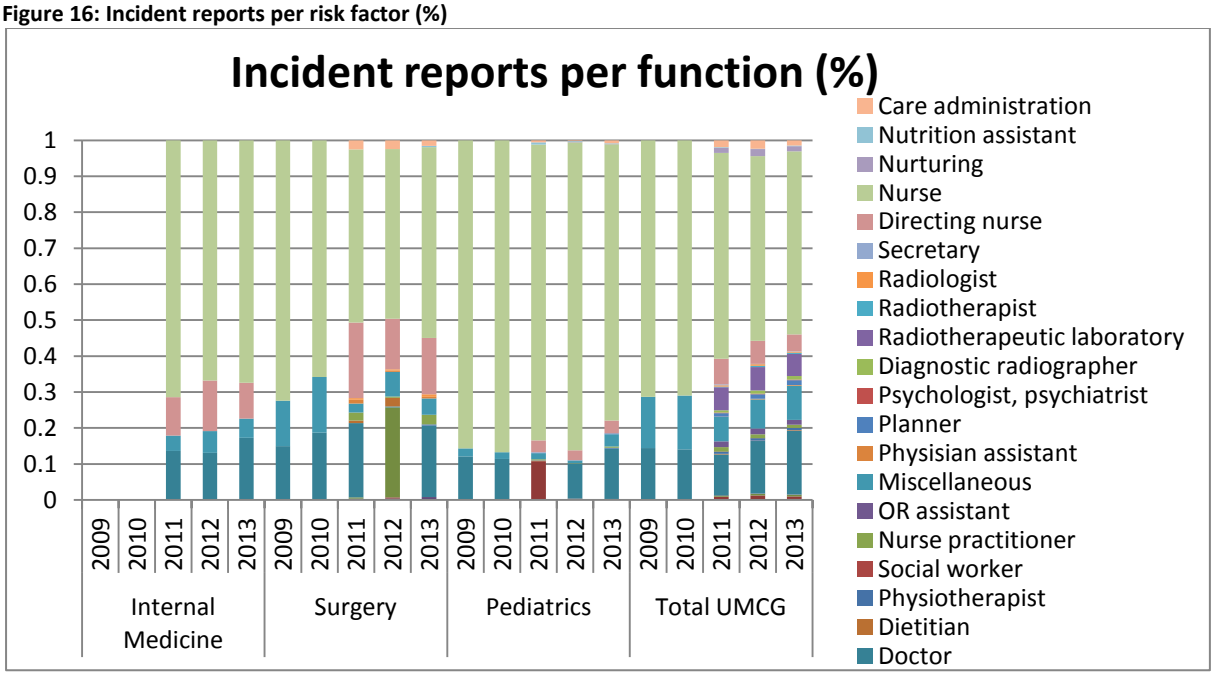


Figure 17: Incident reports per function (%)

After introducing the incident reporting system in the UMCG in 2008, different initiatives lead to an almost uniform system for incident reporting. The department of Internal Medicine is one of the few departments that made another choice; they have their own reporting system. Due to different initiatives in the UMCG, the total number of incidents reported over the past years increased. Although the total number of incidents in the UMCG increased, Surgery and Pediatrics do not show large increases. The number of incidents reported has stabilized. For Surgery it is known that they had their own incident reporting system before the introduction of the hospital wide system, which could explain the very early stabilization.

In the SAQ, Internal Medicine made the biggest improvements. Surgery is the best performing department although it decreased on several points. Pediatrics shows a large decrease, meaning that the employees are less enthusiastic about their own department.

5 Analysis

The most important gap between the literature found and the practice in the UMCG is described. Based on literature and practice the safety culture ladder for improving patient safety is adapted in a way for it to be useful for the UMCG. The framework for the interviews is also based on literature found; the interviews will function as extra input for implementing the safety culture ladder in the UMCG.

5.1 Gap

The gap between literature and UMCG practice is based on a lack of clear indications for system design and organization around incident reporting. Literature describes the ultimate goals for reaching patient safety: acknowledgement – no blaming and shaming – incident reporting – analysis of incident reports and near-miss reports – prevention/improvement measurements. Unfortunately, none of the articles describe tools for assessing the ultimate goal. Additionally, no tools are provided to evaluate a hospital's current state in the field of organizing patient safety.
On the other hand, the UMCG created a system without even looking at the described goals in literature; the system is developed based on common sense and years of experience.

5.2 Similarities

The UMCG works with the safety ladder which is a nice representation of a constructive way towards higher patient safety.
The continuity process described by (J. G. Anderson et al., 2006) overlaps with the Plan-Do-Check-Act-cycle by (Deming, 1994) used in practice. The principle of both models is the circular process. Also the Safety Learning, Safety Action and Safety Performance by (Wakefield & Jorm, 2009) corresponds to the steps of the circular process of Plan-Do-Check-Act. Despite of the different terms, the circular process is the same.

5.3 Use of literature and practice

The safety ladder needs characteristics for measuring and determining patient safety. These characteristics can be found in the different steps described by (Wilf-Miron et al., 2003). This means that every single level has its own specific characteristics. This suggests that there are intermediate levels, that create new levels within the ladder.
The five levels of the safety ladder (Hudson, 2007) are thus expanded by 20 intermediate stages, five extra stages between two consecutive levels. This was demonstrated in Chapter 2 – Methodology.
Another important part of both the literature review and the practice description is the continuous process of improvement. For further research every step on the ladder will be regarded as a cycle, which will continue to improve. Going through the cycle again means an improvement and will lead to a higher level. Because the model that is developed at the end of this research will be used by and in the UMCG, the continuous process of improvement will be described by the PDCA-cycle by (Deming, 1994).

5.4 Safety evaluation instrument

Based on literature found and the practice described, different steps are formulated for improvements within the UMCG. The interviews with different departments will verify the completeness of the statements below and allow us insight into the current position of the

departments. Determining current positions makes it possible to provide appropriate recommendations.

From pathological to reactive:

1. Acknowledgement
   ➔ Acknowledgement of making errors.
2. No blaming and shaming with incidents
   ➔ The first 'no blaming and shaming' should be between staff members, it should be possible to inform colleagues about incidents and to have open discussions.
3. Incident reporting
   ➔ A system for incident reporting should be facilitated and employees should be encouraged to report.
4. Analysis of incident reports and near-miss reports
   ➔ Analyze as many incidents as possible and give priority to high risk incidents.
5. Prevention/improvement measurements
   ➔ Simple improvement measurements should be implemented following the incident reports and all staff concerned should be informed.

From reactive to calculative:

1. Acknowledgement
   ➔ It is already known that everyone can cause an incident; now is the time to acknowledge that the responsibility for reporting is with all staff members.
2. No blaming and shaming with incidents
   ➔ Patients should be informed; there should be no fear of blame and shame from the patients.
3. Incident reporting
   ➔ Near-incidents should always be reported.
4. Analysis of incident reports and near-miss reports
   ➔ Analysis of incidents should be improved with trend analysis.
5. Prevention/improvement measurements
   ➔ Responsibilities regarding the implementation of measures should be confirmed.

From calculative to proactive

1. Acknowledgement
   ➔ Although at this point, departments or hospitals are operating quite well, there are enough opportunities to improve.
2. No blaming and shaming with incidents
   ➔ There should be more openness on incidents involving other, comparable institutions (for example: other UMCs).
3. Incident reporting
   ➔ The reporting system should be integrated with other reporting systems, for example systems for reporting incidents relating to employees or environment.
4. Analysis of incident reports and near-miss reports
   ➔ Analysis should not only be focused on solving the problems retrospectively, prospective analysis should play a key role.

5. Prevention/improvement measurements
   ➔ Prevention and improvement measurements are not restricted to one department; other caregiving departments in the caregiving chain of a patient should be included.

5.5 Interview framework

Interviews with different stakeholders of the DIMs were set within a framework created on the basis of literature. The framework is presented in Table 7. The interview consists of several question, see also Appendix 2.

Corresponding step of safety culture ladder	Subject of interview DIM	Relevant literature
Acknowledgement; no blaming and shaming	Collaboration with (other) department(s)	(J. G. Anderson et al., 2006)
Incident reporting	Incident reporting	(Bagian, 2006; Mahajan, 2010; Wakefield & Jorm, 2009; J. E. Anderson, Kodate, Walters, & Dodds, 2013)
Incident analysis	Incident analysis	
Improvement measurements	Improvement measurements	(J. G. Anderson et al., 2006; (M. D. Cooper, 2000)
No blaming and shaming	Relationship to patients	(Deming, 1994)
Acknowledgement	Data about safety	(Bagian, 2006)

Table 7: Interview framework

5.5.1 Collaboration/link DIM with (other) department(s)

For an optimal functioning of the DIM, the collaboration within the respective departments should be maximized. Every employee, regardless of function, should be aware of the current important incidents and the proposed measures. According to (Wakefield & Jorm, 2009), this is an important condition, because 'actions that only affect individual staff are likely to have little effect in reducing future errors'.

Today's healthcare is organized as integrated care (J. G. Anderson et al., 2006), and involves different departments (Centrale Incident Meldings-commissie, 2013). This means that incident reporting and analysis is improved. Learning from other departments indicates progressiveness. Involving the CIM in incident or trend analysis is a form of collaboration, but a passive, as opposed to active attitude because the incident or incidents are only passed to the CIM.

During the interviews the extent to which the different stakeholders agree with each other is also a criterion for good functioning of the safety management system in the department. Similar answers indicate clear systems and procedures.

5.5.2 Incident reporting

The most important stimulant for incident reporting is an independent and non-punitive system, as well as an enhancement of a learning culture. It is also important that staff is given the opportunity to explain their own story, besides ticking boxes and filling standard questionnaires. (Mahajan, 2013) According to (J. G. Anderson et al., 2006) the first step in reducing medication errors is standardizing the report for the necessary data in a way that the nature of the problem is evident. Stimulating

employees should be done with clear feedback. The involvement of management is also very important. (J. G. Anderson et al., 2006)

5.5.3 Incident analysis

A characteristic of well developed incident analysis is that a method for systematical analysis has been selected. Trend analysis is the next step in systematic analysis, and reporting systems should also contain properties to further improve upon the analyses made. (J. G. Anderson et al., 2006) Analysis of near-incidents should be the same as for real incidents, due to the learning aspect which applies to both. (Wakefield & Jorm, 2009)

5.5.4 Improvement measurements

High-risk or frequently occurring incidents require measures for improvement. The measures should be supported by the management and developed on the working floor (ultimate situation, because this causes the highest involvement) (Mahajan, 2010).
(Anderson, 2006) mentions that the communication of improvement measures is very important, and communication by newsletters or during meetings increase the rate of reporting.

5.5.5 Relationship with patients

Patients are aware of many situations in the hospitals and have the ability to feel things that are going wrong. Also, patients can add value to the incident reports. (J. G. Anderson et al., 2006)

5.5.6 Data about safety

A combination of different data sources is useful for improving safety (Wakefield & Jorm, 2009), therefore the DIM member and the Clinical Manager are asked about the influence of the SAQ and CQ results on the department and its policies. This answer will add information about the usefulness of these studies. Using and involving different studies or data types will improve the insight into the current position, making it easier to improve upon.

6 Interview results

This chapter describes the results of the interviews with the different stakeholders. The total number of interviews is 20; the number of interviews per department can be seen in Table 8. Results of the interviews are described below. The first part is the 'internal interviews', describing the interviews at the departments Surgery, Pediatrics and Internal Medicine in the UMCG. The second part is the results of 'external interviews' which describe the other interviewed UMCs in the Netherlands.

		# DIM	# Clinical manager	# Nurse	# CIM	Total
Internal	Internal medicine	1	1	2	1	5
	Surgery	1	1	2	1	5
	Pediatrics	1	1	2	1	5
External	UMC 1				1	1
	UMC 2				1	1
	UMC 3				1	1
	UMC 4				1	1
	UMC 5				1	1
Total		3	3	6	8	20

Table 8: Overview interviews
DIM = Decentralized Incident Management-commission
CIM = Centralized Incident Management-commission
UMC = University Medical Center

The different subjects of the interviews are:

1. *Composition of DIM (internal)/Organizational position of DIMs (external)*
2. *Collaboration/link with (other) department(s)*
3. *Incident reporting*
4. *Incident analysis*
5. *Improvement measurements*
6. *Relationship to patients*
7. *Data about safety*

6.1 Internal - Interview results of departments in UMCG

Results from the department of Surgery will be described below, followed by a short description (in italics) of the differences in the results of the departments of Pediatrics and Internal Medicine. In the Appendix you can find the total description of the results of Pediatrics and Internal Medicine.

6.1.1 Composition of DIM

The DIM Surgery is composed by various staff members, doctors and nurses (in total about 12 people). The composition changes every few months, because of the involvement of doctors in training. They participate only for 8-12 weeks. The DIM believes that involvement leads to higher awareness of incident reporting. The organization is a centralized system.

In contrast to Surgery, Internal Medicine and Pediatrics have operational miniDIMs. Because of the increasing number of incident reports, Internal Medicine created miniDIMs at all wards to immediately analyze local reports. The size of a miniDIM is one or two nurse(s). The responsibility for analysis and improvement after the incident report is still with the original DIM. This organization of incident analysis was decentralized.

Pediatrics created the DIM Pediatrics after evaluating the different DIMS in the different pediatrics wards. This means that the system of incident reporting in pediatrics was first only decentralized and later on there is a central DIM composed.

6.1.2 Collaboration/link DIM with (other) department(s)

According to the DM, the surgical DIM only works in a centralized fashion, all the tasks and responsibilities are with the DIM. The DM is critical about this working method, because it is a weak system and needs more support from the other employees. The CM is full of praise about the current system and is proud of the DIM members. For the nurses the DIM is a group of analysts, but what they do exactly is not known. The nurses think that increased awareness and thus more insight would increase the willingness to report.

The surgical DIM cooperates very well with other departments. There are already some structures for frequent collaboration, for example with the DIM for operating theaters and also with anesthesiology. The nurses declare that incidents or problems with other departments are communicated in other ways than by incident reports. Often the involved party is called and the incident, or problem, is solved immediately.

Due to the miniDIMs the collaboration and the awareness of incident reporting is well developed in both the Internal Medicine and Pediatrics departments.

Internal Medicine finds difficulties in collaboration with other departments because of a different reporting system. In Pediatrics, the collaboration with other departments is highly developed; regular contact with pharmacy and surgery is made and other collaboration is requested if required.

6.1.3 Incident reporting

The CM and DM of Surgery think that the culture of incident reporting is good, there should be no fears and everyone should be able to report if there is an incident. The same yields for near-incidents, although this category is harder because it is sometimes neglected.

The nurses indicate that reporting one incident takes approximately 5 minutes. The no shaming and blaming is known by the nurses and they confirm that there is no fear to report. The problem that it can take a long time is an issue, and is also mentioned by CM.

The CM is very proud of the doctors who are reporting more frequently, but they are not aware of the nurses who are reporting less (since the total number of reports is constant and the doctors' reports are increasing in number, the number of reports submitted by nurses would, in theory, have decreased). The CR thinks that the DIM has problems with involving the nurses. There is no explanation for the decreasing number of reports, according to the DM. The DM is worried about the participation of other employees besides doctors and nurses for incident reporting. For example the medical administration employees do not report often. The DM made special arrangements with them; they do not report every incident, but they are aware of incidents that occur often and consult the DM on possible remedial action.

The CR explained that even before the implementation of the hospital-wide incident reporting system, the surgical department already had a kind of reporting system. The CR thinks that this could be a reason for the relative high numbers of reports in the early years of the system.

According to the nurses, both internal medicine and pediatrics neglect smaller incidents or near-incidents because of the increasing workload. Internal medicine estimates time for reporting one incident at 5-10 minutes; Pediatrics estimates 5-15 minutes.

6.1.4 Incident analysis

Analysis is done by the DIM, mostly by the secretary. Other DIM members or employees of the department become involved if an incident involves their special field. According to the DM and CM, incidents are methodologically and systematically analyzed. However, the incident reporting system does not facilitate a good analytical system, therefore the DIM uses Excel files instead.
It is notable that every incident is analyzed, because of the belief that the cause of the incident might be bigger than thought at the beginning. Several incidents that were at first sight very simple were caused by bigger problems that could have led to more and riskier incidents. Until now, there is no good method for trend analysis, therefore it is only due to the attentiveness of the DIM members that trends are sometimes noticed.

The analytical structure for Internal Medicine is changing; not only the DM secretary will be responsible for the analysis, other DIM members will also be asked to perform the total analysis. Here also, trend analysis is poorly developed, as there is no standardized method. At Pediatrics most of analyses are performed by the smaller, decentralized DIMs. The DIM Pediatrics reviews the reports and signals trends. Trend analysis is therefore highly developed.

6.1.5 Improvement measures

According to the DM, several reported incidents have led to improvement measures. Although the motto at the department is 'the one who knows the solution may say so', the DM invents most of the improvement measures. The implementation and improvement is divided across several persons within the department (management, doctors, nurses, etc). The CM thinks that the PDCA-cycle is well developed and that the Check and Act only need small improvements. The DM also thinks that the department is lagging behind on the Check-step.

The nurses indicate that they solve problems or incidents immediately, but they do not suggest long-term solutions.

The DM also stated that the latest improvement is making one person responsible for the implementation step. This means that whenever a measure is confirmed by the management team, one employee is made responsible for the implementation and this person can be checked by the DIM.

Nurses in Internal Medicine are not aware of improvement measures having been implemented on the basis of incident reporting. According to the DM, improvement measures are proposed by the DIM or the miniDIMs. The same construction is in place at the Pediatrics unit; both DIM Pediatrics and the smaller DIMs propose improvement measures. There is nobody in particular in charge of controlling the progress of the implementation of the respective measures.

6.1.6 Relationship with patients

According to the nurses, patients are informed about incidents when they may be directly affected by them. The nurses also declare that it is a subjective decision to inform the patient, it is only decided by the nurse and they make an estimate of the risk. The lower the risk, the lower the chance that the patient will be informed. The CM confirms that patients are informed after a risk estimation by the health care professional.

The DM is worried about the small number of incidents reported to the patients due of the risk estimation by the nurses. If patients have the feeling that something is not going well, informing them may increase their trust. However, most of the employees of the department believe that informing the patients could cause agitation instead of increasing trust by acting openly and honestly.

In both Internal Medicine and Pediatrics the nurses decide whether patients should be informed or not. At Pediatrics the parents are informed, instead of the (young) children. Near-incidents are never reported to patients.

6.1.7 Data about safety

The SAQ and CQ data are known to the CM, but the results do not influence the safety policy of the department. The latest scores for surgery are higher than average, but according to the CM this does not affect the choice to not take it into account for policy matters. The same applies for lower scores than average. He emphasizes that significant attention is paid to safety and incident reporting. The DM is not well informed about the SAQ and CQ, but thinks that higher than average scores are caused by the positive environment and the safe and well developed reporting culture.

At Internal Medicine the results of the SAQ and follow-up measures are delegated to the wards. The CQ index is not relevant for Internal Medicine because of the research design. Because of the low scores, Pediatrics has evaluated the results and developed special measurements The most important and additional question besides SAQ at Pediatrics is: would you bring your own child to this hospital for treatment? The results of that questionnaire are leading to new steps and measures towards improvement.

6.2 External – Interview results of other UMCs

In addition to the UMCG, five other UMCs were interviewed about the organization of safety culture and perception of incident reporting, analyzing and improving safety.

6.2.1 Organizational position of DIMs

Hierarchically the DIMs of all UMCs are placed under the heads of departments. UMC 2 mentions that this could only be a problem when the DIM does not function properly and the head of department is not interested in feedback. UMC 4 emphasizes that this decentralized system improves the responsibility of the heads of departments for incidents on their own working floor.

6.2.2 Collaboration/link with (other) department(s)

In UMCG the DIMs are responsible for the incidents, and the CIM is only contacted upon request by DIMs. Nevertheless, the CIM has access to all reported incident and calamities. UMC 3 and 4 have the same system of centralized (CIM) and decentralized (DIM) tasks. In UMC 1 and 5 the CIM is involved in the higher risk incidents (risk 3 and 4 on a scale of 1-4), and also, in UMC 1, all incidents with a risk of 3 and 4 are discussed in the monthly meetings of the CIM.

The visibility of the CIMs in the different hospitals is still quite low. UMC 3 thinks that the visibility to the nurses and management of departments is quite good, but doctors are less interested which can be seen in the number of reports. UMC 1 and 2 noticed an improvement in incident reports and also an improvement in attention paid to reporting, which makes the CIM more visible. Opportunities for improvement are still present and for UMC 1 the absence of policy also influences this point. UCM 4 and 5 report that their CIMs are particularly invisible in the UMC. In the UMCG the visibility of the CIM increased over the years and in particular the visibility for DIMs and head of departments increased (comparable with UMC 3).

All UMCs agree on the point of responsibility for the CIM on the field of reporting culture (no blaming and shaming), extra attention for incident reporting and continuous improvement. Frequent meetings are organized by the CIMs of the different UMCs with the intention to inform the DIMs and other stakeholders as well as stimulate to report, analyze and learn.

6.2.3 Incident reporting

All UMCs have separate systems for complications and incidents. There is extra attention paid to the importance of combining the systems. In some UMCs, i.e. 3, 4 and the UMCG, it may be possible to integrate these systems within the next few years. In the UMCG the department of Internal Medicine is the only department that does not have a separate system, the department developed its own system and integrated complications and incidents in one database.

6.2.4 Incident analysis

Like the UMCG, all UMCs work with a decentralized system, and the responsibility for the analysis of the incidents is always with the DIMs. The CIMs will be consulted if necessary.

Trend analysis is hard for all UMCs. Most of the trends are identified through the reporting system and by analyzing reports manually. According to UMC 4, the quality of the IRS has a strong influence on the trend analysis, since trend analysis improved after a new version of the IRS. UMC 1 and also the UMCG report that due to IRS's limitations, trend analysis is hard.

6.2.5 Improvement measures

The PDCA-cycle is well known in the UMCG, but not in the other UMCs. The UMCG has been trying to implement all steps of the cycle since the beginning of the IMS. UMC 1 does not have anything of the cycle in their system. UMC 2, 3 and 4 implemented the PDCA cycle in their working routine; evaluations are scheduled regularly. UMC 2 and 3 are on a level where the full cycle works already, UMC 4 is still working on improving it. UMC 5 has only implemented the plan and do step and therefore need major improvements.

Major problems vary considerably across the UMCs. UMC 1 has the biggest problems with the absence of policies. UMC 3 has problems with optimizing the 'checks' around the organization of CIM-DIM. UMC 4 and 5, like the UMCG, have the biggest problems with medication errors. UMC 2, 4, 5 and the UMCG mention other typical incidents as most difficult to solve apart from medication errors .

6.2.6 Relationship with patients

Incidents that reached patients are often reported to patients. For UMC 1 it is unknown because they have no data on this aspect. All UMCs reflect on this point that it is their responsibility to report such cases to the patient. Only the UMCG and UMC 3 score around 50% for reporting to patients. However, some incidents may not be worth reporting, such as near-incidents.

7 Discussion of interviews

This chapter describes and discusses the meaning of the interviews. A link between the literature review and the interviews is made in order to give the interviews a meaning. Both the internal interviews (with the three departments) and the external interviews (with the other UMCs) are discussed. The different categories for describing the interview results are based on the interview framework.

7.1 Collaboration/link with (other) department(s)

A construction for (larger) departments with a centralized DIM and several decentralized smaller DIMs works best for collaboration within the department. The role of the CIM is quite simple, have overview of everything and function as an example and inspiration for the DIMs. Being an example means that the CIMs should be (more) advanced in performing their tasks compared with DIMs. Now they function on the same levels as the DIMs, which will not encourage improvement. For help and overview questions, all three researched departments contact the CIM regularly, and the contact is easy to establish. (J.G. Anderson et al., 2006) state that involvement of as many employees as possible is the best way to improve, because organizational change does not exist if only a few employees are involved. Involving the own department is the first step of involvement.

All UMCs agree on the hierarchical construction that heads of departments are responsible for the DIMs. Although there are some drawbacks with respect to confidentiality, benefits dominate. Following from the interviews, a strong integration of the employees at the departments, strongly stimulated by creating decentralized DIMs, is the first step in a solid base for collaboration.

Involving other departments is a broader view of collaboration. Collaboration with other departments is highly developed in Surgery and Pediatrics; Internal Medicine is lagging far behind due to a different reporting system. Surgery and Pediatrics mainly work together with departments that are also in the chain of care of their patients. The organization of care is also called 'chain of care' (in Dutch: ketenzorg), so improving the safety in this chain seems a logical step forward.

Since the involvement of other departments is not yet well developed, this will be the step following the well developed integration of the own employees.

On the highest level of involvement, it is possible to involve all UMCs. The interviews do not show this comparison or collaboration already. Due to system limitations it is not possible to compare or to collaborate. Following the results in collaboration within the UMCG, it is necessary to use the same system for higher collaboration options.

7.2 Incident reporting

The two systems reviewed in this research, the hospital wide system and the system specially designed for Internal Medicine, are both only used for reporting and counting incidents. For analyzing and follow-up the departments have to use their own system (Excel). The use of a unified system would enhance collaboration with other departments, and facilitate comparison. The option to monitor the progress of the analysis would also be helpful and increasing the usability.

Both reviewed systems are time consuming on the reporting point, which is a large drawback for potential reporters.

The system of Internal Medicine does not determine the risk number of the incidents, which makes it impossible to allocate incidents to risk categories.

Responses of other UMCs indicate that no UMC sees the importance of combining calamities and incidents in one system, as done by Internal Medicine in the UMCG.

Although near-incidents are often recognized, reporting near-incidents is underdeveloped in all three departments.

7.3 Incident analysis

Although different incident reporting systems exist, this has no influence on the way incidents are analyzed. Internal Medicine uses the same structures and methods as other departments. This might be due by the training about methodology organized by the CIM.
According to the answers from the other UMCs, the level of involvement of the CIM has no consequences for the responsibilities of the incident analysis.
The trend analyzing is either performed manually, or with the help of simple figures and graphs out of the reporting systems. The upgrade of the reporting system of UMC 4 proved that a system upgrade is useful to improve the trend analysis function.

7.4 Improvement measures

PDCA is seen as a functional tool to overview the whole process of incident analysis in all UMCs, although it is not yet implemented everywhere.
In the UMCG the PDCA cycle is applied in the different departments, but there are problems with the Check and Act step. This means that the intention is good, but due to the threats the cycle does not work yet. The threats are mostly due to the absence of responsibility for system drawbacks.
Despite the initiatives of several people in the UMCG, the implementation of improvement measures seems to be difficult. The measures are generated, but there is no implementation and there are no checks as to their effect.

7.5 Relationship with patients

None of the departments have a policy of always informing the patients. This can be a sign of fear and that the motto ‘no blaming and shaming’ is not sufficiently developed.
Other UMCs have some trouble in checking whether patients have been informed, but they all mention the rules in place for reporting to patients. There is no discussion about whether a patient should be informed once an incident has reached the patient. This means that the UMCG lags behind on this point, with too many subjective judgments by the caregivers and those responsible for causing/discovering the incident.
All UMCs agree that near-incidents should not always be reported to patients.
Feedback or reactions by patients are never registered; the only handling relates to cases of complaints.

7.6 Data about safety

Overall, Surgery was the best scoring department in 2009 and 2012 in the SAQ. Internal Medicine made the biggest improvement in these three years, whereas Pediatrics’ scores mainly decreased. The interviews show that not all departments in the UMCG are using the results of the SAQ. The research methodology of the CQ for Internal Medicine was found to be very poor. Therefore this score cannot be given any meaning. For Surgery and Pediatrics the respective scores are below and above the average. Additional information on this point from the interviews shows us that again, Surgery does not implement measurements based on this information. Pediatrics evaluated the results and decided to take their own initiatives on account of the department.

Since combining data and information from research is very important for managing safety (Helmreich, 2000), Surgery is scoring very low on this point compared to Pediatrics which to a high extent has developed the integration of research results with daily practice.

7.7 Other UMCs

The position of the CIM within the UMCG is the same compared to other UMCGs, hierarchically the CIM is above the DIMs. The CIM of the UMCG has only overarching tasks, this means that the system with decentralized DIMs is well developed in strong contrast to other UMCs where the CIM still has some core tasks (responsibility of the incident reports).

The UMCG scores the same when it comes to the complication registration apart from the incident reporting; only one department within the UMCG is using a combined system. Trend analysis is underdeveloped in UMCG, according to UMC4 trend analysis improved by implementing a new IRS. A strong integration of improvement measures across the departments is difficult in all UMCs. When looking at the PDCA cycle, the Check and Act step are hard to secure. UMCG is lagging behind at informing patients.

In general, UMC1 is performing badly because of the absence of clear and extensive policies. The new IRS of UMC4 brings them several steps ahead of the other UMCs because of the extra possibilities that come together with the system upgrade. Other UMCs, including UMCG are performing at medium levels. UMCG has improvement options in the field of relationship to patients and incident reporting system. For visibility, the incident analysis and improvement measurements in the UMCG are better than or comparable to the other UMCs. This makes the UMCG the third scoring UMC of all six interviewed UMCs.

8 Conclusions & recommendations

Based on literature, practice and interviews several conclusions can be drawn. Conclusions are divided into topics about the gap between literature and practice, adjusting the safety culture ladder, current state of the departments within the UMCG, and the position of the UMCG compared to other UMCs. The conclusions are complemented by recommendations. These recommendations consist of two parts: the first part is specifically for the UMCG, and the second part contains more general recommendations for further research.

8.1 Conclusions

Theory and practice differ from each other in the field of applicability. Literature describes final goals of patient safety; where practice needs an instrument or method for the improvement steps.

The safety culture model of (Helmreich, 2000) should be extended with extra steps in order to improve patient safety. Figure 18 and Figure 19 show the extra integrated steps of the ladder.

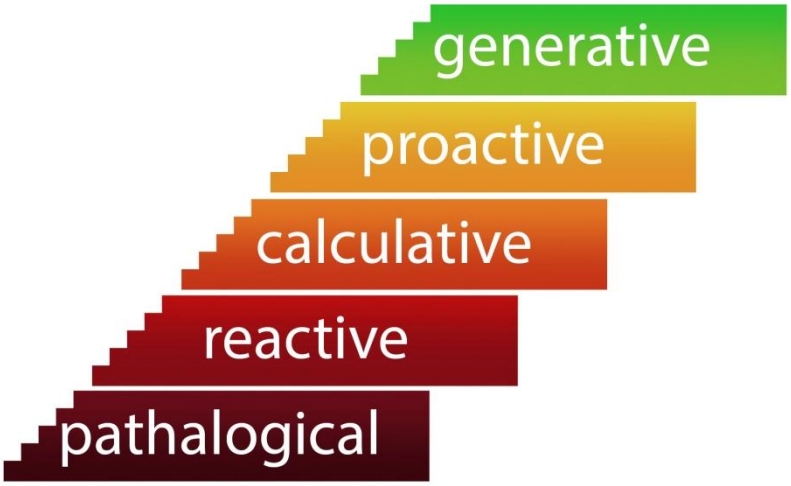


Figure 18: Adjusted safety culture ladder – five steps in every level

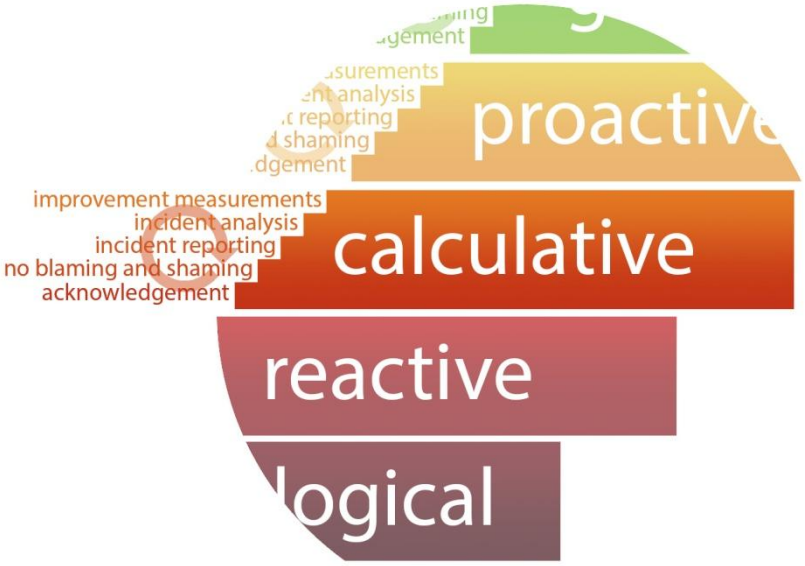


Figure 19: Adjusted safety culture ladder - details

Surgery, Internal Medicine and Pediatrics are between reactive and calculative on the safety culture ladder, following the indications for moving upwards on the ladder as described in Chapter 5.

Collaboration within and with other departments in the UMCG is not well developed. Based on the interviews, three different levels of collaboration can be distinguished:

1 Internal – within the department
2 Internal – with other UMCG departments
3 External – with other UMCs

The construction of DIMs at the wards helps to develop and stimulate the first level of collaboration. The second level will be optimized by equal incident reporting systems in combination with strong collaboration in the 'chain of care' of patients.

Trend analysis of the incident reporting is underdeveloped in the UMCG.

Although improvement measurements are proposed by DIMs, they are not firmly implemented at the departments. The Check and Act steps in the PDCA-cycle are not well enough secured.

Near-incidents are infrequently reported. Mainly because it is time consuming in the current incident reporting system and due to the absence of clear definitions of near-incidents. Besides, not every employee is aware of the near-incident reporting possibilities.

Patients at the UMCG are not always informed about incidents concerning their health; information about incidents is also not always included in the medical report. Potential feedback from patients is hardly registered.

Compared to other UMCs in the Netherlands, UMCG is performing in the third place (out of six).

8.2 Recommendations for the UMCG

Large departments within the UMCG should introduce an incident analyzing system were decentralized miniDIMs analyze local incidents. A central DIM should control these miniDIMs. A large department is a department with more than 250 incidents per year.

A new incident reporting system should be developed and introduced. This allows departments to compare and share reports with others. Also trend analysis should be a feature of this new system. *UMCG is already working on a new IRS, these two recommendations should be implemented if not already decided.*

Improvement measurements are already proposed, but not carried out. This should be top priority for UMCG. Responsibility for proposed measurements should be divided to employees at the wards, both nurses and doctors could be responsible. The responsible makes a timeline and a plan for implementing the measurement. The head of department is responsible for the overall implementation and monitors this responsible person.

The definition of near-incidents should be updated and expanded. This definition should be spread over all the departments. The learning aspect of near-incidents should be explained to employees and employees should be stimulated to report near-incidents more often.

Policy about informing patients about incidents should be explained again to all employees. Also patients should get the opportunity to give a reaction or feedback on incidents. This reaction or feedback should be included in the medical file of the patient.

Between the Dutch UMCs several differences exist in the field of organizing patient safety. This collaboration has to be expanded in order to learn from and with each other. The UMCG can learn from UMC4 about another IRS that supports trend analysis. UMCG should aspire being the best UMC of the Netherlands.
The comparison between UMCs in the Netherlands can be further expanded, when also numbers and underlying causes of incidents are compared.

8.3 Recommendations for further research

This research is mainly to form hypotheses that should be tested in a larger setting and in a larger time frame. There are many more departments that could be included in the research in the UMCG alone; this would improve the quality and specificity of the model characteristics. Expanding the research to other UMCs would make it useful for a broader target group. Also the research in other UMCs should go more in-depth, this research was only a beginning.
A hospital-wide incident reporting system will help improving the collaboration in the chain of care, so departments like Internal Medicine should change their system to the hospital-wide system.
The new incident reporting system that will be implemented in the UMCG at the end of 2014 should help departments with trend analyzing, since manual trend analyses are only done sporadically and are mostly of very low quality.
The PDCA-cycle is well known, but the Check and Act step is not well enough developed. Therefore extra support should be given. This can be done by extra training with tips and tricks, but also an analyzing function in the (new) incident reporting system would be very helpful. Currently the analysis is performed by means of Excel, which means extra workload and therefore is not encouraging.
When all caregiving departments use the same incident reporting system and many improvement steps are made in the area of patient safety the time might be ready to expand the reporting system. The system for incident reporting about employees and environment is now separate from the patient safety. This should be combined.
Like many other studies, the study on hand is focused on the output of a system, but the input of the system also needs to be studied. In this case this means studying the reported incidents, and establishing what makes a report a good report. What are the criteria of a good incident report and what should the reporter memorize in order to decrease the workload of the analyzer?

9 Limitations of the research

The differences between practice and theory have lead to many assumptions; these assumptions are not all tested in this limited research.

Only a few departments within the UMCG were interviewed and studied. Due to the limited timeframe, departments of other UMCs were also not interviewed.

Some specific departments in hospitals might have safety culture characteristics, caused by the nature of their specialization. For example, pediatrics has different relationships with their patients because of the age of their patients. Comparing departments to other UMCs would be interesting, but it will be hard to set all constraints equal.

The interviewed group of stakeholders is small. Although they are representative of their professions and were chosen as randomly as possible, expanding the research group would increase the validity of the research.

The Consumer Quality index is a restricted research and therefore not useful in this format for the representation of patients. New research has to be done or the CQ index has to improve. As the CQ index is a national standard and departments are differently appointed in different hospitals (internal medicine is a broad concept and the included specialties differ per hospital), it is hard to establish comparable results.

Many functions that are also reporters are not represented in this research, for example radiologists, care administrators, secretaries, etc. These are smaller groups than the nurses and doctors, who are included, but reports by these neglected groups are increasing in number. This increase is a very good sign of improved knowledge in these groups.

Calamities are not included in this research because they are very infrequent compared to incidents. Also, the calamities are not always reported in the incident reporting system. Most of the time calamities are directly reported to the special calamity commission.

Also the safety of staff and environment is not included in the research, because of the separate reporting system.

The risk factor for the total UMCG and also Pediatrics decreased over the years. In addition to the improvement of reporting lower risk incidents, there is also an alternative explanation possible for this phenomenon; by repeated incidents the employees can get used to the incident and therefore their assessment of the risk factor might differ. Also when employees get used to report, their assessment skills might improve. This can affect the assessment of an incident.

Appendix to Master Thesis:

Safety does not happen by accident

Improving patient safety using risk management systems and formulating improvement measurements

1 Literature overview

	Author	*Title*	*Publication year*	*Reason for selecting*	*Database*
1	Allen S, Chiarella M, Homer CS	Lessons learned from measuring safety culture: an Australian case study.	2010	Safety improvement	PubMed
2	Anderson JE, Kodate N, Walters R, Dodds A	Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting.	2013	Safety improvement	PubMed
3	Anderson JG, Ramanujam R, Hensel D, Anderson MM, Sirio CA	The need for organizational change in patient safety initiatives.	2006	Safety improvement	PubMed
4	Bagian JP	Patient safety: lessons learned.	2006	Comparison with other industry	PubMed
5	Berwick BW	A user's manual for the IOM's 'Quality Chasm' report.	2002	Safety improvement	WebOfScience
6	Clarke s	The relationship between safety climate and safety performance: a meta-analytic review	2006	Review of relevant literature	WebOfScience
7	Colla JB, Bracken AC, Kinney LM, Weeks WB	Measuring patient safety climate: a review of surveys.	2005	Measuring safety	PubMed
8	Cooper MD	Towards a model of safety culture	2000	Safety improvement	WebOfScience
9	Flemons WW, McRae G	Reporting, learning and the culture of safety.	2012	Safety improvement	PubMed
10	Hofer TP, Kerr EA, Hayward RA	What is an error?	2000	Deffinition	PubMed
11	Hogan H, Olsen S, Scobie S, Chapman E, Sachs R, McKee M, Vincent C, Thomson R	What can we learn about patient safety from information sources within an acute hospital: a step on the ladder of integrated risk management?	2007	Safety improvement	PubMed

12	Isaac T, Jha AK	Are patient safety indicators related to widely used measures of hospital quality?	2007	Safety improvement	PubMed
13	Jackson J, Sarac C, Flin R	Hospital safety climate surveys: measurement issues.	2010	Measuring safety	PubMed
14	Mahajan RP	Critical incident reporting.	2010	Safety improvement	PubMed
15	Mearns K, Whitaker SM, Flin R	Safety climate, safety management practice and safety performance in offshore environments.	2003	Comparison with other industry	WebOfScience
16	Miller MR, Elixhauser A, Zhan C, Meyer GS	Patient Safety Indicators: using administrative data to identify potential patient safety concerns.	2001	Measuring safety	PubMed
17	Noble DJ, Pronovost PJ	Underreporting of patient safety incidents reduces health care's ability to quantify and accurately measure harm reduction.	2010	Measuring safety	PubMed
18	Stelfox HT, Palmisani S, Scurlock C, Orav EJ, Bates DW	The 'To Err is Human' report and the patient safety literature.	2006	Review of relevant literature	PubMed
19	Wakefield JG, Jorm CM	Patient safety - a balacned measurement framework.	2009	Measuring safety	PubMed
20	Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM	Promoting a culture of safety as a patient safety strategy: a systempatic review	2013	Safety improvement	PubMed
21	Wilf-Miron R, Lewenhoff I, Benyamini Z, Aviram A	From aviation to medicine: applying concepts of aviation safety to risk management in ambulatory care.	2003	Comparison with other industry	PubMed

2 Questionnaire for the interviews

Composition of the DIM

1. How is the DIM within this department composed ?
   Number of members, function of members, time spent

Collaboration/link DIM with (other) department(s)

2. What is the function of the DIM within the department?
   Management trust, relation with other employees, openness, transparency and trust of department
3. How well do you know the CIM?
4. Is the CIM involved in your processes?
5. Are you collaborating with departments/DIMs?
6. How is this organized?

Incident reporting

7. How often and how specific are incidents reported?
   Reporting culture, perception of 'always' reporting
8. How often and how specific are near-incidents reported?
9. Does the number of incident reports increased or decreased over the years (IMS data)?
   Explanation of changes (increases, decreases), relation between extra attention for reporting and number of incidents reported, different types of incidents

Incident analysis

10. How are incidents analyzed?
    Who is in charge, damage control, individual or grouped
11. How are near-incidents analyzed?
    Same as incidents, learning

Improvement measurements

12. Are there improvement measurements developed based on incident reports?
13. How are these improvement measurements constructed?
    Every incident a measurement, who takes initiative, who implements
14. Are these improvement measurements evaluated?
    How often, by who, is the influence in incident reports visible

Relationship to patients

15. Are patients always informed about incidents?
16. Are patients always informed about near-incidents?
17. Is the feedback of patients registered?

Data about safety

18. Are you familiar with the scores of your department in the SAQ 2009 and SAQ 2012?
19. What is your opinion about these scores?
    Recognition of the situation or differences
20. Are you familiar with the scores of your department in the CQ index 2013?
21. What is your opinion about this score?
    Recognition of the situation or differences

3 Interview results

3.1 Internal Medicine

3.1.1 Composition of DIM Internal Medicine

Because the number of reports increased at the department of internal medicine over the years, they have decided last year to create miniDIMs at the different wards for analyzing incidents at the departments immediately. These miniDIMs consist of one or two nurses. The responsibility was and is with the official DIM. The composition of the DIM is very various; doctors, nurses as well staff members participate.
The staff employees –non care giving members- of the DIM are still the same as 5 years ago when the system was implemented.

3.1.2 Collaboration/link DIM with (other) department(s)

The DIMmember (DM) and the Clinical Manager (CM) both have the same opinion when it comes to the relation between the DIM and the department. The construction and working procedure of the DIM is developed so that there are so called miniDIMs that are analyzing the smaller incidents that are local or specific for one of the wards. This construction creates a fast method for troubleshooting. During the interviews, the nurses did not mention anything about this system. Also the CIMresponsible (CR) did not mention this construction.
The nurses and the CR did mention the openness of the department, as also did the CM and DM. The diversity of the members of the DIM creates easy access for all employees.
Discussing incident reports in weekly work meetings creates involvement of all employees, believe the CM and the DM. The nurses do not disagree, but mention there is not an incident analyzed every week, once a month would be a better estimate.
An important drawback for the collaboration with other departments is the use of an own incident reporting system, said CR. This opinion is shared with the CM, because forwarding an incident takes extra time for the DIM to copy-paste the information into the other -UMCG wide- system and this could create a threshold. The DM thinks collaboration can be improved, but does not experience the threshold for forwarding an incident because of time.
The nurses think collaboration can be improved, communication incidents with other departments are handled by phone or via the directing nurse, instead of reporting this incident in the reporting system.

3.1.3 Incident reporting

However the CM and DM think that the incident reporting culture is good and nearly all incidents are reported, with only the remark that these statements are not controllable, the nurses indicate there is a certain threshold for reporting. This is mainly because of the time it takes to report, this has to be done after service. During the day the workload is mostly too high to take time to report, the estimated time for reporting is 5-10 minutes. Also subjects of incidents that occur often are not always reported, because of negligence by the frequency. The nurses are stimulated to report by the directing nurse (‘regieverpleegkundige’) or the head nurse (‘hoofdverpleegkundige’), in the case of often occurring incidents this is a good reminder. The nurses experience at least once a shift a situation that is called

report worthy, but often this is forgotten by the end of the shift.
The DM thinks that the diversity in reporters is an indication for willingness to report.
According to the nurses are near-incidents often neglected, because the time aspect and it is hard to determine whether it is reporting-worthy. The learning aspect of reporting near-incidents is not extra mentioned by someone of the management. The DM says that near-incidents are reported and treated the same as incidents and the CM think it can be done better. The CM thinks on this point that the department Internal Medicine is not operating different than other departments.

3.1.4 Incident analysis

Incident reports are received by the DIM and analyzed for the first, rough view. Both the CM and the DM confirm this construction. A broader or deeper analysis was always done by the DIM secretary, but this will be outsourced to other DIM members from now on.
Incidents are only analyzed in groups when one of the DIM members noticed an increase in a specific type. There is no system for this, it draws on the attention of the DIM members.

3.1.5 Improvement measurements

Asking the nurses about improvement measurements after reporting incidents did respond in the remark that there has never been an improvement measurement based on incident reports, as far as they know. This is in great contrast to the explanation of the CM and DM; they pronounce that several incidents were the base for improvement measurements. The CM emphasizes the importance of the mini DIMs, because they resolve many incidents very fast.
The DM sais that the DIM proposes several improvement measures, whereas the CM thinks the DIM is only a registration and counting institution.

3.1.6 Relationship to patients

All of the interviewees tell that incidents are in principle always told to the concerned patient. In principle, because sometimes the patient is not approachable (for medical reasons or language problems) or sometimes the patient was not able to notice the incident (very low risk). All of the interviewees think that telling too much to patients, for example also near-incidents, would negatively influence the safety feeling of the patient.

3.1.7 Data about safety

The DM and CM have been informed about the results of the Safety Attitude Questionnaire of 2009 and 2012. For both of them the results, they scored lower than the average of the UMCG, did not trigger to change attitudes or methods. Safety is always an important subject and can be reached by combining several initiatives. The CM is not impressed by the results, but he knows that the wards did ‘something’ with the results. The nurses are not familiar with the results, it might be possible that they have seen this graphs and figures before, but they cannot remember.
The CQ index is not relevant for internal medicine because of the research design.
During the past years more attention is paid to incident reporting, the CM hopes this is the reason for improvement in reports. The DM and also the nurses think that extra attention for reporting has a positive result and for example a training is seen back in the number of reports.

3.2 Pediatrics

3.2.1 Composition of DIM Pediatrics

DIM pediatrics is composed after evaluating the different DIMs of the different wards belonging to pediatrics. This means, the system of incident reporting of pediatrics was first decentralized and later on there is a central DIM composed. This is different than other departments in the UMCG. This system is good for all interviewees and has enough background of the different functions and due to the decentralized DIMs of the wards the connection to the working floor is good.

3.2.2 Collaboration/link DIM with (other) department(s)

Due to the system of decentralized pediatric-DIMs and one centralized it is good embedded in the department. The decentralization makes the distribution of tasks very clear, said DM and the nurses confirm this.

Collaboration with other departments is highly developed; the DM emphasizes the regularly collaboration with the pharmacy and the recently developed collaboration with surgery. The CM said that whenever an incident is larger than the department, help is always requested at other departments or other departments are asked to involve in the analyzing process.

The contact and collaboration with the CIM is good, but improvement is possible. The CM thinks that de CIM should fulfill a more informing role at other information moments than only for the DIM (other staff meetings) by, for example, spreading annual reports. Because of the other organization of the DIM pediatrics, the CIM functions as an example because of the helicopter view.

3.2.3 Incident reporting

The nurses of the wards think that incident reporting is easy, there is a real 'no shaming and blaming' culture. The only drawback for incident reporting is the time it takes, depending on the report it can take 5-15 minutes to answer all the (open) questions. The time it takes influences the choice to report; when the workload is too high, smaller incidents might be neglected because of lack of time.

The DM emphasizes the influence of new protocols or instruments on the incident reporting numbers; introducing something increase the reports immediately. The CM thinks that irritation plays an important role in incident reporting, the larger the irritation the more often it is reported. The irritation has a relation with the impact of the incident. The CM thinks that possible underreporting is caused by negligence and not by fear.

The DM recognizes los of near-incidents in the reports, while the nurses said that near-incidents are not often reported. For the nurses it is faster to resolve the near-incident and therefore it is not always reported. The CM thinks that near-incidents due to medication errors are often reported, but in other areas it is not so common to report.

3.2.4 Incident analysis

Analysis of the incidents is in the first place the role of the decentralized DIM, the corresponding DIM of the ward or outpatient clinic. The role of the DIM pediatrics is to make an analysis of the total of reports and signaling trends. The CM thinks that trends are often signaled and analyze very well by the DIM.

For every miniDIM the target to start analyzing the incident report is within one week; within 3 months it should be finished. The analysis is, according to DM, fast and effective. Extra information is asked at

the nurses or doctors involved. The nurses declare that there is not often asked for more information. Feedback on the incident reported is given by e-mail.

3.2.5 Improvement measurements

Improvement measurements are proposed by the miniDIMs to their supervisor. This works not as good as it should be, according to DM, because the supervisor is sometimes outsourcing the implementation to the DIM. This is not possible, because the DIM has no competence to do so. Also the CM emphasizes the importance of supervisors in the departments, this works not optimal yet but is of big concern and the improvement program is already started.

3.2.6 Relationship to patients

The nurses declare every incident that reached the patient is reported to the patient and/or the parents of the patient, this is done because of the impact it can have and because it is policy to report it. Near-incidents are not reported because it could cause agitation, which is not desirable said the DM and nurses. The CM is not aware of the incidents reported to patients and/or parents.

3.2.7 Data about safety

The SAQ and CQ data is known by the DM and CM. The department has as a whole several improvement measurements implemented thanks to these results, besides their own observations. The wards have also specific improvement measurements, based on the results of that specific ward. The CM emphasizes that the workload of the department increased enormously and this could have a negative influence on the next CQ index. Therefore she is wondering what it will do with the results on this point. The SAQ and CQ is complemented at the departments by asking the employees if they would bring their own child to the department. The result was slightly negative a few years ago, but it is rising.

3.3 Surgery

3.3.1 Composition of DIM Surgery

The DIM Surgery is composed by different staff members, doctors and nurses. The composition changes every few months, because of the involvement of doctors in training. They participate only 8-12 weeks. This is remarkable, because not all DIMs use this system. This involvement leads to higher awareness of incident reporting.

3.3.2 Collaboration/link DIM with (other) department(s)

The DIM surgery works only centralized, all the tasks and responsibilities are with the DIM, said DM. The DM is critical about this working method, because it is a weak system and needs more support from the other employees. The CM is very praiseful about the current system and is proud of the DIM members. For the nurses the DIM is an analyzing group of people, but what they exactly are doing is not known. This can better, think the nurses, because more insight would increase the willingness to report.
With other departments the DIM surgery cooperates very well. There are already some structures for frequently collaboration, for example with the DIM of operating rooms and also with anesthesiology. The nurses declare that incidents or problems with other departments are communicated by other ways than the incident report. Often the involved party is called and the incident, or problem, is solved immediately.

3.3.3 Incident reporting

The CM and DM think that the culture of incident reporting is good, there should be no fears and everyone should be able to report if there is an incident. The same yields for near-incidents, although this category is harder because it is neglected sometimes.

The nurses indicate an incident report on approximately 5 minutes. The no shaming and blaming is known by the nurses and they confirm that there is no fear to report. The problem that it can take lots of time is an issue, is also mentioned by CM.

The CM is very proud of the doctors that are reporting more and more, but they are hardly not aware of the nurses that are reporting less (since the total number of reports is constant and the doctors are increasing, the nurses should decrease). The CR thinks that the DIM has problems with involving the nurses. There is no declaration for the decreasing number of reports, according to the DM. The DM is worried about the participation of other employees besides doctors and nurses for incident reporting. For example the medical administration employees do not report often. The DM made special arrangements with them; they do not report every incident, but they are aware of incidents that occur often and consult the DM for possible measurement options.

Before the implementation of the hospital-wide incident reporting system, the department surgery had already a kind of reporting system, explained the CR. This could be a reason for the relative high numbers of reports in the early years of the system, thinks the CR.

3.3.4 Incident analysis

Analysis is done by the DIM, mostly the secretary is analyzing. Other DIM members or employees of the department are involved when it is about their specialty. Analysis of incidents is done methodological and systematically, according to the DM and CM. The incident reporting system does not facilitate for a good analyzing system, therefore the DIM uses excel files instead.

Notable is that every incident is analyzed, because of the believe that the cause of the incident might be bigger than thought at the beginning. Several incident that were at first sight slightly simple, were caused by bigger problems that could have lead to more and riskier incidents.

3.3.5 Improvement measurements

Several reported incidents lead to improvement measurements, according to the DM. Although the motto at the department is ‘who knows the solution, may say so’, said by the CM, the DM has most of the improvement measurements invented. The implementation and also the improvement of the measurement is divided over several persons within the department (management, doctors, nurses, etc). The CM thinks that the PDCA-cycle is well developed and that the Check and Act only need little improvements. The DM thinks that the department is lacking behind on de Check-step.

The nurses indicate that they solve problems or incidents immediately, but do not come with longer lasting solutions.

The latest improvement step on implementing measurements, according to DM, is making one person responsible for the implementation step. This means that whenever a measurement is confirmed by the management team, one employee is made responsible for the implementation and this person can be checked by the DIM.

3.3.6 Relationship to patients

Patients are informed about incidents when it reached the patient and it might have an effect on the patient, according to the nurses. The nurses also declare that it is a subjective decision to inform the patient, it is only decided by the nurse and they make an estimate of the risk. The lower the risk, the lower the chance to inform the patient. Also the CM says that patients are informed after a risk estimation of the health care professional.

The DM is worried about the quantity of incidents that is reported to the patients, because of the risk estimation of the nurses less is reported. If patients might have the feeling that something is not going well, informing them might increase their trust. Most of the employees of the department believe that informing the patients could cause agitation instead of higher trust by openness and honesty.

3.3.7 Data about safety

The SAQ and CQ data is known by the CM, he thinks that these researches are worthless and they do not influence the policy of safety on the department. The last scores for surgery are higher than average, but according to the CM this does not make any difference. Also lower than average scores do not encourage to change plans. He emphasizes that lots of attention is paid on safety and incident reporting, but this is not caused by these researches.

The DM is not well informed about the SAQ and CQ, but thinks the scores higher than average are caused by the positive environment and the safe and well developed reporting culture.

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