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A Critical Perspective on Organisational Development and Patient Safety in Austria

Konstantin Karl Weicht, MRes

A thesis submitted in partial fulfilment of the requirements of Sheffield Hallam University for the degree of Doctor of Philosophy

February 2012
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<td>AHRQ</td>
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<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>AIMS</td>
<td>Australian Incident Monitoring Study (Australia)</td>
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<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>APS</td>
<td>(German: Aktionsbundnis Patientensicherheit) German Coalition for Patient Safety (Germany)</td>
</tr>
<tr>
<td>BBC</td>
<td>British Broadcasting Corporation (United Kingdom)</td>
</tr>
<tr>
<td>BMJ</td>
<td>British Medical Journal (United Kingdom)</td>
</tr>
<tr>
<td>BMG</td>
<td>(German: Bundesministerium fuer Gesundheit) Federal Ministry of Health (Austria)</td>
</tr>
<tr>
<td>BIQG</td>
<td>(German: Bundesinstitut fuer Qualitaet im Gesundheitswesen) Federal Institute for Quality in the Health Care System, belongs to BMG</td>
</tr>
<tr>
<td>BRI</td>
<td>Bristol Royal Infirmary (United Kingdom)</td>
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<tr>
<td>CAST</td>
<td>Commercial Aviation Safety Team (United States)</td>
</tr>
<tr>
<td>CIRS</td>
<td>Critical Incident Reporting System(s)</td>
</tr>
<tr>
<td>CIRS2</td>
<td>Critical Incident Reporting System 2 from Expert 1</td>
</tr>
<tr>
<td>CIRSE</td>
<td>Cardiovascular and Interventional Radiological Society of Europe</td>
</tr>
<tr>
<td>CIRSmedical</td>
<td>a CIRS brand name</td>
</tr>
<tr>
<td>CPSI</td>
<td>Canadian Patient Safety Institute (Canada)</td>
</tr>
<tr>
<td>C1</td>
<td>Closed Question 1 in the questionnaire</td>
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<tr>
<td>DOH</td>
<td>Department of Health (United Kingdom)</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>EUNetPas</td>
<td>European Union Network for Patient Safety</td>
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<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>GMC</td>
<td>General Medical Council</td>
</tr>
<tr>
<td>HM</td>
<td>Ministry of Health (United Kingdom)</td>
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<tr>
<td>HMPS</td>
<td>Harvard Medical Practice Study (Brennan et al., 1991)</td>
</tr>
<tr>
<td>ICS</td>
<td>The Intensive Care Society (United Kingdom)</td>
</tr>
<tr>
<td>IHI</td>
<td>Institute for Health Care Improvement (United States)</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine (United States)</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations (United States)</td>
</tr>
<tr>
<td>NASA</td>
<td>National Aeronautics and Space Administration (United States)</td>
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<tr>
<td>NHS</td>
<td>National Health Service (United Kingdom)</td>
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<td>NPSA</td>
<td>National Patient Safety Agency (United Kingdom)</td>
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<tr>
<td>NPSF</td>
<td>National Patient Safety Foundation (United States)</td>
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<tr>
<td>NRLS</td>
<td>National Reporting and Learning System (United Kingdom)</td>
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<tr>
<td>OAK</td>
<td>(German: Österreichische Arztekammer) Austrian Association of Resident Doctors (Austria)</td>
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<tr>
<td>OD</td>
<td>Observation Day</td>
</tr>
<tr>
<td>OEGGG</td>
<td>(German: Österreichischen Gesellschaft für Gynäkologie und Geburtshilfe) Austrian Society for Gynaecology and Obstetrics</td>
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<tr>
<td>ORF</td>
<td>(German: Österreichischer Rundfunk) Austrian national public service broadcaster (Austria)</td>
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<td>0.15</td>
<td>Open Question 15 in the questionnaire</td>
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<tr>
<td>QuIC</td>
<td>Quality Interagency Coordination Task Force (United States)</td>
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<tr>
<td>SHU</td>
<td>Sheffield Hallam University</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>StPO</td>
<td>(German: Strafprozessordnung) code of criminal procedure (Austria)</td>
</tr>
<tr>
<td>UCS</td>
<td>Utah and Colorado Study (Thomas et al., 2000)</td>
</tr>
<tr>
<td>WAPS</td>
<td>World Alliance for Patient Safety, belongs to WHO</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WKAV</td>
<td>Vienna City Hospital Association</td>
</tr>
<tr>
<td>WMA</td>
<td>World Medical Association</td>
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Declarations

I, Konstantin Karl Weicht, hereby certify that this thesis has been written by me, that it is the record of work carried out by me and that it has not been submitted in any previous application for a higher degree.

Date___________ Signature of candidate____________________

I was admitted as a research student in March, 2005 and as a candidate for the degree of Doctor of Philosophy, the higher study for which this is a record was carried out at Sheffield Hallam University between 2005 and 2012.

Date___________ Signature of candidate____________________

I hereby certify that the candidate has fulfilled the conditions of the Resolution and Regulations appropriate for the degree of Doctor of Philosophy at Sheffield Hallam University and that the candidate is qualified to submit this thesis in application for that degree.

Date___________ Signature of supervisor__________________

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Abstract

Contrary to the international trend of building Critical Incident Reporting Systems (CIRS) into national health systems there is no national CIRS in Austrian hospitals. In response to this lack of a national policy the Austrian Association for Gynaecology and Obstetrics (OEGGG) has started an initiative enabling Women Hospitals in Austria to join a voluntary international online CIRS. This study critically addresses the problem of preventable error leading to patient harm and investigates the contribution that CIRS, arguably one key element in the new patient safety movement, may have so that fewer patients die. This is necessary as progress in patient safety has been much slower than anticipated, despite the patient safety revival around the year 2000, increasing attention and numerous initiatives. Moreover there is little systematic documentation and contemporary knowledge about the implementation, management, and effect of CIRS in health care.

This study critically investigates this gap from a critical ethnographic perspective and provides an in-depth account of CIRS in an Austrian context. The study uses interviews, a questionnaire, and fieldwork observation over a period of two years at one Women Hospital in Vienna. Interviews and questionnaire are used to assess the organisation and these data provide ground for subsequent critical ethnographic observation. The fieldwork observation in the hospital is used to illustrate ways in which this type of research can contribute to the growth of knowledge on managerial (non-clinical) aspects of patient safety. Observational studies can serve to identify latent managerial system vulnerabilities and leverage points that can aid the identification, development and implementation of overall system improvements. In addition a continuous in-depth literature review is being employed.

Findings suggest that the current hospital organisation is ill resourced in implementing new patient safety strategies and effectively identifying and addressing critical incidents. In particular the study identifies latent managerial factors that complicate the performance of health care professionals and potentially contribute to adverse outcomes. It suggests that the ‘systems approach’ to error in health care currently focuses too much on core medical tasks and a principal separation between clinical and non clinical aspects of service provision needs to be made. Key contributions emanating from this research are a clinical / non-clinical patient safety continuum model, a patient safety framework, three phases of CIRS operationalisation, the research method employed, as well as the notion that different research ethics in different health systems require more careful interpretation of research contributions. In addition the continuous literature review reveals that one of the key arguments of the new patient safety movement, the high number of preventable errors leading to death in health care, is incorrect. This is critical as it does not allow channelling limited resources to where they are most needed. The study emphasises the need for more research in this subject area and more organisational support in health care organisations.
A Critical Perspective on Organisational Development and Patient Safety in Austria

Konstantin Karl Weicht, MRes

A thesis submitted in partial fulfilment of the requirements of Sheffield Hallam University
for the degree of Doctor of Philosophy

February 2012
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<thead>
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<th>Description</th>
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<tbody>
<tr>
<td>AHRQ</td>
<td>Agency for Health Care Research and Quality (United States)</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>AIMS</td>
<td>Australian Incident Monitoring Study (Australia)</td>
</tr>
<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>APS</td>
<td>(German: Aktionsbundnis Patientensicherheit) German Coalition for Patient Safety (Germany)</td>
</tr>
<tr>
<td>BBC</td>
<td>British Broadcasting Corporation (United Kingdom)</td>
</tr>
<tr>
<td>BMJ</td>
<td>British Medical Journal (United Kingdom)</td>
</tr>
<tr>
<td>BMG</td>
<td>(German: Bundesministerium fuer Gesundheit) Federal Ministry of Health (Austria)</td>
</tr>
<tr>
<td>BIQG</td>
<td>(German: Bundesinstitut fuer Qualitaet im Gesundheitswesen) Federal Institute for Quality in the Health Care System, belongs to BMG</td>
</tr>
<tr>
<td>BRI</td>
<td>Bristol Royal Infirmary (United Kingdom)</td>
</tr>
<tr>
<td>CAST</td>
<td>Commercial Aviation Safety Team (United States)</td>
</tr>
<tr>
<td>CIRS</td>
<td>Critical Incident Reporting System(s)</td>
</tr>
<tr>
<td>CIRS2</td>
<td>Critical Incident Reporting System 2 from Expert 1</td>
</tr>
<tr>
<td>CIRSE</td>
<td>Cardiovascular and Interventional Radiological Society of Europe</td>
</tr>
<tr>
<td>CIRSmédical</td>
<td>a CIRS brand name</td>
</tr>
<tr>
<td>CPSI</td>
<td>Canadian Patient Safety Institute (Canada)</td>
</tr>
<tr>
<td>C1</td>
<td>Closed Question 1 in the questionnaire</td>
</tr>
<tr>
<td>DOH</td>
<td>Department of Health (United Kingdom)</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<td>EUNetPas</td>
<td>European Union Network for Patient Safety</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>GMC</td>
<td>General Medical Council</td>
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<tr>
<td>HM</td>
<td>Ministry of Health (United Kingdom)</td>
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<td>HMPS</td>
<td>Harvard Medical Practice Study (Brennan et al., 1991)</td>
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<tr>
<td>ICS</td>
<td>The Intensive Care Society (United Kingdom)</td>
</tr>
<tr>
<td>IHI</td>
<td>Institute for Health Care Improvement (United States)</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine (United States)</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations (United States)</td>
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<tr>
<td>NASA</td>
<td>National Aeronautics and Space Administration (United States)</td>
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<td>NHS</td>
<td>National Health Service (United Kingdom)</td>
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<td>NPSA</td>
<td>National Patient Safety Agency (United Kingdom)</td>
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<td>NPSF</td>
<td>National Patient Safety Foundation (United States)</td>
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<td>NRLS</td>
<td>National Reporting and Learning System (United Kingdom)</td>
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<tr>
<td>OAK</td>
<td>(German: Österreichische Ärztekammer) Austrian Association of Resident Doctors (Austria)</td>
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<tr>
<td>OD</td>
<td>Observation Day</td>
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<tr>
<td>OEGGG</td>
<td>(German: Österreichischen Gesellschaft für Gynäkologie und Geburtshilfe) Austrian Society for Gynaecology and Obstetrics</td>
</tr>
<tr>
<td>ORF</td>
<td>(German: Österreichischer Rundfunk) Austrian national public service broadcaster (Austria)</td>
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<td>0.15</td>
<td>Open Question 15 in the questionnaire</td>
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<tr>
<td>QuIC</td>
<td>Quality Interagency Coordination Task Force (United States)</td>
</tr>
<tr>
<td>SHU</td>
<td>Sheffield Hallam University</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
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<tr>
<td>StPO</td>
<td>(German: Strafprozessordnung) code of criminal procedure (Austria)</td>
</tr>
<tr>
<td>UCS</td>
<td>Utah and Colorado Study (Thomas et al., 2000)</td>
</tr>
<tr>
<td>WAPS</td>
<td>World Alliance for Patient Safety, belongs to WHO</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WKAV</td>
<td>Vienna City Hospital Association</td>
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<tr>
<td>WMA</td>
<td>World Medical Association</td>
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Declarations

I, Konstantin Karl Weicht, hereby certify that this thesis has been written by me, that it is the record of work carried out by me and that it has not been submitted in any previous application for a higher degree.

Date___________ Signature of candidate___________________________

I was admitted as a research student in March, 2005 and as a candidate for the degree of Doctor of Philosophy, the higher study for which this is a record was carried out at Sheffield Hallam University between 2005 and 2012.

Date___________ Signature of candidate___________________________

I hereby certify that the candidate has fulfilled the conditions of the Resolution and Regulations appropriate for the degree of Doctor of Philosophy at Sheffield Hallam University and that the candidate is qualified to submit this thesis in application for that degree.

Date___________ Signature of supervisor___________________________

-XIII-
Abstract

Contrary to the international trend of building Critical Incident Reporting Systems (CIRS) into national health systems there is no national CIRS in Austrian hospitals. In response to this lack of a national policy the Austrian Association for Gynaecology and Obstetrics (OEGGG) has started an initiative enabling Women Hospitals in Austria to join a voluntary international online CIRS. This study critically addresses the problem of preventable error leading to patient harm and investigates the contribution that CIRS, arguably one key element in the new patient safety movement, may have so that fewer patients die. This is necessary as progress in patient safety has been much slower than anticipated, despite the patient safety revival around the year 2000, increasing attention and numerous initiatives. Moreover there is little systematic documentation and contemporary knowledge about the implementation, management, and effect of CIRS in health care. This study critically investigates this gap from a critical ethnographic perspective and provides an in-depth account of CIRS in an Austrian context. The study uses interviews, a questionnaire, and fieldwork observation over a period of two years at one Women Hospital in Vienna. Interviews and questionnaire are used to assess the organisation and these data provide ground for subsequent critical ethnographic observation. The fieldwork observation in the hospital is used to illustrate ways in which this type of research can contribute to the growth of knowledge on managerial (non-clinical) aspects of patient safety. Observational studies can serve to identify latent managerial system vulnerabilities and leverage points that can aid the identification, development and implementation of overall system improvements. In addition a continuous in-depth literature review is being employed.

Findings suggest that the current hospital organisation is ill resourced in implementing new patient safety strategies and effectively identifying and addressing critical incidents. In particular the study identifies latent managerial factors that complicate the performance of health care professionals and potentially contribute to adverse outcomes. It suggests that the ‘systems approach’ to error in health care currently focuses too much on core medical tasks and a principal separation between clinical and non clinical aspects of service provision needs to be made. Key contributions emanating from this research are a clinical / non-clinical patient safety continuum model, a patient safety framework, three phases of CIRS operationalisation, the research method employed, as well as the notion that different research ethics in different health systems require more careful interpretation of research contributions. In addition the continuous literature review reveals that one of the key arguments of the new patient safety movement, the high number of preventable errors leading to death in health care, is incorrect. This is critical as it does not allow channelling limited resources to where they are most needed. The study emphasises the need for more research in this subject area and more organisational support in health care organisations.
Acknowledgements

This study was funded by the Faculty of Organisation & Management Bursary Award 2005 at Sheffield Hallam University for which I am grateful for. I owe thanks to Emeritus Professor John McAuley, Emeritus Professor David Megginson, as well as Dr. James Pinder who took on the daunting task of supervising this thesis and endured to the very end. I also wish to thank all of the personnel at the Women Hospital in Vienna who participated in the study and without whose cooperation this research would not have been possible, as well as a number of international patient safety experts for their valuable comments and critique.

I want to thank my examiners Dr. Paul Forrester and Dr. Murray Clark for their interest in my work, for their encouragement, and for some very helpful comments during the viva voce.

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taught me how to learn; the late Dr. Erika Gutbrodt-Zimmerl, and Mrs Edith Schimek. Without them I would not have come anywhere near doing a PhD and critically engaging with the world we live in. Thank you all very much.

My final thanks can only go to my wonderful wife 1-Ting from whom I learn something useful and new every day and who has led me into a life with Jesus Christ. May God bless her!
CHAPTER 1: INTRODUCTION

Too many people die or are unnecessarily harmed by our health systems. Current patient safety and organisation improvement initiatives in health care often strongly focus on clinical aspects of service provision. However, how health care organisations cope with non-clinical demands that come along with these initiatives is an area largely unaddressed in the new patient safety era- and organisation and management literature. This thesis aims to narrow this gap by deliberately focusing on non-clinical aspects of safety endeavours in health care. It critically investigates the endeavours of a Women Hospital in Vienna in setting up and running a critical incident reporting system in order to find out how CIRS relates to current conceptualisations of organisational error in health care, if and how CIRS makes a contribution to patient safety, and to explore how CIRS' strengths and weaknesses may be related to and / or consciously controlled by the organisation and management of the hospital. The research question around which this thesis is framed may therefore be formulated as “What can conceptualisations of organisational error show about attempts to implement CIRS; how is CIRS implemented in practice and to what effect?”

It is hoped that answering this question will lead to a stronger conceptualisation of organisational error that will aid the identification of system vulnerabilities and foster the development and implementation of whole system improvements. This is expected to result in an original contribution to the patient safety and organisation and management discourse. It is hoped that in providing evidence of supportive measures or otherwise barriers to CIRS and patient safety this thesis will provide a framework that other researchers may want to use for structuring their inquiries and on the other hand (management) practitioners may find useful in their endeavours of improving safety and critically reflecting
on organisational development in their organisations. Research findings may provide answers as to why progress in patient safety has been so slow, especially when CIRS has proofed to be much useful in other complex industries. Last but not least this thesis is written with the many people in mind which have been unnecessarily harmed by our health systems. By stressing what seem to be commonly known but not very well documented and hence largely unaddressed organisational and non-clinical mishaps it is hoped that this thesis makes a contribution so that fewer patients die or are harmed.

This introduction chapter ‘sets the scene’ with the following section on safety in health care and the role that critical incident reporting systems play, section 1.2 explicitly stating the research-problem, -question, aims and objectives, section 1.3 introducing the conceptual framework of the thesis, and section 1.4 ‘flow of the thesis’ to facilitate the reader in navigating through the thesis.

1.1. Safety in health care

In most developed countries the health care sector represents about 8-15 percent of economic activity and is therefore one of the largest industry sectors. One out of 10 workers is employed in the health care sector. The social, political and economic context in which health care organisations have to exist is often a hostile, fast changing and pressured environment. The hospital today is a highly complex and interactive system, with personnel clustered in over a thousand job categories (Koeck, 1998). Work in a hospital represents a mix of technical expertise, emotions and individual differences, which makes managing people a complex task. Different competencies need to be co-ordinated to deliver a service to the patient. Managers and leaders strive to balance competing, shifting and irreconcilable demands from a wide range of stakeholders - and do so while under close public scrutiny (Walshe and Smith, 2006).
Expectations in the provision of health care in hospitals in developed countries have been on a steady increase. This is because medical knowledge has increased significantly and constantly over the years. There are new treatments and the facilities in which health care is provided are modern and equipped with state of the art equipment. But not only has medical knowledge increased. Also understanding of organisations and complexity of work tasks has increased. Organisations have become ‘learning organisations’ (Senge, 2006), employees have transformed into ‘knowledge workers’ (Drucker, 2003), and organisations employ quality strategies to pursue excellence.

But there is a paradox here. Despite an increased understanding of medicine, better health care facilities, increased understanding of organisations, and numerous quality improvement programmes, recent years have brought increasing attention to error in health care. It appears as if health care organisations in developed countries are not as safe as they ought to be and there is a growing consensus amongst safety experts that all health care systems around the world occasionally unintentionally harm patients whom they are seeking to help (Lewis and Fletcher, 2005). The US Institute of Medicine (IOM, 2000) estimates that each year between 44.000 and 98.000 Americans die as a result of medical errors in the US health system. In the United Kingdom there are an estimated 900.000 incidents each year that either harm or nearly harm a NHS hospital inpatient (NPSA, 2005b).

While this thesis will give considerable attention to and discuss the reliability of those numbers there seems to be a consensus that health care is not as safe and reliable as it ought to be (Amalberti et al., 2005). Cook et al (1998:5) ascertain that “health care stands in 1998 where nuclear power stood at the end of 1979”. This statement has since been substantiated in the work of others (for example Gaba, 2000; Shojania et al., 2001; DOH, 2004; NPSA, 2005b). Due to the (alleged) inattention of the medical professions towards medical error and
other deficiencies, such as a lag in introducing sophisticated information technologies, health care is increasingly and unfavourably compared to other complex industries (Shojania et al., 2001; Leape, 1994; IOM, 2000; Helmreich, 2000; Barach and Small, 2000; Reason, 2000). Other industries have invested heavily in quality management and improvement strategies and have made remarkable progress in error reduction and safety improvement (QuIC, 2000). Accordingly these non-medical complex industries, so called high reliability organisations such as aviation, have an exemplary track record of safety (Shojania et al., 2001; Pizzi et al., 2001; Leape, 1994).

High reliability organisations are organisations that create safety by anticipating and planning for unexpected events and future surprises. They have been named prime examples of the system approach (Reason, 2000). These organisations invest in anticipating the changing potential for failure regardless of past success. They do so because they appreciate that their knowledge is imperfect and that the environment in which they operate continues to change (Woods, 2000). High reliability organisations do everything possible to avoid altogether certain kinds of negative outcomes (Klein et al., 1995). These organisations do not claim to be immune to catastrophic accidents but accept that catastrophes can happen and do happen, even to the best of organisations, (Reason, 2000) and they invest intensively in error avoiding strategies (Klein et al., 1995). High reliability organisations expect to make errors, at the same time they have a collective preoccupation with the possibility for error, and they train their workforce to recognise and recover from them (Reason, 2000).

High reliability industries offer lessons that may be applicable to reducing errors in health care. It is generally acknowledged that no one method will cure all problems, but that there is a generalisable approach (including the strategies discussed below) that is likely to yield favourable outcomes if applied vigorously (QuIC, 2000). These characteristics include the following (QuIC, 2000:34):
• not tolerating high error rates and setting ambitious targets for error reduction initiatives

• developing tracking mechanisms that expose errors

• **relying on the abundant reports of errors and near misses**

• thoroughly investigating errors and analysing them and the use of various tools, including root cause analysis

• applying to error reduction a systems approach that embraces a wide array of human factors, technical, and organisational remedies

• focusing on systems solutions that do not seek to find individual fault and blame

• changing the organisational culture so that it enhances safety and error reduction

• allocating adequate resources to error prevention initiatives and the development of a knowledge base to support them

• recognising that solutions often come from unexpected sources, ‘out of the box’ thinking, and new combinations of disciplines (e.g. human factors psychology with aeronautical engineering)

The underlying concept of systems design in high reliability industries, where work environments are designed to make it difficult for humans to err and which minimize the consequences of error, was not institutionalized in health care because it did not present a major focus of hospital medical activities (Leape, 1994). Recognising this shortcoming has marked a change in the way safety is seen in health care. Subsequently health care organisations, as yet high risk
organisations, have come to appreciate a systems perspective to safety. There is a growing acceptance that the management of error requires an acceptance of error with consideration given to the relationship between individual human behaviour and the factors that influence this behaviour (Reason and Hobbs, 2003). In order to improve safety and to operate in hazardous settings with reliability many health care organisations strive to emulate high reliability organisations from other industries that have a proven track record of safety (Carroll and Rudolph, 2006; Weick et al., 1999). Following Reason’s (2000) system approach to human error the correct response to medical error is to redesign the system, based on understanding the nature and extent of error, changing conditions that induce error, determining behaviours that prevent or mitigate error, and training personnel in their use (Helmreich et al., 1999). Bundling of efforts to improve safety in health care organisations has become commonly known over the past decade or so under the term patient safety.

Patient safety was a fairly new field when the IOM report captured the world’s attention in late 1999/early 2000 (AHRQ, 2009) and within the emerging framework of patient safety many different patient safety interventions quickly sprung up. As a consequence health care organizations wanting to engage in patient safety are faced with an array of areas with the potential for improvement. In the UK “An Organisation with a Memory” (DOH, 2000), or in the US the IOM report To err is human’ (IOM, 2000) presented wide ranging recommendations for improving patient safety. In the US these recommendations were framed in five principles for the design of safety systems in health care organizations (IOM, 2000:166ff):

**Principle 1: Provide leadership**

- patient safety as a priority corporate objective
- patient safety is everyone’s responsibility
• clear assignments for and expectation of safety oversight

• provision of human and financial resources for error analysis and systems redesign

• development of effective mechanisms for identifying and dealing with unsafe practitioners

**Principle 2: Respect human limits in process design**

• design jobs for safety

• avoid reliance on memory

• use constraints and forcing functions

• avoid reliance on vigilance

• simplify key processes

• standardize work processes

**Principle 3: Promote effective team functioning**

• train in teams those who are expected to work in teams

• include patient in safety design and the process of care

**Principle 4: Anticipate the unexpected**

• adopt a proactive approach: examine processes of care for threats to safety and redesign them before accidents occur

• design for recovery

• improve access to accurate and timely information
Principle 5: Create a learning environment

- use simulations whenever possible
- *encourage reporting of errors and hazardous conditions*
- ensure no reprisals for reporting of errors
- develop a working culture in which communication flows freely regardless of authority gradient
- implement mechanisms of feedback and learning from error

The Quality Interagency Coordination Task Force, a United States federal government group, released the QuIC report (2000), a response to the IOM report and directly ordered by the US President, and was built on a four-tiered approach (1) to establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety (2) to identify and learn from medical errors through both mandatory and voluntary reporting systems (3) to raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups (4) to implement safe practices at the delivery level (QuIC, 2000:4). This report alone contained more than 100 actions to be taken by several agencies.

Shojania et al. (2001) identified specific safety related topics and practices that could be derived from outside health care. These include (Shojania et al., 2001:25):

- incident reporting systems
- root cause analysis
• computerised physician order entry and decision support as a means of reducing medication errors

• automated medication dispensing systems

• bar coding technology to avoid misidentification errors

• aviation-style preoperative checklists for anaesthesia equipment

• promoting a “culture of safety”

• crew resource management, a model for teamwork training and crisis response modelled after training approaches in aviation

• simulators (of patients or clinical scenarios) as a training tool

• human factors theory in the design of medical devices and alarms

With all these reports and recommendations some of the basic theoretical principles for safer health care had been documented. The reality however was that an extensive foundation needed to be built before any meaningful improvements could be put into action (AHRQ, 2009). Since the time of the IOM report in 1999 increased efforts, attention and resources have been given to patient safety (Benning et al., 2011). Health organisation networks have launched programmes and individual nations set up national patient safety programmes. Progress has been made over the past decade with documented evidence bearing witness to the many individuals and organisations who are conducting patient safety research and translating it into useful tools and strategies for innovation (AHRQ, 2009). Yet, even in the leading countries in patient safety such as the United States no one is completely satisfied with the extent of the progress.
Chapter 1: Introduction

While certain areas for improvement have been marked out, amongst them patient safety culture change, systems and clinical process redesign, reporting systems, health IT, medication safety, physical environment design, or simulation and training, more work is needed in demonstrating how practices get implemented and integrated into the everyday clinical workflow in order to ensure that there is full commitment to providing safe care (AHRQ, 2009). This is a challenging task and various authors have described progress in patient safety as frustratingly slow (Leape and Berwick, 2005; Benning et al., 2011; Leistikow et al., 2011) or even insufficient (Wachter, 2004). It appears as if we are at “the end of the beginning” (Wachter, 2004:534) with only modest improvement made over the past few years that ‘saw unmistakable progress but also reveals troubling gaps’ (Wachter, 2010). Overall patient safety turns out to be a very tough nut to crack (Leistikow et al., 2011).

While patient safety is concerned with entire (national) health systems one of the recurring themes in endeavours to improve safety is the concept of incident reporting. Experience from high reliability industries shows the common use of designated incident reporting systems (Waring, 2005). This is based on an understanding that errors can serve as a great source of information about a system and its systemic vulnerabilities, and can point out multiple directions for improvement. Collecting reports on errors and on those events that lead to error in a systematic way is one way of learning from experience and creates the opportunity to share with others lessons that have been learnt. Incident reporting has become a general term for all voluntary patient safety event reporting systems. These systems rely on staff who are directly involved in events to voluntarily provide detailed information (AHRQ, 2011). Incident reporting systems enable front-line staff to communicate their safety concerns and experiences of error to those responsible for safety and quality. Thus many believe that incident reporting systems are the cornerstone to safe practice (IOM, 2000; WHO, 2005a, NPSA, 2005).
Successful incident reporting systems outside health care have been described as being non-punitive, confidential, independent, analytically capable, and systems-oriented and responsive in developing solutions (Farley et al., 2008). Incident reporting should be one element of a cohesive patient safety programme that establishes a patient safety infrastructure, processes and a climate that supports the reduction of adverse events (Farley et al., 2008). Efforts have been made to create incident reporting systems for medical near misses (for example Pateisky 2005; NPSA 2005; DOH, 2004; Shojania et al., 2001; QuIC, 2000; IOM, 2000; van der Schaaf, 1998; Battles et al., 1998; Kaplan et al., 1998; Runciman et al., 1993). Several countries have launched national reporting systems in health care, apparently with Denmark and the UK being at the forefront and starting in early 2004. Despite activity to install and improve incident reporting systems in health care organisations around the world little is documented systematically about the management, use, and effect of such systems.

When this study commenced in 2005 Austria did not have a pan-Austrian quality system (BMG, 2005a) and no nationwide reporting system for medical near misses. Against a backdrop of pro-active government involvement in patient safety a group of gynaecologists and obstetricians strove to participate in and join an existing profession wide reporting system. This thesis will investigate patient safety through the lens of incident reporting systems and in an Austrian context, thoroughly investigating the introduction of an incident reporting system at one hospital department in Vienna.
1.2. Research problem, question, aim and objectives

1.2.1. Research problem

Although the exact scope of preventable error in health care is subject to debate there is consensus amongst safety experts that health care is not as safe as it ought to be. One important aspect in creating safer systems, investigating how organisational errors unfold and how they may be prevented, is the use of designated incident reporting systems. While efforts have been made to create incident reporting systems for medical near misses (for example Pateisky 2005; NPSA 2005; DOH, 2004; Shojania et al., 2001; QuIC, 2000; IOM, 2000; Schaaf, 1991; Battles et al., 1998; Kaplan et al., 1998; Runciman et al., 1993) and several countries have launched national reporting systems, still very little is documented systematically about the management, use, analysis and effect of such systems in health care. The literature on CIRS consists largely of experiences outside health care.

The success of CIRS outside health care has been attributed to a substantial approach to creating a supportive environment to reporting (Billings, 1998; Johnson, 2003). Many of the characteristics of good reporting that can be found in the patient safety literature are direct quotes to CIRS outside health care and not first hand experiences from within the health care industry. These characteristics and recommendations are therefore to be seen as implications rather than evidence of how CIRS works in health care. There is very little contemporary evidence of how incident reporting systems actually work in health care. First hand accounts on the implementation of CIRS in hospitals are rare, for example what kind of problems hospitals face when trying to apply those good characteristics or how problems have been approached and solved. In which (organisational) circumstances and environments do CIRS work effectively, and which environments make it more difficult for CIRS to work?
Can the implementation of CIRS fail, how is its success being measured, and what are the practical outcomes of using CIRS? Qualitative and ethnographic accounts of the implementation and management of CIRS are sparse. This presents a gap in the literature on which context influences affect CIRS in health care and what this ‘supportive environment to reporting’ may actually look like in a health care context.

Regarding the national context of this study very little is known about this phenomenon in Austria. It is not known if/how the new patient safety movement is perceived by medical professions and authorities in Austria and if/how patient safety recommendations will be institutionalised in the Austrian health system. When this study commenced in 2005, at the time of the introduction of a new ‘Health Care Quality Act’ (BMG, 2005a and 2005b), Austria did not have a pan-Austrian quality system (BMG, 2005a) and no nationwide reporting system for medical near misses. Against this backdrop of pro-active government involvement in patient safety, in line with the new patient safety movement, Austrian Gynaecologists and Obstetricians voluntarily joined an existing international anonymous and voluntary profession wide CIRS. This study takes an in-depth look at the implementation of CIRS in one clinic and investigates whether current practice at the hospital is commensurate with the idea of critical incident reporting and the implications this has on the use of CIRS at the hospital.

1.2.2. Research question

This research addresses the question of whether current conceptualisations of organisational error are adequate for application in a health care context. It investigates what these conceptualisations show about attempts of implementing a CIRS in a public health care setting. Do they adequately encompass all elements of organisational error in a health care setting, does
current thinking and action of stakeholders relate to these conceptual frameworks? The **overall research question** may therefore be formulated as:

**What can conceptualisations of organisational error, in particular those in health care, show about attempts to implement a Critical Incident Reporting System (CIRS) in a health care setting?**

In order to project these questions onto the present research setting and available resources this may be rephrased in a **refined research question**:

**How is a CIRS implemented in a public hospital in Austria and how is it perceived by staff?**

1.2.3. **Aim and objectives**

The **aim** of this research is to:

*provide an in-depth account of CIRS at a public Women’s’ Hospital in an Austrian context in order to find out how it relates to current conceptualisations of organisational error in health care, if and how it makes a contribution to patient safety, and to explore how its strengths and weaknesses may be related to and / or consciously controlled by the current organisation and management of the hospital. This should lead to a stronger conceptualisation of organisational error in health care, (a more generalisable) identification of system vulnerabilities and leverage points that can aid or hinder identification, development and implementation of system improvements, and make an important contribution to the current discourse on patient safety and organisation and management in a critical ethnographic tradition.*

The **objectives** of the study are to:
1. understand the practical nature of organisational error in health care
2. understand the practical nature of CIRS
3. investigate why CIRS has been implemented from a stakeholder perspective
4. collect empirical evidence of supportive measures or otherwise barriers to CIRS
5. investigate how meaningful it is for staff to use CIRS
6. enrich current conceptualisations of error in health care through interpretation of and generalisation from field data

1.3. Conceptual Framework

The conceptual framework pertaining to this thesis may be seen as consisting of three levels: research perspective (level 1), research phenomenon (level 2), and filters (level 3). This conceptual framework is exemplified in figure 1.1.
The hospital setting and clinical domains pose a natural challenge to the non-clinical observer. Doctors and nurses are highly trained professionals and a

1 clinical: Throughout this thesis the terms 'clinical' and 'non-clinical' defer from standard dictionary definitions where the word 'clinical' refers to practitioners (of medicine or psychology) who do clinical work instead of laboratory experiments. In this thesis the word 'clinical' refers to the work of either
non-clinical observer cannot be expected to rapidly learn enough about the
domain to confidently understand and document the details of many of the
activities. A non-clinician does not have the necessary background knowledge
to recognise standard versus non-standard procedural execution, to infer intent,
or to identify medical adverse events and near-misses and the potential and
severity of their impact (Roth et al., 2004). However, at the same time medical
and nursing professionals, while they have the appropriate clinical background,
often do not have management skills and knowledge of system factors and
conceptual frameworks for handling non-clinical, managerial systemic threats to
safety. The bottom level of the framework (figure 1.1) refers to the ‘research
perspective’, how the researcher sees the world, decides on, approaches and
analyses a certain research phenomenon, and what expert knowledge the
researcher possesses to offer a perspective on this phenomenon. It exemplifies
the critical ethnography perspective of a student of organisation and
management (this is elaborated in section 5.2.1 of the methodology chapter) as
well as the researcher as an individual with management expertise and ‘insight’
into the realm of health care (see sections 5.2.3 and 5.2.4 of the methodology
chapter).

The centrepiece of the framework ‘research phenomenon’ can be found at the
second level in table 1.1. Patient safety, error science, and CIRS represent the
core elements of the phenomenon and are, in themselves, inherently complex
constructs. However, it is at the front line of care, such as at the hospital
department that has been studied, where all these influences come together
and result in the quality and safety of care that patients receive. Hence these

medical or nursing professionals. This is to make a principal distinction to other individuals in the
hospital who do not have a medical or nursing background (the terms medical and nursing respectively
are only used when referring to just either one of these two groups of professions). Non-clinical in that
sense refers to anyone who does not have any medical or nursing knowledge and who may or may not
work in a hospital (i.e. a secretary would be a non-clinical person, the author of this study is a non-clinical
observer).
three elements are exemplified to overlap, merge, and ‘come to life’ at a hospital level and result in an opportunity for investigation in a real world setting (PhD). Accounts of this synergy of elements are rare and do not yet provide sufficient feedback to trigger change in current hospital activities, business functions, or procedures. Much emphasis seems to be on “numbers” and more positivistic approaches to handling patient safety.

A number of ‘filters’ had to be introduced to allow applying contributions, stemming from various health systems and authors, pertaining the core elements patient safety, error science, and CIRS (research phenomenon - level 2) to the particular research context. This is shown in the top level of figure 1.1 and includes national, cultural, political, or taxonomical factors. This might best be explained by using an example. The JCAHO in 2005 (Chang et al., 2005) and the WHO in 2009 (WHO, 2009) have published a proposal for a standardised terminology and classification schema for near misses and adverse events, a patient safety event taxonomy. As the output language of both of these institutions is English and has not (yet) been translated to or applied in a German context it cannot easily be applied to the German reporting system used in this study. Likewise studies on CIRS in the NHS in the UK are to be seen in the context of the endeavours of the NPSA (National Patient Safety Agency) and its budgetary possibilities, as well as the hospitals’ inherent organisational structure (for example several ‘risk leads’ for an NHS hospital trust that uses the National Reporting and Learning System), as compared to the lack of a national patient safety agency or national reporting system in Austria at the commencement of this study.
1.4. Flow of the thesis

The layout of this thesis largely follows the conceptual framework set forth above in figure 1.1. The thesis has a chapter on each of the three core elements pertaining to the research phenomenon: patient safety (chapter 2), conceptualisation of error (chapter 3), and incident reporting (chapter 4). This is followed by a chapter on research methodology (chapter 5) and two chapters on research findings and analysis (chapters 6 and 7). Chapter 8 uses this information as a basis for discussion of the results, conclusion and pointing out areas for future research.

After this introductory chapter, chapter 2 sets out in section 2.2 by providing definitions for the terms ‘patient safety’, ‘error’, and ‘adverse event’ and stressing the need for a clear, comprehensive and universally accepted definition. Section 2.3 on errors in health care introduces statistical accounts of error in health care. Based on the popular Institute of Medicine report it presents one of the key arguments of the new patient safety movement, namely that preventable errors in health care is a leading cause of death, and subsequently reviews generalisations based on the report for the UK, EU, and Austria. The reliability of these generalisations is the critically investigated in section 2.4.

Chapter 3 provides background information on organisational error and investigates if the call for a systemic approach to safety, as carried forward in the patient safety literature, can be substantiated. The chapter sets out in section 3.2 with a brief first level categorisation of error (active / latent), an explanation of ‘organisational accidents’ in section 3.3, as well as responses (person / system) to organisational accidents in section 3.4.

Chapter four starts with providing contextual information on where health care aims to go with the contribution of incident reporting, namely safe systems (4.2.1). It stresses that although the new patient safety literature promotes a
kind of systems thinking that encourages the use of CIRS this new kind of thinking has to come up against another strand of safety initiatives, notably evidence based medicine (4.2.2), which might sit much more comfortably with clinicians who are supposed to use it. The chapter then introduces the purpose (4.3.1), the characteristics of good (4.3.2), and the barriers (4.3.3) to incident reporting.

Chapter 5 on research methodology sets out in section 5.2 discussing critical realism as the fundamental philosophical underpinning that informs the methodological choices and design of the study, and explains how the research topic was found in an amalgamation of philosophical stance and the researcher's personal and professional background. Section 5.3 discusses the research methodology employed in this thesis, as well as the scope of the study and issues pertaining to research ethics and confidentiality. The first (qualitative) part of this study employed semi-structured interviews and a self administered questionnaire (section 5.4) and the second (ethnographic) part of the study used fieldwork observation (section 5.5).

Section 6.2 in chapter 6 provides contextual information pertaining quality management in hospitals in Austria in general and CIRS in the Vienna City Hospital Association in particular. Section 6.3 discusses observations at the CIRS training session at the department. Section 6.4 presents findings from interviews, which aimed to identify the medical lead- and the nursing lead-perspective on the CIRS implementation. Section 6.5 presents findings from the self-administered questionnaire that sought to capture the general safety attitude and perception of CIRS from front line staff.

Chapter 7 starts with information on the reporting frequency to CIRS over the period of the study (section 7.2). Subsequent sections introduce findings of the fieldwork observation according to the four themes ‘possible CIRS reports’ (section 7.3), ‘barriers to reporting’ (section 7.4), ‘organisational issues’ (section
7.5), and ‘practical implications’ (section 7.6). These findings are followed by information on the CIRS feedback meeting and a discussion of some of the consequences of the project in section 7.7.

This final chapter presents the conclusion to this research. Section 8.2 on patient safety and incident reporting in Austria discusses the findings emanating from this research and conclusions drawn. Section 8.3 presents a summary of the contribution to knowledge. Section 8.4 discusses the limitations of this study before section 8.5 points out areas for future research. This chapter closes with some reflections in section 8.6.

These chapters are complemented by nine appendices, which have been used in those instances where additional information may be insightful but where placing it into the main text might have distracted the flow of the thesis.

A note on the use of literature: The reader will notice that extensive reference is made to patient safety literature from the US and the UK and comparatively little about patient safety in Austria. Although from the researcher’s point of view (as an Austrian) this is regrettable it nevertheless is inevitable and presents a true reflection of the lack of available literature on patient safety and CIRS in Austria.
CHAPTER 2: PATIENT SAFETY

The purpose of this chapter is to provide the reader with an overview of what the apparent key safety problem in the delivery of modern health care is. The critical analysis of popular claims reveals problems with their trustworthiness. On one hand this constellation should give the reader insight into what kind of picture those at the forefront of health care are likely to have of patient safety, i.e. what kind of perception and attitude the researcher can expect from the health care organisation. On the other hand digging below the surface of these claims and showing the complexity of the underlying problem this chapter gives a first taste of the challenges the researcher is likely to face in his investigation of practitioners, managers, policy makers and fellow researchers.

2.1. Introduction

*It was the best of times,*  
*it was the worst of times,*  
*it was the age of wisdom,*  
*it was the age of foolishness,*  
*it was the epoch of belief,*  
*it was the epoch of incredulity,*  
*it was the season of Light,*  
*it was the season of Darkness,*  
*it was the spring of hope,*  
*it was the winter of despair,*
we had everything before us, we had nothing before us, we were all going direct to Heaven, we were all going direct the other way— in short, the period was so far like the present period, that some of its noisiest authorities insisted on its being received, for good or for evil, in the superlative degree of comparison only. (Charles Dickens, A Tale of Two Cities, 1859)

Charles Dickens (1812-1870), one of England’s most popular novelists, wrote the classic novel “A Tale of Two Cities” (1859) to describe events before and during the French Revolution in Paris. He compared it with the many unflattering parallels of social life in London at the same time. More than 150 years later the opening lines of his classic novel have become a widely used analogy for describing the contrasts and paradoxes surrounding the delivery of health care services around the world (see for example Cook et al., 1998). Because in many ways it is also ‘the best of times and the worst of times’ for health care.

Cook et al. (1998) bring it to the point:

“On the one hand, splendid new knowledge, more finely honed skills, and technical advances bring sophisticated treatments to larger and more fragile populations of people than ever before. On the other hand, media and the public attention is focused on ‘celebrated’ medical accidents-chemotherapy overdoses, wrong limb surgeries, catastrophic missed diagnoses. Stunning success and appalling failure are arrayed in contrast to each other. It is in this setting that discussions about patient safety are now taking place.” (Cook et al., 1998: vii)
The growing interest and prominence of patient safety is evident by a growing body of literature. At a glance patient safety may be seen as unfolding in three eras: before, around, and after the year 2000. All major original studies on the occurrence of error fall into the first era (before 2000). These studies differ in scope and methods and received moderate to low attention from the public and media. The second era, around 2000, saw the inception of national patient safety agencies in the United States in 1997 and in England in 2001. This era is also coined by the landmark publications To Err is Human’ from the United States IOM (IOM, 2000) and the Department of Health report ‘An Organisation with a memory’ (DOH, 2000) in England. This era is characteristic for the outcry, previously unseen to such an extent, of the public on the high occurrence of error in health care. The third era, after 2000, saw an increasing interest in patient safety, together with the introduction of one of the earliest and to date the world’s biggest CIRS in health care, the National Reporting and Learning System (NRLS) for adverse events in England in 2004 and a continuously growing body of literature (publications from eras two and three will be referred to in this thesis as the ‘new patient safety movement’ literature). It suggests that errors are much more common in health care than previously assumed.

This chapter sets out in section 2.2 by providing definitions for the terms ‘patient safety’, ‘error’, and ‘adverse event’ and stressing the need for a clear, comprehensive and universally accepted definition. Section 2.3 on errors in health care introduces statistical accounts of error in health care. Based on the popular Institute of Medicine report it presents one of the key arguments of the new patient safety movement, namely that preventable errors in health care is a leading cause of death, and subsequently reviews generalisations based on the report for the UK, EU, and Austria. The reliability of these generalisations is the critically investigated in section 2.4.


2.2. Definition

Several authors have aimed to define patient safety and to place it into some kind of framework. Gaba (2000) for example notes that patient safety can be seen as the equivalent of operational safety in other industries. It is different from occupational safety of employees, which deals with things such as needlesticks and back injuries. It is also different from the more complex goals of ‘quality’ or of achieving ‘good clinical outcomes’ (Gaba, 2000). Gaba (2000) and Cooper et al. (2000) describe patient safety as the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care. These include errors, deviations, and accidents. Battles and Lilford (2003:ii3) define patient safety as

“to reduce the risk of injury or harm to patients from the structure and process of care. This can be accomplished by eliminating or minimising unintended risks and hazards associated with the structure and process of care. A vision for patient safety would be ‘zero health care associated injuries or harm’.”

Another definition is brought forward by the IOM (2000). They (IOM, 2000) define patient safety as

“Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur.”

The growing body of literature on patient safety makes apparent the need for a unified terminology if health care providers, policy makers, and researchers are to collaboratively improve patient safety. Grober and Bohnen (2005), two medical doctors, stress this in their contribution "Defining medical error" (Grober
and Bohnen, 2005:39) by calling for "a clear, comprehensive and universally accepted definition of medical error that explicitly includes the key domains of error causation and captures the faulty processes that cause errors, irrespective of outcome".

The IOM (2000) provides a definition for error and adverse event, which is based on Reason (1990) and Brennan et al. (1991):

"An error is defined as 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)." (IOM, 2000:28)

"An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a preventable adverse event. Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question)." (IOM, 2000:28)

According to the above definitions the following categorisation can be made. Figure 2.1 shows the categorisation and relationship between the different terms. From all errors that happen in all episodes of care:

- some errors do not result in adverse events (near misses).
- not all adverse events involve error
- all preventable adverse events involve error
- all negligent adverse events are preventable
2.3. Errors in health care

Patient safety has the important role of ensuring that patients are not unnecessarily harmed when they consult health care services. Unfortunately errors do occur and the history of errors in health care is probably as long as the history of medicine itself. Lewis and Fletcher (2005) have noted that all health care systems around the world occasionally unintentionally harm patients whom they are seeking to help. Some patients even die as a direct result of errors that occur in the treatment they receive, and not because of their underlying health condition (for example Brennan et al., 1991; Thomas et al, 1999; IOM, 2000; BMJ, 2000; DOH, 2000; Aylin et al. 2004 ).
The increasing prominence of patient safety in health care is fuelled by a growing body of literature that shows a high incidence of error in health care organisations (for example Brennan et al., 1991; Leape, et al., 1999; Wilson et al., 1995; Wilson et al., 1999; Thomas et al., 1999; IOM, 2000; DOH, 2000; BMJ, 2000) and raises concerns about the safety of modern health care delivery. The amount of research on patient safety is greater than ever before (Lilford et al., 2006; Stelfox et al., 2006). The publication of the US IOM report “To err is Human” (IOM, 2000) and the UK Department of Health report “An organisation with a memory” (DOH, 2000), together with the establishment of national patient safety agencies in both countries (the National Patient Safety Foundation (NPSF) in the US, and the National Patient Safety Agency (NPSA) in England), have increased awareness of medical errors and adverse events in health care. But how big a problem is medical error? How often do medical errors occur, and more importantly, how many injuries and deaths could be avoided if optimum care was provided? This is an important question as the alleged scope of the problem is one of the pillars and driving force of the patient safety movement.

A review of the literature shows that a number of large scale, multi-institutional analyses on the occurrence of error in health care have been conducted and that statistics on the frequency of errors and adverse events in health care have existed for a long time. Studies are usually classified into overall error and adverse event rates in hospitals; speciality specific studies in hospitals; medication related studies; general practice studies; and cost of error studies. These studies differ in scope and methods. However, most studies use structured implicit review instruments (Gray, 2003) and many of these studies are on patients experiencing medication related errors (Gray, 2003; IOM, 2000; Brennan, 2000). Most studies focus on hospital settings and very little is known about the occurrence of errors outside hospital settings (Leape, 2000; Brennan, 2000; Gray, 2003).
The IOM report (2000) and a study by UK health economist Gray (2003) both provide extensive reviews of studies of error in health care. Together they list about one hundred studies on the occurrence of error in health care. Providing a full review of all those studies is beyond the scope of this research. The following is therefore a selective overview of major studies, with particular attention being given those statistical accounts on which the IOM report To Err is Human’ (IOM, 2000) is based upon. This is for the following three reasons.

First, the three most extensive investigations on medical error are the Harvard Medical Practice Study (HMPS) by Brennan et al. (1991), the Utah and Colorado Study (UCS) by Thomas et al. (2000), and the study of health care in Australia (Wilson et al., 1995) (for example Grober and Bohnen, 2005). The IOM report is based on two of them (HMPS; UCS) and makes reference to the other one.

Secondly, although studies on the occurrence of medical error have existed for a long time, for example Barr (1955), Moser (1956), Schimmel (1964), Mills (1977), Steel et al. (1981), or Brennan et al. (1991) (see also the next section 2.3.1 on statistical accounts of error), it is the IOM report (IOM, 2000) that caught everyone’s attention. Authors (Stelfox et al., 2006) have found the dramatic increase in patient safety publications, from 59 to 164 articles per 100,000 articles (see also later in section 2.3.3 and figure 2.3), to be in direct correlation with the publication of the IOM report (IOM, 2000). It is referred to as a landmark publication in the patient safety movement. In addition, one of the studies on which the report is based, (Brennan et al., 1991), is the highest cited patient safety paper, with an average of 64 citations per year (Lilford et al., 2006).

Thirdly, as can also be seen later in section 2.3.3 and figure 2.3, the biggest increase in publications after the IOM report (IOM, 2000), occurred in editorials, letters, reviews and guidelines; not so much in reports of original research.
(Stelfox et al., 2006). Review of the literature makes apparent that many authors appear to trust these numbers without questioning them and/or testing their reliability. It is often not mentioned that these numbers are ‘only’ extrapolations and many do not mention any of the limitations associated with the methods used in either the original studies (HMPS; UCS) and/or the extrapolation study (To Err is Human). As a consequence to date the IOM remains the main reference to the scope of the problem of error in health care on a representable scale. Data and methods from the report have been used to make extrapolations in other countries, including the UK. Amongst others the European Union Network for Patient Safety, the World Health Organisation, as well as government reports in Austria rely on data presented in the IOM report.

The following overview gives insight into the kinds of methods that have been used in those studies. After introducing these basic statistical accounts of error in health care this chapter will investigate how this data has been interpreted in the IOM report, making it such a prominent claim that every given year 100,000 die in the US due to preventable medical errors, and determines the reliability of those extrapolations.

### 2.3.1. Statistical accounts of error in health care

Accounts of the occurrence of adverse events and errors in health care are manifest in the literature from as early as 1955. Barr (1955) described them as "the price we pay for modern diagnosis and therapy". Moser (1956) referred to them as "diseases of medical progress" (Moser, 1956). Schimmel (1964) observed that the occurrence of occasional reactions had become an “accustomed and almost predictable hazard rather than improper medical care” (1964:100). With time came the understanding that medical progress doesn’t come for free. While medical progress brings dramatic advances in methods of diagnosis and treatment, it is usually accompanied by adverse reactions (Schimmel, 1964).
While Moser’s (1956) study provided data on adverse outcomes, these reports usually included unusual reactions, or very severe ones. There were however no data on the overall occurrence of incidents, the ones that lead to minor or no complications. Therefore, in 1964, as chief resident at Yale University Hospital, Department of Internal Medicine, Schimmel (1964) initiated a study “The hazards of hospitalization” that would become the first study to quantify the occurrence of errors and adverse events in hospitals. The aim of the study was to conduct "an assessment of all untoward reactions, regardless of severity...to determine their total incidence and to indicate the cumulative risk assumed by the patient exposed to the many drugs and procedures used in his care" (Schimmel, 1964:100). Over eight months his team assessed 1,014 patients that were admitted to hospital one or more times, a total of 1,252 admissions. In 198 patients they recorded 240 episodes of ‘noxious responses’ to medical care. Noxious responses were described as untoward events, complications, and mishaps that resulted from acceptable diagnostic or therapeutic measures deliberately instituted in the hospital (Schimmel, 1964). Of 198 patients these noxious responses resulted in prolonged hospitalisation of 105 patients. Thus, 20 per cent of the patients admitted to the medical wards experienced one or more untoward episode and 10 percent had a prolonged or unresolved episode. The severity of these 240 episodes was minor in 110, moderate in 82 and major in 48 patients. Of those 48 major episodes 16 were fatal.

Schimmel’s findings are important as he noticed a direct correlation between length of stay and the risk of encountering such an episode. Patients with noxious events had a mean total of hospitalisation of 28.7 days, while other patients only stayed an average of 11.4 days in the hospital. Furthermore, he detected an entire spectrum of nosocomial disorders, even in the cases where
patients were not severely harmed. He stressed that physicians with an interest in patient safety need to understand this spectrum of nosocomial disorders, but that in practice not all physicians do. His study emphasised that modern medicine introduces potent procedures that cannot always be used harmlessly. With each new drug or procedure come new potential hazards, which are not immediately apparent. They may only be discovered over time or after harm is done (Schimmel, 1964).

It also became apparent in the study (Schimmel, 1964) that patients who suffered from adverse episodes were no different to other patients, except that they had spent more time on the wards. They had similar clinical patterns, mean age and had been readmitted to the hospital at the same frequency. This underlined how important it is to identify adverse events. It rejects the assumption that adverse events only happen to terminally ill/end of life patients, who would have died anyway. Schimmel (1964) made clear that in his study it was not a patient’s underlying condition that somehow furthers the occurrence of an adverse event.

Mills, in 1977, conducted a study for the California Medical Association. This was a detailed analysis of hospital records of two Californian hospitals in order to estimate the number of events which had the potential to give rise to litigation. Steel et al. (1981) reviewed data of 815 consecutive patients over a five-month period, with patient data coming from an American university hospital in 1979. They found that 36 percent of all patients were suffering from iatrogenic illnesses, nine percent of which resulted in a life threatening incident or produced considerable disability. In two percent of the cases it is believed that the contributing iatrogenic factors were so severe that they played a major reason in the patients’ death (IOM, 2000; Gray, 2003).

The first HMPS (Brennan et al., 1991) which applied methods used by Mills in 1977, but to a much larger sample, was conducted in the State of New York in
1984, and remains the biggest study of its kind. Figure 2.2 gives an overview of the review process. Brennan et al. (1991) used data from 51 randomly selected hospitals in the State of New York. From the original random sample of 31,429 records 30,195 records were reviewed. From those, 7,817 were positive to the screening criteria, and 7,743 of those were reviewed. The results in the study are thus based on 30,121 records, of which 22,378 were negative screens and 7,743 were reviewed by physicians (Brennan et al., 1991).
The initial findings were then extrapolated to the New York State level. The result was that adverse events, prolonged hospitalisation and/or disability at the time of discharge occurred in 3.7 percent of hospitalisations. Of these, 58 percent were attributable to errors, and 27.6 percent were due to negligence. The majority of these adverse events resulted in disability lasting less than six months, but 13.6 percent resulted in death and 2.6 percent caused permanently disabling injuries. Drug complications were the most common type of adverse
events (19 percent), followed by wound infections (14 percent); 13 percent were due to technical complications (Brennan et al., 1991; Leape et al., 1991).

Using these extrapolations it was estimated that among the 2.672 million hospital discharges from New York hospitals in 1984 there were likely to be 98.609 adverse events and 27.179 negligent adverse events each year across the state of New York. Therefore it was concluded that a substantial amount of injury results from medical management and many injuries are the results of substandard care (Brennan et al., 1991).

The “Quality in Australian Health Care Study” (Wilson et al., 1995) and the “UCS” (Thomas et al., 2000) are two other large studies that employed the methods of the HMPS (two stage medical record review). First, in the Australian study, a total of 14.655 patient records from 28 hospitals in New South Wales and South Australia were reviewed. Wilson et al. (1995) found adverse events to occur in 16.6 percent of admissions; 51 percent of adverse events were thought to be preventable. Adverse events were classified as resulting in minor events from which patients recovered within 12 months (77.1 percent), permanent disability (13.7 percent), and contributing to patient death (4.9 percent) (Gray, 2003).

The UCS by Thomas et al. (2000) used a random sample of 15,000 patient records from a representative sample of hospitals in Utah and Colorado (United States) from 1992. Adverse events occurred in 2.9 percent of patients, of which in Utah 54 percent were thought to be preventable and 32.6 percent attributable to negligence. In Colorado 56 percent of adverse events were seen as preventable and 27.4 percent due to negligence. Overall, death occurred in 6.6 percent of adverse events, 6.9 percent of preventable adverse events and 8.8 percent of negligent adverse events. Table 2.1 provides an overview of the sample size and adverse event rate of the studies included in the above literature review.
Table 2.1: Overview of “adverse event” occurrence in cited studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Sample Size</th>
<th>“Adverse Event” Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schimmel (1964)</td>
<td>1.014</td>
<td>23.7 %</td>
</tr>
<tr>
<td>Steel (1981)</td>
<td>815</td>
<td>36 %</td>
</tr>
<tr>
<td>Brennan et al. (1991)</td>
<td>30.121</td>
<td>3.7 %</td>
</tr>
<tr>
<td>Wilson et al. (1995)</td>
<td>14.655</td>
<td>16.6%</td>
</tr>
<tr>
<td>Thomas et al. (2000)</td>
<td>15.000</td>
<td>2.9 %</td>
</tr>
</tbody>
</table>

This review of statistical accounts on error suggests that error is a somewhat natural companion of medical progress. The delivery of health care services brings with it unwanted consequences and dangers. However, despite publications on the occurrence of error in health care, it seems that the subject did not get the attention it deserved (AHQR, 2001; Shortell and Singer, 2008). This did not change until the publication of the IOM report (2000) “To err is Human” in late 1999.

2.3.2. Errors in health care a leading cause of death?

The US IOM is the health arm of the US National Academy of Sciences and is an independent non-profit organisation that works outside of government to provide unbiased and authoritative advice to decision makers and the public (IOM, 2011). It was their report “To err is human” in late 1999 that awakened much of the health care system to the challenge of reducing the number of

---

3 The term adverse event is put under quotation marks because, as section 4.5.6 will show, the term has not one universally accepted use. Studies may have labelled differing events as “adverse event”.

4 There were no constructive developments and improvements to reduce the occurrence of error, as happened in other high risk industries. Errors were of course mentioned in the media and this will be discussed later in this chapter (section 4.6).
adverse events (Brennan, 2000; Stelfox et al., 2006). Although not collecting any primary data the authors of the IOM report managed to extrapolate from and present existing data in a way that caught the attention of the masses. Data from the HMPS (Brennan et al., 1991; discussed in section 2.3.1) and of the, at the time yet unpublished, UCS (Thomas et al., 2000; also discussed in section 2.3.1) were extrapolated to the 33.6 million hospital admissions to United States hospitals in 1997. These extrapolations resulted in the message that between 44,000 and 98,000 people die every year in American hospitals as a result of preventable errors, and not because of an underlying health condition (IOM, 2000).

Following the publication of the IOM report (IOM, 2000) in late 1999, Hayward and Hofer (2001) recall TV and newspaper headlines stating that more people are killed in American hospitals every six months than died in the entire Vietnam War, which lasted 20 years. Others, for example Gaba (2000), have compared these numbers to the equivalent of three fully loaded jumbo jets crashing every day or two with no survivors. In comparison, in 1984, the year from which the patient records for these extrapolations were drawn, a total of 52 people died in 8 accidents in commercial aviation (Gaba, 2000 citing the National Transportation Safety Board, 2000). Even when using the lower estimates of the IOM report (IOM, 2000) of 44,000 annual deaths attributable to preventable adverse events, this ranked as the seventh leading cause of death in the United States. Therefore, according to these publications, more people die from preventable adverse events in health care than in car crashes (43,458), from breast cancer (42,297) or from AIDS (16,516) (IOM, 2000).
Apart from the personal sufferings, occurrences of errors to this extent also create immense costs for the health system. Thomas et al. (1999) and the IOM (IOM, 2000) calculated that the total costs of these errors, incorporating health care costs, disability, lost income and lost household production, are between 37.6 and 50 billion USD for adverse events and between 17 and 29 billion USD for preventable adverse events. Another study by Bates et al. (1997), that was cited in the IOM report found that two percent of hospital inpatients suffered from preventable adverse drug events and that this resulted in extra costs of 4.700 USD per patient, or 2.8 billion USD for a 700 bed teaching hospital.

2.3.3. Generalisations from IOM report

Stelfox et al. (2006) conducted a study to investigate the impact of the To Err is Human’ report (IOM, 2000) on patient safety publications. They (Stelfox et al., 2006) found an increase in patient safety publications from 59 to 164 articles per 100,000 MEDLINE6 publications (from January 1st, 1995 until January 1st, 2005) following the release of the report. Figure 2.3 shows patient safety publications before and after the release of the IOM report To Err is Human’ (IOM, 2000). The biggest increase became evident in the ‘editorials, letters, reviews, guidelines and other items’ section (Stelfox et al., 2006).

(2005) to name just a few), and the remainder of the chapter will show this in more detail, who cite IOM numbers without questioning the reports accuracy.
6 Medline: (Medical Literature Analysis and Retrieval System) is a bibliographic database of life sciences and biomedical information. It includes bibliographic information for articles from academic journals covering medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care. The database includes more than 18 million records, and dates back to 1950. 88 percent of records are in English.
Due to its popularity the IOM report is frequently cited and used as a basis for extrapolations in other countries. The critical approach in this study has led to an investigation of the apparent bona fide that IOM numbers experience throughout the patient safety literature. This section will briefly review the influence IOM data had on patient safety in the (1) UK, (2) the EU, and (3) Austria before the next section 2.4 will discuss the reliability of these studies.

(1) Several publications suggest that there is no representative original data on the occurrence of preventable adverse events in the UK (for example Vincent, 2001; email conversation with Vincent, 2010; Lilford et al., 2006; Sari et al., 2006) and that extrapolations are currently based on IOM data. For example the DOH (2000) made extrapolation based on the IOM report and concluded that an estimated 850,000 incidents each year either harm or nearly harm an NHS hospital inpatient in England (DOH, 2000; NPSA, 2005), resulting in 40,000...
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decades each year (Aylin et al., 2004). Based on IOM data several publications, for example a special edition from the British Medical Journal entirely devoted to patient safety (BMJ, 2000) and others (for example DOH, 2000; Leape, 2000) suggest that preventable errors in medicine have become an infamous and leading cause of death. IOM data and methods are thus perceived as trustworthy and reliable in the UK.

(2) EU involvement in patient safety policy dates back to the year 2002 at the World Health Assembly resolution, which led to recommendations by the High Level Group on Health Services and Medical Care in 2005 (EC, 2008b). Although patient safety is identified as a key area for action in the Commission’s Health Strategy White Paper (EC, 2007) the EU does not come up with original data on error occurrence in health care but base their estimations for the entire EU on three studies which are all based on the IOM report, “An Organisation with a Memory” from the UK, the 2008 ENEAS study in Spain (Aranaz-Andres et al., 2008), and a 2008 study from France by Michel et al. (2008), as well as a couple of “interviews with key stakeholders” (EC, 2008a:4), for which no further information is provided. The European Commission (EC, 2008a) published that “between 6.7 and 15 million hospital admissions and over 37 million consultations in the primary care setting result in an adverse event for the patient as a result of receiving that healthcare” (EC, 2008b:v). They further calculate that health care associated infections affect an average of five percent of hospital inpatients. In total they estimate that every year 4.1 million hospital patients suffer from health care associated infections, resulting in 37,000 deaths each year from these infections (EC, 2008b).

7The EC 2008b paper mentions a 2006 Spanish ‘ENEAS’ study without giving any references; the Spanish ENEAS study however was published in 2008 by Aranaz-Andres et al. (2008).
8The EC paper 2008b mentions a French study by Michel in 2007 without giving any reference. Findings of a national study in France were published in 2008 by Michel et al. (2008)
(3) This review found that the literature in general suffers from in-depth accounts of patient safety and CIRS in Austria. Back in 1998 the Supreme Audit Institution of Austria (Rechnungshof, 1998), since then and until submission of the present study there has been no further report on the WKAV by the Supreme Audit Institution of Austria or another independent body, criticised the lack of a standardised or unitary approach to quality management, with a lack of differentiation between quality assurance and quality management and a lack of reference towards an entire hospital or specific areas of medical expertise in the hospital. The report especially criticized a lack of documentary evidence and reports accompanying any such efforts. The quality endeavours were therefore not possible to be traced down and WKAV hospitals did/do not fulfil the requirements of the Viennese hospital act of creating the conditions for comparative analysis and assessment of quality assurance between hospitals (Rechnungshof, 1998).

In this light it might not come as a big surprise not to find much information on the health system in Austria in general and the documentation of quality endeavours and the safety of patients in particular. How often adverse events occur in general in Austria cannot be said with any certainty due to a lack of systematic data collection and interpretation. Those publications that refer to an adverse event rate cite numbers suggested by the IOM (2000), may it be reports in the local media, statements from politicians, or books on patient safety (for example Langbein, 2009; Pateisky, 2005). Langbein (2009), an uncoverer-journalist in Austria, based on the German APS study (2007) - which ultimately is derived from the IOM - that 4 percent of hospital inpatients suffer from preventable adverse events, 1 percent from medical malpractice, and that 0.1 percent of all cases result in preventable deaths he calculates that in 2.5 million hospital inpatients in Austria 100.000 patients suffer from preventable adverse events, 25.000 from medical malpractice, and that every year 2.500 hospital inpatients die in Austria as a result.
There is some debate about whether the numbers of adverse events leading to death have been over- or underestimated in the patient safety literature and the IOM report. While the IOM (2000) states that the actual number of adverse events leading to death (half of which they deem to be ‘preventable’) is likely to be even higher than their own estimation of 44,000 to up to 98,000 deaths per year, some authors argue that these numbers are more likely to be overestimations. Therefore the following section approaches this issue by investigating details of major patient safety studies on which the IOM report and subsequent publications in the international patient safety literature are based. For example, how were patients selected for studies, what was the screening criteria and sampling method? How much attention was paid to methodological issues and how much information did authors provide on these issues? For instance, many of these studies are retrospective record reviews. What are the limitations of using this method? Have causal relationships been made, and if so, was this appropriate? And how accurate are these studies in general?

### 2.4. Reliability of current extrapolations

Reference to IOM numbers can be found in literally all major patient safety publications, including the UK DOH, EU, WHO, and BMG Austria. However, a handful of authors also raised doubts about the reliability of the report, especially around the estimates of number of deaths (for example McDonald et al., 2000; Sox and Woloshin, 2000; Hayward and Hofer, 2001; Gray, 2003) and the subjectivity involved when judging adverse events and errors in health care as being preventable or not (Brennan, 2000; Hayward and Hofer, 2001; Grober and Bohnen, 2005). It has been argued that the IOM report employed studies that were either flawed or not designed for extrapolation purposes (McDonald et
al., 2000) Critics of the IOM report (IOM, 2000) agree that more emphasis should have been given to the original studies on which the To Err is Human’ report (IOM, 2000) is based. The next section will portray these studies in light of their limitations, with special consideration of screening and sampling methods, limitations of retrospective record reviews, causal relationships, preventability of adverse events, immediate and short term survival of patients, reproducibility, terminology, and accuracy.

2.4.1. Screening and sampling methods

An important issue pertaining patient safety studies is screening and sampling methods, on what basis patient files have been included in a study. Naturally different studies use different screening criteria and this can make it difficult to compare them with each other. The sampling method used for the HMPS was criticised for inflating the proportion of adverse events leading to death (McDonald et al., 2000). Screening criteria were applied to the initial 31,429 records to find a subgroup of 7,743 eligible cases. The screening criteria included death, returned admission to intensive care, and excessive length of hospital stay. The sampling method ensured that all ‘deaths’ were included, but not necessarily all adverse events (McDonald et al., 2000).

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9 McDonald et al. (2000) are referring to a study by Phillips et al. (1998) Increase in US medication-error deaths between 1983 and 1993; Lancet; 351:643-644
### Table 2.2: Harvard medical Practice Screening Criteria

- Prior hospitalization with 1 y (6 mo if older than 65 y)
- Subsequent admission to any hospital, after this discharge
- Prior failure or unfavorable results of medical management
- Hospital-incurred trauma
- Adverse drug reaction in hospital
- Transfer from general care to special care unit
- Transfer to another acute-care hospital
- Unplanned return to operating room during this admission
- Treatment or operation for damaged organ subsequent to invasive procedure
- Acute MI, CVA, or PE during or following invasive procedure
- Neurologic deficit at discharge
- Death
- Temperature >38.3°C (110°F) on day of or prior to discharge
- Cardiac/respiratory arrest
- Obstetrical mishap/complication of abortion or labor-delivery, or Apgar score <6 at 5 minutes
- Other undesirable outcomes
- Correspondence indicating litigation
- Hospital stay >90th percentile for diagnosis related group in patients <70 y, or 95th percentile in those aged ≥70 y

*MI indicated myocardial infarction; CVA, cerebrovascular accident; and PE, pulmonary embolism. Table adapted with permission from Hiatt HH, Barnes BA, Brennan TA, et al. A study of medical injury and medical malpractice. N Engl J Med. 1989;321:480-484. Copyright © 1989 Massachusetts Medical Society. All rights reserved.

While trying to defend his study (Leape is the second author of the HMPS)\textsuperscript{10} Leape (2000) actually uncovered another methodological flaw. Namely, patients only had to meet one of the screening criteria, including death. It is not known if patients who died met a screening criterion other than death. What would have been really significant is the death rate for patients who met a screening criterion other than death. Unfortunately these data were not collected (Leape, 2000).

According to Leape (2000) the screening criterion was not so as to inflate the number of deaths. Providing more details about the study he insists that terminally ill patients were excluded from the study. However, he (Leape, 2000) does so by referring to unpublished data from the HMPS that is only available to him. If the information Leape (2000) provides is correct then the subset group of negligent cases consisted of two groups: 14 percent were severely ill and the adverse event “tipped the balance” (Leape, 2000:96); for the other 86 percent error was perceived as the major factor leading to a patient’s death. This is important methodological information because it is important for interpretation of data. It only seems credible to make further calculations using the 86 percent rate (McDonald et al., 2000). As this information was not included in the original publication it is likely that interpretations of the data did not take account of this limitation.

2.4.2. Limitations of retrospective record reviews

Many important events occur in a patient’s journey through the health system and not all events are recognised or recorded in the patient record. Accordingly Brennan et al. (1991) or Weingart et al. (2000) contend that retrospective record

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reviews tend to underestimate occurrence of events rather than overestimate them. Moreover some effects of (mis)treatment only become evident once the patient has left an institution. As authors of the HMPS notice (Brennan et al., 1991) an additional six percent of hospital-caused adverse events were discovered after discharge of patients. However, these data were not included in the study because they were “an unknown fracture of all such events (Leape, 2000:97). The statement that retrospective record reviews are likely to result in under-estimation of adverse event rates is also supported when comparing them with prospective studies of adverse event rates. Prospective studies, for example by Bates et al. (1993), Bates et al. (1995), Classen et al. (1991), or Andrews et al. (1997) found much higher occurrence of adverse events (Leape, 2000).

However, another weakness of retrospective reviews, the one of hindsight bias, favours the view that the numbers are more likely to be overestimations. It has become evident that knowledge of the outcome of an event biases peoples’ judgment about the processes that led to that outcome, even when judges have been warned and are aware that knowledge of the outcome may influence their ability to make assessments. Once people know about the outcome it is easy to oversimplify the situation practitioners had to face when they made an error. This is illustrated in figure 2.4. In error science the hindsight bias effect has become a well reproduced research finding which is of important relevance to accident analysis and reactions to failure (Woods et al., 1994; Cook et al., 1998). In that respect hindsight bias is a great obstacle to seeing the more complicated story that lies beyond a “simple” human error (Cook et al., 1998). Considering the effect of hindsight bias it is possible that the number of deaths attributable to adverse events found in the HMPS are also overestimations (Leape, 2000).
In favour of all those who claim that current numbers are underestimations it has to be noted that the HMPS (Brennan et al., 1991) and all other large studies on the extent of errors in health care so far are limited to hospital environments (for example Leape, 2000). Leape (2000) stresses that more than half of all surgical procedures in the United States, which are tens of millions, occur outside hospitals and that nothing is known about the occurrence of adverse events in those settings. Leape (2000) argues that even if complication and death rates were considerably lower than in hospitals, the absolute number would be substantially higher than the numbers presented in To Err is Human’. As yet however these are just speculations.
2.4.3. Causal relationships

McDonald et al. (2000) argue that data from the HMPS (198411) and the UCS (199212) were not designed for describing causal relationships. Limitations of both of these studies were not brought forward in the IOM report. For example, while the HMPS included information such as “lead to death” and “died at least in part because of adverse event" authors of the UCS only reported a proportion of patients that died in the adverse event group, but did not provide information on the cause of patients’ deaths.

McDonald et al. (2000), who otherwise praise the report for its call to better understand causes of error, and for its call to develop safe systems that incorporate computerised and other mechanical supporting elements, criticise the “unstated corollary...that eliminating preventable adverse events also will eliminate deaths? (McDonald et al., 2000:93). They (ibid) argue that most people who enter a hospital already have a high disease burden and high death risks. Indeed, the HMPS (Brennan et al., 1991) does not include any information about the baseline risk of death in these patients, or about deaths in a control group. This puts the IOM’s interpretation (IOM, 2000) of the HMPS’s adverse event rate of 13.6 percent leading to death (Brennan et al., 1991) under a different light. The IOM (IOM, 2000) suggests that 13.6 percent of patients who experienced adverse events died as a result of these adverse events. And that they would not have died if all adverse events could have been avoided. However, clinical experience shows that this is not true (McDonald et al., 2000). Considering the original data (Brennan et al., 1991), as it does not include
information about preventability of deaths and risk of death, such a conclusion should be considered highly suspect.

2.4.4. Preventability of adverse events

The HMPS (Brennan et al., 1991) and the UCS (Thomas et al., 2000) relied on implicit judgements of physicians. Efforts were made to reduce subjectivity by training reviewers and using highly structured data collection instruments, duplicate review, and review and resolution of disagreements. However, there is still a risk that some physicians over- or under-interpret the occurrence of error. In Leape’s (2000) view [bearing in mind that he is second author of the HMPS (Brennan, Leape, Laird et al., 1991) and is therefore trying to defend the reliability of the study] this is not a problem as errors of this sort probably levelled themselves out (Leape, 2000).

However, Brennan (the first author of the HMPS) had always warned about extrapolations on the basis of their study (Brennan et al., 1991; Brennan, 2000; McDonald et al., 2000; Hayward and Hofer, 2001). To clarify some of the issues surrounding the discussion of the preventability of injuries and deaths in the IOM report Brennan (2000) commented that physician reviewers of the HMPS were not 100 percent convinced that all deaths attributable to adverse events could have been prevented if care was optimal. Therefore the original study (Brennan et al., 1991) did not judge on the likelihood of preventability of deaths if optimum care had been provided.

In the HMPS (Brennan et al., 1991) and the UCS (Thomas et al., 2000) reviewers did not include judgements of whether or not injuries were actually caused by errors. Even if they had it would have been difficult to classify an event as preventable or not, and to judge if it could be attributable to error. These judgements would always be highly subjective. Brennan (2000) explains that in an example: surgeons know that post operative haemorrhage can occur
in a number of cases. It is also known that the occurrence rate decreases with good surgical care. However, even with the best surgical techniques and precautionary measures, haemorrhages can still occur. In the HMPS reviewers classified post operative haemorrhages as preventable if they occurred after what would be considered as a simple procedure; even if there was no apparent blunder or slip by the surgeon. However, the IOM report (IOM, 2000) interpreted these cases as medical errors. This may seem inappropriate to some observers (Brennan, 2000).

That preventability often seems to be in the eye of the reviewer (Hayward and Hofer, 2001) also becomes clear when pondering about what authors mean when stating that deaths are preventable. Preventability is often closely linked to expenditures. For example, all allergic drug reactions could be prevented if every patient was tested for drug allergies upon admission. However, this is not cost effective and no health insurer would bear the extra costs (Brennan, 2000). Nevertheless, authors can still call for a stop of these ‘preventable’ events.

The following two short examples, provided in the National Patient Safety Agency report ‘Building a memory: preventing harm, reducing risks and improving patient safety’ (NPSA, 2005), illustrate how difficult it is for reviewers to decide whether a patient was actually harmed by the health care treatment, or if an event occurred because of his underlying health condition.

“An older patient has cancer and a chest infection. Probably because of the antibiotics used to treat the chest infection, he develops a Candida (fungal) infection which makes his mouth sore and tender. He eats very little over the following week, and his discharge is delayed by concerns about his weight loss and weakness. It is difficult to judge whether the Candida infection, and consequent eating problems, could have been avoided.” (NPSA, 2005:35)
“A small child is rushed to an emergency department with very severe head injuries after a road traffic accident. She is already receiving cardiopulmonary resuscitation as her heart and breathing stopped during the ambulance journey. During attempts to resuscitate her, she is mistakenly given an adult dose of a drug. Attempts to restart her heart fail. It is difficult to judge whether the medication error contributed to the death of this child.” (NPSA, 2005:35)

2.4.5. Immediate and short term survival of patients experiencing adverse events

Hayward and Hofer (2001) examined the reliability of physician reviewer ratings on medical error and the probability of immediate and short-term survival in deaths described as preventable if care had been optimal. They conducted a retrospective implicit medical record review using data from seven ‘Department of Veterans Affairs13’ medical centres from 1995. Fourteen board certified internists were trained to review charts. This training established that reviewers understood the review instrument. Review of actual study charts only started once training results had shown that disagreements between reviewers were based on different opinions and not on misunderstandings or chart information being overlooked. Reviewers did not know the intention behind the study. They never reviewed the same chart twice or reviewed charts of patients they had been caring for. Results from previous reviews were blinded. End of life ‘comfort care’ patients were excluded from the study and markers previously found to be

13 The United States Department of Veterans Affairs (VA) is a government-run military veteran benefit system which runs hundreds of hospitals across the United States. They have a reputation for being a leader in implementing new safe policies and practices (Leape and Berwick, 2005).
associated with high rates of preventable deaths were over-sampled (Hayward and Hofer, 2001).

After screening criteria was applied to about 125,000 hospital admissions the final sample consisted of 383 reviews of 111 active-care-in-hospital deaths. Reviewers were asked questions about the timeliness of diagnostic evaluations, overall quality of care, if the patient’s death would have been preventable by better quality of care, as well as a percentage estimation of preventability of death if care had been optimal. In addition reviewers were asked to rate the probability of survival over three months or more if care had been optimal and resulting in a good physical and good cognitive state of the patient, meaning that the patient would have a reasonable quality of life and meaningful social functioning (Hayward and Hofer, 2001).

The initial results of the study were similar to previous studies. 22 percent of deaths were rated as at least possibly preventable and six percent as probably or definitely preventable through optimum care. However, after adjusting results for variability and skewness of reviewers’ ratings, and considering a three month prognosis, this rate dropped to 0.5 percent. This means that the actual number of patients who would be still alive three months after the incident is much lower than implications from previous studies have suggested. Therefore, previous interpretations of these studies may be considered unreliable or misleading when causal relationships were established between errors and patient outcomes (Hayward and Hofer, 2001) (see also section 2.4.3 on causal relationships).

2.4.6. Reproducibility

Sox and Woloshin (2000) found the IOM extrapolations highly subjective and argue that the reliability and reproducibility of both estimates, 44,000 and 98,000, are unknown. Citing the IOM report (IOM, 2000:1):
“Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively (Brennan et al., 1991; Leape et al., 1991; Thomas et al., 2000 forthcoming). In Colorado and Utah hospitals, 6.6 percent of adverse events lead to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented. When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors (AMA, 1999; Thomas et al., 2000 forthcoming; Thomas et al., 1999). The results of the New York study suggest the number may be as high as 98,000 (AMA, 1999; Brennan et al., 1991; Leape et al., 1991).”

Looking at the above citation, the IOM reports that adverse events “occurred in 2.9 and 3.7 percent of hospitalizations”. Critics have found these calculations to be reliable. It has been noted (Sox and Woloshin, 2000) that authors of the original studies had made every effort to avoid misclassification of events and that these studies can be seen as role-models for studies involving subjective statements. However there is less agreement about further interpretations of these studies. The IOM report (IOM, 2000) did not provide information on how it calculated the number of deaths due to preventable errors. The report (IOM, 2000) did only refer to the HMPS (Brennan et al., 1991) and the UCS (Thomas et al., 2000). However, the numbers presented in the IOM report (IOM, 2000) cannot be found in any of these two, or any other major study cited by the IOM (Sox and Woloshin, 2000).
Sox and Woloshin (2000) tried to reconstruct how authors of the IOM report (IOM, 2000) reached those numbers. They (Sox and Woloshin, 2000) created a formula to estimate the number of deaths as a result of medical error (figure 2.5). To determine the number of people who die as a result of medical errors one needs to know the total number of admissions, the proportion of those with an adverse event, of those which are preventable, of those that lead to death. The following section will investigate which of this information was available to the authors of the IOM report (IOM, 2000) according to references they give, and in what context such information has to be seen.

Figure 2.5: Formula to estimate the number of deaths as a result of medical errors

Number of people who die as a result of medical errors = Total number of admissions × Proportion of admissions with an adverse event × Proportion of adverse events that are preventable × Proportion of preventable adverse events that lead to death

Source: Sox and Woloshin (2000)

Critics (for example Hayward and Hofer, 2001; Sox and Woloshin, 2000; Brennan, 2000) have found that the statement that “over half of these adverse events resulted from medical errors and could have been prevented” is not substantiated. Neither of the original studies (Brennan et al., 1991; Thomas et al., 2000) tried to estimate the number of preventable adverse events, nor did they define what a preventable adverse event or medical error was. Two of the original authors later attempted to determine preventability of these cases (Leape et al., 1993), and found 69.6 percent of events to be preventable, 6 percent as potentially preventable and 24.4 percent as not being preventable. However, these studies were criticised for being methodologically flawed (Sox and Woloshin, 2000), inter alia because they did not calculate inter-rater reliability of reviewers’ judgements.
Thomas et al. (1999) also reviewed the Colorado and Utah cases. However, this review, which stated that “about half of events were preventable”, was, according to Sox and Woloshin (2000) and Sari et al. (2007a), not based on a review of the original cases, but only on summaries of cases. Sox and Woloshin (2000) further criticised them for not using duplicate reviews, and not including information on how reviewers concluded if an adverse event contributed or caused a patient’s death. It may also be questionable because all reviews were done by only three physicians. This procedure was also criticised by Brennan, one of the authors of the original study (Brennan, 2000).

How the IOM concluded the number of deaths per year to be in a range from 44,000 to 98,000 remains a mystery. Sox and Woloshin (2000) tried to reconstruct the IOM’s calculation. Leape et al. (1993) extrapolated 13,451 adverse events that were associated with death in the State of New York in 1984 to the United States population, stating that 198,000 adverse events led to death in 1984. They (ibid) judged that 78 percent of those adverse events that were a proximal cause of death were preventable. However, a preventable adverse event does not necessarily mean a preventable death, since many of those patients would have died even if the adverse event had not occurred (Sox and Woloshin, 2000; McDonald et al., 2000). Leape et al. (1993) then estimated that about half of the deaths caused by iatrogenic adverse events were preventable, without explaining how they decided which of those adverse events lead to a death that would not have occurred otherwise (Sox and Woloshin, 2000). Therefore investigators of the studies are left to speculate. Accordingly, Sox and Woloshin (2000) assume that the high end number of 98,000 deaths per year as published in the IOM report (2000) are ‘about half of the 198,000 adverse event leading to death in 1984, which is 99,000 - close to the number cited by the IOM. This number is also similar to the total number of adverse events (98,609) in New York hospitals in 1984, as extrapolations from
Brennan et al. (1991) have shown (see section 4.3). Is it possible that authors of
the IOM report (IOM, 2000) may have confused those numbers?

Gray (2003) provides another explanation of how the higher bound estimate of
98,000 deaths could have been achieved. He (ibid) calculated the annual total
of United States hospital admissions in 1997 (33.6 million) multiplied through by
(overall adverse event rate x proportion attributable to error x proportion of
events attributable to error resulting in death). For the HMPS (Brennan et al.,
1991) this gives following equation:

Annual total of U.S. hospital admissions in 1997 (33.6 million)
multiplied through by [overall adverse event rate (3.7 percent) x
proportion attributable to error (58 percent) x proportion of events
attributable to error resulting in death (13.6 percent)], resulting in
98,000 deaths per year.

However, although resulting in the correct number, the data used for the
calculation itself is questionable in two ways. First, the proportion of adverse
events resulting in death was calculated as 13.6 percent. According to Brennan
et al. (1991) and Gray (2003) this was actually the rate for all adverse events
rather than adverse events due to error. Secondly, in contrast to Sox and
Woloshin’s (2000) formula, this calculation does not consider ‘preventability’ of
events.

As for the lower bound estimation of 44,000 deaths per year (IOM, 2000), Sox
and Woloshin (2000) could not find out how these number had been obtained.
In the original paper Thomas et al. (2000) extrapolated data from the Utah and
Colorado sample to the entire population of the United States (see section 4.3).
These extrapolations resulted in a different number: 64,809 deaths in patients
with adverse events and 24,979 deaths in patients with adverse events due to
negligence in 1992. However, the article did not give an estimate of the number
of preventable adverse events. Hence, the study does not explain how the IOM could have calculated the lower bound of deaths caused by preventable error (Sox and Woloshin, 2000).

Using Gray’s (2003) formula for reconstructing the lower bound estimate, using Utah and Colorado data, the annual total of United States hospital admissions in 1997 (33.6 million) multiplied through by (overall adverse event rate x proportion attributable to error x proportion of events attributable to error resulting in death), the calculation is as follows:

Annual total of U.S. hospital admissions in 1997 (33.6 million) multiplied through by [overall adverse event rate (2.9 percent) x proportion attributable to error (53.3 percent) x proportion of events attributable to error resulting in death (6.9 percent)], resulting in 35.835 deaths per year.

This does not reconcile with the IOM lower bound estimation of 44,000 deaths per year. Gray (2003) assumes that authors of the IOM report accidentally transposed the overall adverse event rates of the two studies, giving the HMPS a 2.9 percent rate and the UCS a 3.7 percent rate, and then used the 3.7 percent rate for both calculations. Accordingly, the lower estimate calculation, based on the Utah and Colorado data (Thomas et al., 2000) is as follows:

The total of U.S. hospital admissions in 1997 (33.6 million) multiplied through by [overall adverse event rate (3.7 percent) x proportion attributable to error (53.3 percent) x proportion of events attributable to error resulting in death (6.6 percent)].

Using these data, and in this way, the calculation would have an additional flaw, since “they also used the 6.6% death rate for all adverse events rather than 6.9% for preventable adverse events” (Gray, 2003:6), resulting in a total of
43.733 deaths, which can be rounded up to 44,000 deaths per year. Therefore, the IOM numbers (IOM, 2000) are not well substantiated (Sox and Woloshin, 2000; Hayward and Hofer, 2001; McDonald et al., 2000).

2.4.7. Terminology

The literature review indicates a wide variance in the definitions of the vocabulary used in patient safety. The lack of an agreed definition limits the contribution of patient safety research. Without a uniform definition of these terms researchers are unable to select an appropriate definition for a given context and develop valid measures of and/or compare and interpret empirical results. Patient safety researchers (for example Brennan, 2000; Sox and Woloshin, 2000; Hayward and Hofer, 2001) have contended that these problems are pervasive and important.

Brennan (2000), first author of the HMPS on which the IOM extrapolations were based, criticises the unwary use of the term “error” in the literature, including interpretation of his own study in the IOM report (IOM, 2000). Many studies, including the two studies on which the IOM extrapolations (IOM, 2000) were based upon, do not clearly differentiate between errors, adverse events, preventable adverse events, and negligent adverse events. Brennan (2000:1123) argues that: “The combination of the strikingly large numbers of errors cited by the report and the connotations of the word ‘error’ create an impression that is not warranted by the scientific work underlying the IOM report.”

Although the IOM (IOM, 2000) suggests a definition for “error” in its report (see section 2.2 on definition), this does not change the fact that studies in patient safety (and on which the To Err is Human’ report is based on) did not use such a uniform definition of the term error. In the absence of a uniform definition of error one study may count a delay in diagnosis as a medical error. If that patient
later dies, because of any other reason, and using the HMPS criteria (Brennan et al., 1991; see figure 2.1), he would then, through meeting the screening criterion ‘death’, be included in a sample. Another study using different screening criteria may have excluded such an event from its sample.

The use of multiple and overlapping definitions in the patient safety literature hinders data synthesis, analysis, collaborative work and evaluation of the impact of changes in the delivery of health care (Grober and Bohnen, 2005). This makes it inadvisable to add up numbers from different studies into one total rate of ‘medical error’. It also makes it difficult to compare error rates from the published literature, especially if studies do not include detailed information on methods used and any limitations they may have. Studies that have done so may be misleading, unreliable or invalid, and as yet this problem has not been adequately addressed.

2.4.8. Accuracy

Limitations of other studies that were used to back up the To Err is Human’ report (IOM, 2000), especially a lack of control groups, were not mentioned in the report. Furthermore, a study on medication errors that claimed that 7,000 people died in 1993 (Phillips et al., 1998) was included in the report. However, Phillips et al. (1998) apparently miscalculated deaths attributable to medication error and those that were due to drug abuse (Rooney, 1998). Therefore, this study should have not been included in the IOM report (McDonald, 2000). On top of that the report (IOM, 2000:248), to give one example, cites Phillips et al’s. study as “Phillips et al., 1974, Increase in U.S. Medication-error deaths between 1983 and 1993”, giving the wrong reference. Errors can happen and mistakes
are allowed but a report on errors might be expected to have taken extra care and not to add to the confusion by making preventable errors itself.

Co-incidentally the German Coalition for Patient Safety (APS, 2006) in their quantitative report on the scope of the problem medical error seems to mock up on this very study by Phillips et al. 1998. Although a lot of credit is owed to the German Coalition for Patient Safety for their engagement and contribution to patient safety they also are not immune to error. Their 2006 quantitative report on the extent of medical error (APS, 2006) appears to include large samples that lack sufficient information and might have been misinterpreted. Quite a substantial amount of APS study (2006) includes for example Phillips et al. (1998) investigation of increase in US medication-error deaths over a ten year period (1983-1993). While Phillips et al. (1998) point out the problem of a shift to outpatient treatment. In 1983 physicians had more control over the drug intake of their patients while by 1993 much of the drugs were taken with the patient, not medical personnel, exercising quality control. Therefore they blame a shift in the location of medication consumption from clinical to domestic settings for the steep increase in fatal medication errors and not medical personnel per se. However, in APS study (2006) the increase in deaths of Phillip et al’s study is listed as ‘preventable adverse event leading to death’, which in the eyes of the author of the thesis is a misinterpretation of data gathered in Phillip et al’s study. Moreover, the APS study (2006) also includes those studies that have been criticised above for inclusion in the IOM report and for as a basis for further extrapolations. Another noticeable shortcoming of the APS study is that they base their calculations on 151 studies worldwide on the occurrence of adverse events which they list in table 3 of their study (APS, 2006:41-55). This list makes four references to Phillips et al. (1998) and includes very large samples of 1,195,000, 504,000, 182,375, and 86,000 deaths with preventable adverse event rates ranging from 0.1 percent to 0.8 percent, making up a substantial amount of their own “world’s biggest sample”. However,

Calling their own review the largest study on a global basis so far on the occurrence of error in health care (APS, 2006) conclusions at which they arrive should be thoroughly tested and not just blindly trusted. It might lie in the nature of those quantitative studies to look for breadth at the expense of depth. However, it should be questioned how meaningful reviews are that mix reports from various different health care settings, different methodologies, different national contexts (25 different countries), and different sample sizes and without investigating the accuracy of the data used.

2.5. Conclusion

There will always be areas for improvement in organisations. Whether or not they are implemented is often a matter of cost and benefit. For patient safety interventions such as CIRS to be effective they need to be founded on a rigorous and systematic evidence base, representing a blend of theories and approaches that fit particular circumstances and cultures (Fillingham, 2005). A good part of this “evidence base” in patient safety consists of statements on allegedly high numbers of preventable errors in health care and suggests they are a leading cause of death. Although there is agreement that the exact number can never be known an estimation of the size of the problem has been built up as one of the pillars of the new patient safety movement. This high rate manifests a stance for patient safety, and allows and justifies allocation of funds. It has been argued that the currency of patient safety can only be measured in
terms of prevented harm and saved lives (WHO, 2005a). Subsequently an estimation of the scope of the problem also serves as a (necessary) measure for success and improvement.

Figures used in the international patient safety literature are based mainly on the US IOM report. Based on the most extensive studies on error in health care it is recognised as a landmark publication in patient safety. Findings from the report have been reproduced widely in key publications, both on a national level in the UK and Austria, and internationally in the EU and WHO. The chapter focused on the work underlying the IOM report and extrapolations from the report. It gave particular attention to screening and sampling methods, limitations of retrospective record reviews, causal relationships, preventability of adverse events, immediate and short term survival of patients experiencing adverse events, reproducibility of numbers, terminology, and accuracy of studies. This pointed to a number of important issues which authors have not always factored into their calculations. Preventing an adverse event does not automatically mean that death will also be prevented. The kind of data that are available (for example original patient records as compared to summaries of events), subjectivity of reviewers, hindsight bias, and how these can be mitigated, as well as causal relations between events and outcome, have great influence on the reliability of a study. Often it is not clear if harm to a patient was actually caused by an adverse event or not. This however was not considered in the IOM report or in many of the extrapolations following it.

The IOM report To Err is Human’ has taken error studies out of their context. Accordingly the allegedly high error rates presented by IOM are not well substantiated. Likewise extrapolations derived from the IOM report, either directly through quoting from the report or indirectly through using its methods, such as 37 million adverse events in the EU, 37,000 deaths due to health care acquired infections in the EU, and 2,500 annual deaths due to medical
malpractice in Austria, are also incorrect. That the numbers against which improvement should be measured are not well substantiated, regardless if the actual numbers are lower or higher, means that this pillar of patient safety stands on very loose ground. It is often argued that one of the key issues in patient safety is a shift from a “blame and shame culture” to a “reporting-” or “learning culture” on the hospital wards. However this review shows that the “blame and shame culture” may as well be inherent in the patient safety literature itself. Headline messages of unsubstantiated high error rates may be questionable in light of an effort to narrow the trench between medical staff and management.

Although the resources of a conventional PhD thesis are not adequate to determine a reliable figure on the occurrence of error the findings presented here may put patient safety under a different light and instigate a more critical view towards it. The critical stance in this thesis has been valuable in approaching one of the key arguments in the patient safety literature. Especially considering the involvement of a consultancy in this project (i.e. for CIRS training sessions) other philosophical approaches might have made it easier to, likewise, jump on the ‘blame train’ and (mis)use the sensational number of preventable errors. Those responsible for patient safety should make every effort to ensure that scarce resources are used where they are most needed and to best effect. It is suggested that this includes determining a correct estimate of the occurrence of adverse events in health care.

Before closing this chapter it is important to stress that not everything in the IOM report is unreliable and bad. The report contains a very important second message on how to improve health care services and this, regardless of how often errors occur, can only be welcomed. The next chapter on the conceptualisation of error in health care will provide the basis for understanding improvements in patient safety using CIRS.
CHAPTER 3: CONCEPTUALISATION OF ERROR IN HEALTH CARE

The purpose of this chapter is to provide the reader with a perspective of error from the error sciences and outside the realm of health care. It shows that other high risk industries are more advanced in dealing with error and that there are lessons to be learnt. Different conceptualisations of error provide possible explanations for current, often less successful, scenarios of dealing with error in health care. It opens up the perspective of safer health care in the future. Experiences from outside health care show that reaching this goal is the result of a whole system approach to improvement, and one that comes with substantial human and financial demands.

3.1. Introduction

The previous chapter showed that although it is not clear how often preventable errors in the health system actually harm patients organisational errors in health care are a real phenomenon. This chapter aims to provide a background understanding of organisational error, how it might be tackled, and investigates if the call for a systemic approach to safety, as carried forward in the patient safety literature, can be substantiated. After this short introduction the chapter sets out in section 3.2 with a brief first level categorisation of error (active / latent), an explanation of ‘organisational accidents’ in section 3.3, as well as responses (person / system) to organisational accidents in section 3.4.
3.2. Categorisation of error

A principal distinction can be made between active and latent errors. Active errors occur at the human-system interface. In healthcare this is where frontline operators are in direct contact with the patient. The effects of active errors are felt almost immediately and they are often referred to as human errors (Reason, 1990 and 2000; Battles, 2001; Cook et al., 1998; Leape, 1994). Individuals who commit these errors are at the “sharp end” (for example Reason, 2000; Cook et al., 1998).

Latent errors on the other hand occur out of the direct control of frontline operators. Prevention of these errors is beyond the capabilities of the operator and in some way he has been set up to make an error (Leape, 1994). Latent errors are delayed consequences of technical and organisational actions and decisions; they include for example poor design, incorrect installation, faulty maintenance, bad management decisions and poorly structured organisations. Latent errors can also create pathologic situations which result in working conditions that “invite” errors (Reason, 1990). For example high workloads with tight schedules or lack of training that emphasises recognising hazards can lead to a great variety of errors (Leape, 1994). Latent errors are “accidents waiting to happen”. Latent errors occur at the “blunt end” (Leape, 1994; Battles, 2001).

3.3. Organisational accidents

In error sciences a system is seen as a set of interdependent elements interacting to achieve a common aim. When large systems fail it is due
to multiple faults that occur together in an unanticipated interaction (Perrow, 1984) creating a chain of events in which the faults grow and evolve (Gaba et al., 1987). Those incidents where errors result in major catastrophes have been termed ‘organisational accidents’ by psychologist and accident expert James Reason (1990). Building on earlier work about ‘systemic influences’ in the aetiology of major accidents by Turner (Turner and Pidgeon, 1997 - originally published in 1978) and Perrow (1984) Reason et al. (2006:9) describe organisational accidents as “the concurrent failure of several defences, facilitated, and in some way prepared, by sub-optimal features of the organisation design”. Recent examples of organisational errors are the capsize of the ‘Costa Concordia’ cruise ship on the Italian coast in 2012 and the ‘Deepwater Horizon Oil Spill’ in the Gulf of Mexico in 2010.

A body of knowledge on the contribution of humans to safety and failure has emerged mostly from areas outside medicine, for example in transportation and aviation, or the chemical and nuclear industry. Clues have been drawn from various disciplines, including human factors research, human performance, cognitive psychology, social psychology and organisational behaviour (for example Cook et al., 1998; Leape, 1994; Helmreich, 2000; Reason, 1990). This intense cross-disciplinary investigation led to a new understanding of risk and safety that goes beyond the individual and acknowledges technological and organizational factors as equally important factors that contribute to error.

Errors of many individuals (active errors) converge and interact with system weaknesses (latent conditions), increasing the likelihood that individual errors will do harm (Reason, 1990; Chassin and Becher,
2002). Also supposedly trivial incidents do have the potential to lead to organisational accidents when they are coupled together in an unfortunate way. The error science literature provides many ostensible examples of latent conditions. To name but two an underlying latent error in the Titanic disaster in 1912 was that the number of lifeboats was regulated according to the tonnage of the ship and not the number of passengers, as a result there was an insufficient number lifeboats (Battles, 2001). Another example is the Challenger disaster in 1986, where the space shuttle disintegrated 73 seconds into its flight. The remarkable finding of the investigation was that a brittle O-Ring was the ultimate cause of the accident (Rogers Commission, 1986).

However, one single individual error can never cause an organisational accident. Organisational accidents happen to complex, (and also) modern organisations, and not to individuals. How individual errors (whether active or latent) may or may not lead to an adverse outcome is illustrated in figure 3.1 and figure 3.2. In the Swiss cheese model the slices of cheese represent the defence mechanisms of an organisation. High risk systems usually have many of those defence mechanisms. Some of them come in the form of alarms, physical barriers or automatic shutdowns and are engineered. Other defences can rely on people on the sharp end, like surgeons or pilots; others yet depend on procedures and administrative controls. In an ideal world these slices of Swiss cheese would be intact. But every step in a process has the potential for failure. There are always weaknesses, which are represented through the holes in the cheese. These holes are the active failures and latent conditions of an organisation. Unlike in the cheese though, these failures and conditions, or holes, are continually opening, closing, shifting and showing up in different locations (Reason, 2000).
Figure 3.1: Swiss Cheese model: averted system failure

Some holes due
to active failures

HAZARDS

Other holes due
to latent conditions

SUCCESSIVE LAYERS OF DEFENSES

The presence of holes in any one slice does not normally cause a bad outcome (see figure 3.1). A hazard may be able to pass through a hole in one layer, but in the next layer the holes would be in a different place and the problem should be averted. A tragedy can only happen if holes in many slices momentarily line up and allow ‘a trajectory of accident opportunity-bringing hazards into damaging contact with victims’ (see figure 3.2). It is believed that more defensive layers and fewer and smaller holes make a system safer (Reason, 2000).
This knowledge is only recently and slowly being applied to health care. When patients are harmed in the care delivery system as a result of the services they receive it “only” happens to one patient at a time. Fatal outcomes are spread over time and a greater number of locations than in other industries. History shows that those accidents that remain in the public’s perception for a long time have a higher chance of being adequately analysed, which often reveals underlying systemic errors that go beyond blaming an individual. In health care however public attention often turns elsewhere and a thorough investigation does not come through. The accident is then often blamed on an individual. This partly explains how health care could remain quiet and indeed inactive.
for so long about error prevention and patient safety (Chassin and Becher, 2002). Therefore in-depth accounts of organisational error are much rarer in health care. For example not one example can be found in the literature dating from the last century.

However, with the increasing interest and attention given to patient safety this is slowly changing. Although the author has no knowledge of accounts from the Austrian health system Chassin and Becher (2002) and NPSA (2005a) set excellent examples of “organisational accidents” in a health care context showing the convergence of active errors with system weaknesses. System weaknesses in health care may be things such as imperfect communication. Especially in hospitals imperfect communication may be fostered by what Chassin and Becher (2002) call the ‘information system disease’, where a number of unconnected home-grown information mini-systems co-exist and information on a patient is not readily available to all staff. A department may have multiple brands for a certain type of instrument, all with different physical appearance as well as functionality. The AHRQ (2012) reports of emergency teams unable to administer a potentially life-saving shock because the defibrillator pads and the defibrillator itself could not be physically connected. The CIRS that will be investigated in this study aims to identify latent conditions such as the aforementioned for the particular hospital department.

Other than in the literature review in chapter two, where claims about high numbers of preventable errors leading to death in health care had to be rejected, the literature investigated for this chapter well substantiates the systemic nature of error in health care. The next section will look at responses to organisational accidents.
3.4. Responding to organisational accidents

The error sciences literature differentiates between two kinds of responses once an organisational accident has occurred. Pointing to an individual (person approach) or to a faulty system (system approach) (DOH, 2004; Reason, 2000). In the person approach the investigation focuses on the wrongdoing of the person, his forgetfulness, inattention, poor motivation, carelessness and the like. Consequently countermeasures to error also focus on the person, trying to make the individual error free, for example in retraining, reminding, or also through threatening, naming, blaming and shaming an individual (DOH, 2004). In contrast the system approach concentrates on conditions under which individuals work and tries to build defences to avert errors or mitigate their effects. The systems approach accepts that humans are fallible. Errors are expected to happen even in the best organisations (Reason, 2000). Figure 3.3 compares these two approaches with each other before the next two sections elaborate on the person and the system approach respectively.
### Figure 3.3: The person and the system approach compared

<table>
<thead>
<tr>
<th>THE PERSON APPROACH</th>
<th>REACTION TO ERROR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forgetfulness</td>
<td>Poster campaigns</td>
</tr>
<tr>
<td>Inattention</td>
<td>Procedure review</td>
</tr>
<tr>
<td>Poor motivation</td>
<td>Disciplinary action</td>
</tr>
<tr>
<td>Carelessness</td>
<td>Threat of litigation</td>
</tr>
<tr>
<td>Negligence</td>
<td>Retraining</td>
</tr>
<tr>
<td>Recklessness</td>
<td>Naming, blaming and shaming</td>
</tr>
<tr>
<td>Distraction</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUSES OF ERROR</th>
<th>THE SYSTEMS APPROACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error provoking conditions within the workplace e.g. time pressure, understaffing, inadequate equipment, fatigue, inexperience.</td>
<td>System is reviewed so that if an error occurs its damaging effects are minimised</td>
</tr>
<tr>
<td>Weaknesses in defences e.g. unworkable procedures, design deficiencies, equipment failure</td>
<td></td>
</tr>
</tbody>
</table>

Source: DOH (2004:27)

### 3.4.1. Person approach

As the name suggests the person is the focus of attention in the person approach to error. In the person approach it is believed that unsafe acts are primarily the result of aberrant mental processes. It therefore focuses on the active errors of individuals, blames them for forgetfulness, inattention or moral weaknesses, poor motivation,
carelessness, negligence and recklessness (Reason, 2000). Indeed, analyses that focus on individuals will always reveal wrongdoing of individuals. One example, a study by Chassin and Becher on events leading to the operation of a wrong patient (Chassin and Becher, 2002), revealed that at least 17 individual errors had been made.

Errors of individuals are more or less obvious. They do not require a thorough investigation and one may arrive at conclusions without consulting any particular error detecting and analysing tools. If the bad apple, the culprit, is found consequences can be taken. These ‘countermeasures’ in the person approach are then directed mainly at human behaviour and how to control the unwanted variability that comes with it. Often this includes disciplinary measures, threat of litigation, naming, blaming and shaming (DOH, 2000; Reason, 2000). Findings in psychology suggest that it is emotionally more satisfying to blame individuals than to dig deeper into the system (Reason, 2000). The consequence is a belief that bad things happen to bad people, and that separating individuals from the system they belong to will improve safety (Reason, 2000).

Hospitals have been described as bureaucratic organisations (Albrecht et al., 2000; Mintzberg, 1988; Drucker, 1999 and 2003). Bureaucratic organisations in turn are often associated with ‘the person approach’. Traditionally errors in health care have been associated with a person approach (AHRQ, 2008 and 2011; Reason, 2000) and hospitals in particular have been mentioned in connection with a ‘blame and shame’ mentality (Waring, 2007; DOH, 2000). This may be for at least two reasons: first, the way health care personnel themselves perceive and handle error, and secondly the way the media handles error.
Hospitals usually respond to errors as if they were anomalies, blame one individual, and promise that “anything like that will never happen again” (Wu, 2000). Therefore, in stark contrast to other high risk organisations, health care organisations have long been characterised by a perfection myth where the provision of error free services is assumed possible just by relying on peoples’ attentiveness, attitude and concentration (Reason, 2000; AHQR, 2011). A number of sociological studies have shown that the way doctors give meaning to error, how errors are perceived, interpreted and understood is formed within the lived experience of medical practice and formed by shared cultural norms, attitudes and beliefs into which members are socialised (Paget, 2004; Waring, 2007). Authors (for example Coburn and Willis, 2000; Waring, 2007) note that this is linked to the inherent complexity and uncertainty of medicine (Fox, 2000; Rosenthal, 1995), professional training (Bosk, 1979), normalising and rationalising wrongdoing (Mizrahi, 1984), and the exclusivity and credibility of clinicians (Freidson, 1975; Rosenthal, 1995). This, what is sometimes referred to as the “perfection myth”, seems to be somewhat justified by doctors themselves when swearing the Hippocratic Oath not to harm patients at the beginning of their career. When errors become apparent, for example when a patient is harmed, the person approach is a common and easy way of dealing with the problem. This leads to an ‘analysis’ of the case in a way that will inevitably identify personal failure (albeit conditioned by a systems failure) which is often also followed by consequences on an individual ‘personal’ level.

Even when errors are discussed, for example at morbidity and mortality conferences, this is often purely to discuss medical facts rather than feelings of the patient, members of the care team (Wu, 2000; Rosenthal,
1995), or underlying conditions. Physicians often respond to their own mistakes with anger, denial, or covering up. Being aware of the danger and consequences of facing a malpractice suit they may act cold and defensively, or blame other members of the team. Deeply wounded it is not uncommon that even some of the most reflective and sensitive staff loose their nerve, suffer from burn-out, and seek solace in alcohol or drugs (Wu, 2000).

At the same time hospitals lack of constructive mechanisms for physicians and to “recover” from any wrong they may have done, whether their error actually resulted in harm or not. An environment that does not leave space for (non-punitive) discussion of probable errors, but puts additional pressure on medical and nursing personnel in falsely expecting them to work error-free is counter productive to creating a culture that has the potential of identifying errors that are hidden deep within the system (Wu, 2000). Wu (2000) concludes that there is no space for error in modern medicine. Patients have an understandable desire for their doctors to be infallible, but developments of various kinds have set up a myth of infallibility that cannot be met.

Newspapers frequently report about medical errors in health care and public attention quickly focuses on pursuing the person approach and blaming one individual (AHRQ, 2011; DOH, 2000; IOM, 2000). ‘Celebrated’ newspaper stories usually end once one individual is found to blame and there is no further investigation of the case (Cook et al., 1998; Dentzer, 2000). These celebrated stories do not reflect or address the deeper rooted problems of medical error (for example AHRQ, 2005a and b; NPSA, 2005; IOM, 2000; Pateisky, 2005). While there are exceptions to the blame and shame game that many news
agencies play journalists live from analysing complex chains of events and from writing about it in a sensational way. In doing so journalists often seem to not get the balance right and it seems that not many of them are aware of the implications, for example the reinforcing of medical professionals’ fears about legal liability in connection with greater error disclosure (Brennan, 2000; Dentzer, 2000).

A different kind of constructive and more investigative journalism can help give voice to people who otherwise would have not been heard and fulfil an uncovering role in society that can create public and political pressure to change things. To mind come the undercover investigation “Midwives Undercover” from the BBC documentary series “Panorama” (BBC, 2007a) and the BBC documentary “Can Gerry Robinson fix the NHS” (BBC, 2007b). However, these examples are an exception to the rule.

Intense public interest in medical accidents also bears potential disadvantages. While it can leverage political will combined with economic investment, at the same time it gives rise to calls for quick action or visible evidence of progress (Cook et al., 1998). This may be counterproductive to safety when unproductive, counterproductive or inefficient programs are imposed on professionals in a “quick-fix” kind of manner to promote political or economic interests (Leape, 1994; Berwick, 2000). In systems thinking these quick fixes get special attention, as quick fixes have the inherent risk of being “fixes that backfire” (for example Senge et al., 2005; Senge, 2006).

In summary the person approach restricts organisational learning because it not only neglects latent factors that produce error but also because it fosters a culture of blame where individuals are often held
responsible and reprimanded for active errors that are actually conditioned by the wider system (Waring, 2007). An alternative response to organisational accidents, the system approach, will be discussed in the next section.

### 3.4.2. System approach

In the system approach stories move away from blaming one individual to investigating system weaknesses. The systems approach rejects the perfection myth that “if we try hard enough we will not make any errors” (usually associated with a bureaucratic culture), or the punishment myth that “if we punish people when they make errors they will make fewer of them” (usually associated with a pathologic culture) (NPSA, 2005c). “Human beings make mistakes because the systems, tasks and processes they work in are poorly designed” (Leape, 1994). It is not so important who made an error but to identify which factors in the system made it so easy for an individual to err. Systemic vulnerabilities are seen as the result of multiple and combined interacting factors in complex systems. In the eye of a systems analyst these are more interesting than human errors because they can point out a way to more effective learning and whole system improvements. In this way human error serves as a starting point of an investigation, not as the end of it. It thus allows uncovering systemic vulnerabilities that are hidden behind human error (Cook et al., 1998) and it encourages clinicians to look past individual error and to recognise the underlying threat of latent conditions (Waring, 2007). The system approach is based on the belief that changing the system will improve safety. This approach is usually associated with a learning culture and is considered a key component of a safety culture (DOH, 2000; Waring, 2007; Waterson, 2009).
However, very little is known about whether the type of ‘systems thinking’ as promoted by the patient safety movement is informing how doctors think about the threats to patient safety (Waring, 2007) and if clinical professions are reaching out or being reached by experts in other fields to challenge and change their way of thinking (Rosenthal, 1999), even in those countries that run substantive national patient safety programs such as in the UK. Investigations on this issue so far, such as Waring’s (2007), looked at this in a particular policy context, i.e. a governing body in charge of patient safety suggested or imposed a kind of ‘systems thinking’ on clinicians. In the UK this happened primarily as a consequence of major inquiries, such as the Bristol Inquiry (Kennedy, 2001) and the Shipman Inquiry (Smith, 2005), which resulted in a much greater exposure to a type of ‘systems thinking’ as advocated in policy (Waring, 2007). The present study differs in that respect, as the there is no nationwide CIRS in Austria and the CIRS investigated in this study was instigated and controlled by clinicians themselves - as a response to a lack of a policy in Austria.

3.5. Conclusion

Organisational accidents can happen to all organisations, even very safe ones, and follow a common basic scheme. Different organisations and industries perceive and subsequently respond to errors in different ways - in the person or in the system approach. Under the person approach a scapegoat is quickly identified, blamed and shamed. It can be easier, more satisfying and convenient to point the finger at and blame an individual. The systems approach acknowledges that humans
are fallible and do err. Therefore the focus is not on improving human performance but on designing safe systems and environments in which humans work. In this way inevitable human errors can be intercepted and prevented from causing harm. Traditionally errors in health care have been associated with a person approach, and this may be due to the way errors in health care are communicated through the media, and also through the way health care professionals themselves deal with error.

Despite the complexity behind organisational error and evidence, mainly from analyses in industries outside of health care, suggesting that systemic failures need to be treated systematically, health care organisations have been criticised for relying too heavily on “infallible individuals”. As a consequence health care staff often work in systems that are devoid of many of the safety measures that have already become standard in high reliability industries. Without safe systems health care staff are ‘set up’ to make errors. This is not congruent with the medical profession’s ethical principle ‘not to harm’ people but might be a reflection of the bureaucratic culture in health care organisations. However, it has been argued that it is exactly this culture that restricts organisational learning because it neglects latent factors that produce error and fosters a culture of blame where individuals are held responsible for active errors that are actually conditioned by the wider system.

Although this chapter has focused on the key aspects of organisational error the substantial literature reviewed for this chapter substantiates the systemic nature of error in health care and confirms the applicability of the system approach used in error science to health care. The
literature presents a red line of the concept of organisational error across different industries, including health care, with the only difference that health care seems to be lagging behind in its application. Under the new patient safety movement health care organisations with an interest in safety increasingly aim to develop a system approach to safety as exemplified in high reliability industries and promote the kind of systems thinking set forth in this chapter. This means that the management of error requires an acceptance of error with consideration given to the relationship between individual human behaviour and the factors that influence this behaviour (Reason and Hobbs, 2003). This commonly involves the introduction of designated incident reporting systems that enable front-line staff to communicate their safety concerns and experiences of error to those responsible for safety and quality (Waring, 2005). In health care efforts are being made to create incident reporting systems for medical near misses (for example Pateisky 2005; NPSA 2005; Battles et al., 1998; Kaplan et al., 1998; Runciman et al., 1993; Gambino and Mallon, 1991).

The review in this chapter suggests that the investigation in this study will need to be sufficiently flexible and broad in order to identify and cover a range of systemic issues that may influence CIRS or impact safety. The concept of incident reporting will be introduced in the next chapter.
CHAPTER 4: INCIDENT REPORTING

The purpose of this chapter is to provide the reader with an understanding of safe systems - the ultimate goal of patient safety initiatives. It discusses various approaches to safety and critically analyses the role of CIRS in safety. The chapter elaborates how an organisation should ideally approach CIRS and presents a framework against which the CIRS project in the study hospital can be measured.

4.1. Introduction

The new patient safety movement is built on a systems approach to error. Hence, patient safety is concerned with redesigning the system of service provision. Chapter three discussed the person and the system approach to error and concluded that in order to improve safety health care needs to move from a patient or condition specific based view to a systems based view (Shortell and Singer, 2008). There is now growing consensus amongst experts that the health care industry as a whole needs to rethink its actions and that there is a need to redesign the system of health care delivery in order to provide safe services.

Discussing the entirety of how to make the health care system safe and then transposing it on to the Austrian health care system would exceed the scope of this study. The scope of this study only leaves room for a discussion of a fraction of these elements and the focus here will be on critical incident reporting systems. This is for the following reasons. Critical incident reporting systems (CIRS) are common practice in high reliability industries and contribute to their exemplary safety records. Health care institutions have started to use CIRS and some countries have launched national incident reporting systems
(the biggest one is the UK National Reporting and Learning System). Although CIRS is considered key in improving safety it is under-utilised in health care systems (Mahajan, 2010). At the commencement (as well as conclusion) of this study Austria did not have a nationwide incident reporting system. Nevertheless an initiative for incident reporting was about to be launched by the Austrian Society for Gynaecology and Obstetrics, thus providing a platform for this investigation (and therefore largely in a non-policy context). Although critical incident reporting systems appear to be a popular, some even argue a key, element in the new patient safety movement, little is known about the management of such systems. This presents an opportunity for research.

This chapter starts with providing contextual information on where health care aims to go with the contribution of incident reporting, namely safe systems (4.2.1). This section stresses that although the new patient safety literature promotes a kind of systems thinking that encourages the use of CIRS this new kind of thinking has to come up against another strand of safety initiatives, notably evidence based medicine (4.2.2), which might sit much more comfortably with clinicians who are supposed to use it. The chapter then introduces the purpose (4.3.1), the characteristics of good (4.3.2), and the barriers (4.3.3) to incident reporting. The chapter draws conclusions in section 4.4.

4.2. A context for change?

Investigation of organisational accidents in high risk industries suggests that errors happen to all organisations and all humans, regardless of how hard they try. The analysis of organisational accidents has lead to a body of knowledge on the contribution of humans and ‘systems’ to safety and failure. CIRS play an important role in providing information about system behaviour and allow the
detection of unsafe conditions and acts before they cause harm. This serves as a basis for improving safety before major accidents occur. The following section will first introduce the concept of safe system design as proposed in the recent patient safety literature and will then bring this in relation with the current prominent procedures of safety improvement, especially evidence based medicine.

4.2.1. Safe systems

Extensive investigations of organisational accidents and information drawn from incident reporting systems outside health care have greatly influenced the way these industries operate today. High reliability organisations, notably in aviation, transportation, and nuclear power generation have learnt lessons from past accidents and designed safety into their systems to counteract the problem of human error and to minimise the occurrence of system failure or mitigate its outcomes. High reliability industries deal with a high number of errors but at the same time they have a high number of systemic defences that prevents errors from causing harm. An example of a high reliability industry is aviation, and just a glance in an airliner cockpit reveals the extensive feedback that is provided to pilots by means of monitoring instruments (Leape, 1994). This should not imply that nothing goes wrong in such systems. Research on cockpit crews for example shows that human errors and instrument malfunctions occur on average every four minutes during a transatlantic flight (Perrow, 1984; Leape, 1994). The difference to other industries is that events are promptly recognized and corrected before they have any untoward effects (Leape, 1994). Moreover, buffers and redundancies are built into the system. Critical instruments exist in duplicate or triplicate so that failure does not result in loss of the function (Leape, 1994). Unusual incidents are often reported in anonymous reporting systems. These reports are then analysed and fed back into the system, often through
industry wide design changes, for example a modification of a certain type of aircraft.

Positive effects of safe design, consciously or unconsciously, affect peoples every day life. Not only when taking a transatlantic flight, also in much more common situations like driving a car. Built in ‘forcing functions’ don’t allow the user to act until a certain precondition has been met (Leape, 1994). For example is it impossible to release the parking gear of a car unless the break pedal is depressed. One might also say that the design of a cash machine is, from a safety aspect, superior to many hospital facilities. These machines force the customer to take back his card before any money is given out, thus preventing the user from taking the money and forgetting the card. In comparison to other high risk industries relatively little has been done in that respect in the health care industry. Safe systems have become the norm in many high risk areas but they have not (yet) become standard in health care organisations (for example AHRQ, 2008; Emanuel et al., 2008a and b; DOH, 2000; IOM, 2000). Staff still have to rely heavily on their memory or on imperfect communication. When a doctor orders a drug for a patient there is no alert telling him that the patient is allergic to that drug. When tube fittings for anaesthesia in an operation theatre fit into both openings for carbon dioxide and oxygen and have been connected incorrectly there is very little chance for a doctor to find out that something is going wrong.

From his own experience in working in hospitals the author of this thesis can say that there are examples in health care where redundancies have been built into systems and work already for a long time. One example is the uninterruptible power supply in operating theatres. In case of a power failure the hospitals’ own secondary power supply (mostly diesel aggregates that can independently supply electricity for the entire hospital and for several days). For an operating theatre this level of safety is still not sufficient. A failure of
instruments for even just a second could have fatal effects. Therefore these machines are additionally supplied with batteries that cover for the time until power supply is restored. However this example is only one a few isolated areas in health care where this works well. High reliability organizations are different in that they operate safely as an entire system, in all parts of the system, not merely in isolated parts.

Another important element of safe systems design is standardization of processes. Using the example of aviation again, this is an area that is highly standardized. For example, before each takeoff pilot and co-pilot have to go through a routine pre-flight checklist that also includes apparently simple items, such as if the plane’s door has been shut. People may argue that no sensible pilot would start takeoff before the door has been shut. However, experience shows that people, however trained, experienced or skilled they may be, sometimes react irrational when under stress or under influence of other possible contributing factors. A safe system doesn’t leave any space for error, including simple ones like taking off with an open door, and is designed in a way to make it extremely difficult for individuals to err. In addition training, examination, and certification in high reliability organizations is highly developed and enforced. Pilots need to take a proficiency test every six months on a flight simulator. Data from those proficiency tests are directly concerned with procedures to enhance safety (Leape, 1994). In many health care organisations the mere thought of having experienced surgeons operate on a dummy twice a year for safety and education purposes is perceived as ridiculous (Pateisky, 2008 personal communication), let alone simulation projects in health care are much less advanced than in aviation.

These components of safe systems have been institutionalized in aviation. There are independent agencies with government-mandated responsibilities for regulating and prescribing safety procedures, monitoring them, and a safety
board to investigate every accident (Leape, 1994). These procedures of safe systems, for example checklists, can also be used in health care organisations, and they are in use in certain areas and institutions. But again, the overall problem is that this has not yet become the standard procedure and a requirement for all hospitals, and the organisation of hospitals in general seems to allow this to prevail. Accordingly organisations with an interest in safety can apply such methods, but they don't have to, and some might not even know about it.

It has been argued that the health care industry is different to other industries in terms of place of professions, role of patients and the nature of the health care process. Hospitals in particular have been described as having similarities with marketplaces, a place of unmanaged and undocumented processes where no one person acts as the “process manager” (Walshe and Smith, 2006). However, various safety experts (such as Leape, 1994; Reason, 2000; BMJ, 2000; Helmreich, 2000; IOM, 2000; Waring, 2005; Walshe, 2003; Pateisky, 2004) argue that from an error science perspective they actually have a lot in common and that hence the health care industry can learn a lot from other high-risk industries. But they (ibid) also stress that the health care industry as a whole lags behind in understanding its systems of delivery and in building preventative measures to detect, prevent, or mitigate effects of errors, and that the whole system of delivery needs to be redesigned.

This idea of systems redesign is not entirely new. Already in 1998 Ronald Coase, a British economist and winner of the Nobel Prize, suggested that if care was to be of higher quality and lower cost, it needed to organise the structures and processes involved better (Koeck, 1998). Koeck (1998) stressed that it is the organisation of the health care organisation that has to improve and criticises how little existing knowledge was put into practice. From a management perspective this is probably best epitomised in his statement that
“a student of management and organisation theory could only be stunned by how little the efforts to improve quality (in health care) have learnt from current thinking in management theory and from the experience of other industries” (Koeck, 1998:1268). Why change in this regard hasn't come across much earlier might be explained by looking at other ways of safety improvement. To provide a richer context and to understand the environment in which CIRS is expected to prosper this is shortly discussed in the next section on evidence based medicine.

4.2.2. Evidence based medicine

Why ‘systems change’ in health care is apparently difficult (Christian et al., 2006; Waring, 2007; Wachter, 2010; Leistikow, 2011) might become more apparent when looking into popular improvement mechanisms in health care, notably the concept of evidence based medicine. Evidence based medicine aims to apply best available evidence gained through the scientific method to clinical decision making (Timmermans and Mauck, 2005) from a stance that many aspects of health care depend on individual factors. Although its traces go back to ancient times it has only become a generally accepted concept across the several health care domains in the 20th century. The term as such, evidence based medicine, first appeared in the medical literature in 1992 in a paper by the Evidence-based Medical Working Group.

A review of the literature makes apparent that several recommendations for the improvement of safety in health care exist. The U.S Agency for Health Care Research and Quality for example reviewed 79 practices and ranked them in terms of strength of evidence supporting more widespread implementation. These revealed that, contrary to the current excitement in the patient safety movement to adapt practices from outside the realm of health care, evidence provided by the U.S. Agency for Health Care Research and Quality suggests that more clinical practices for the improvement of patient safety are potentially
The top eleven patient safety practices, where most evidence is available, were identified as (Shojania et al., 2001:6) (numbering occurs here purely as an orderly mean and is not to be understood as a ranking):

1. Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk;
2. Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality;
3. Use of maximum sterile barriers while placing central intravenous catheters to prevent infections;
4. Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections;
5. Asking that patients recall and restate what they have been told during the informed consent process;
6. Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia;
7. Use of pressure relieving bedding materials to prevent pressure ulcers;
8. Use of real-time ultrasound guidance during central line insertion to prevent complications;
9. Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications;

This was just about a year after the major publications IOM report and UK ‘An Organisation with a memory’ which suggested ‘less traditional approaches’ to safety improvement.
10. Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients; and

11. Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.

Accordingly the same report presents the most beneficial opportunities for research on patient safety in those clinical areas. The top twelve opportunities for research were identified as (Shojania et al., 2001:7):

1. improved perioperative glucose control to decrease perioperative infections;

2. localising specific surgeries and procedures to high volume centres;

3. use of supplemental perioperative oxygen to decrease perioperative infections;

4. changes in nursing staffing to decrease overall hospitality morbidity and mortality;

5. use of silver alloy-coated urinary catheters to prevent urinary tract infections;

6. computerised physician order entry with computerised decision support systems to decrease medication errors and adverse events primarily due to drug ordering process;

7. limitations placed on antibiotic use to prevent hospital-acquired infections due to antibiotic-resistant organisms;

peri-operative = the time period describing the duration of a patient’s surgical procedure; perioperative generally refers to the three phases of surgery, preoperative (before), intraoperative (during), and postoperative (after); this commonly includes ward admission, anaesthesia, surgery, and recovery
8. appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections;

9. appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk;

10. appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and post-surgical patients;

11. use of analgesics in the patient with an acutely painful abdomen without compromising diagnostic accuracy; and

12. improved hand-washing compliance (via education / behaviours change; sink technology and placement; or use of antimicrobial washing substances).

The above recommendations are clearly important to improvements in safety. However, they represent a view on patient safety through the lens of evidence based medicine. This does not mean that practices drawn from outside medicine have no validity in patient safety. Rather, as is suggested by Shojania et al. (2001), the above evidence is simply a reflection of the significant resources provided from governments and industries to promote clinical research. In this respect the introduction of methods from outside industries, such as the use of CIRS, presents a major leap in patient safety. For many of the new patient safety initiatives, and in contrast to evidence based medicine practices, there is little experience and assessment of how they might work in a health care context. They need to be tested and proofed useful in health care. The fact that there is little evidence (Landrigan et al., 2010; Vincent, 2010; Vincent et al., 2008) has been named as one of the reasons why progress in

19 Thrombophlebitis is the swelling (inflammation) of a vein caused by a blood clot
20 Enteral nutrition = feeding through a feeding tube
the new patient safety movement is so frustratingly slow (Leistikow et al., 2011; Wachter, 2010; Wachter, 2004). Policy makers have a lot of work to do in order to transpose this new kind of patient safety thinking into the minds of practitioners in health care organisations and provide evidence, or otherwise conclusive arguments, that applying these methods in health care indeed improves safety (Landrigan et al., 2010; Vincent, 2010; Vincent et al., 2008; Waring, 2007).

This adds to the discussion about whether certain endeavours to improve safety are attributable to and fall into the realm of patient safety, medical knowledge, or best practice. Moreover the above ‘opportunities for research’ also point to a cross-clinical-professional nature of many of those activities, as well as an overlap of clinical and organisational events. For example recommendations on limiting antibiotic use in order to prevent occurrence of antibiotic-resistant organisms (opportunity 7 in the above list) will require interaction between attending (and according to shift altering) physicians. Considering that physicians are primarily not pharmaceutical experts and often unaware of drug-drug interactions and/or side effects, or overlaps of effects, when patients receive high numbers of several different drugs, a successful implementation of this recommendation would further require acquaintance of a clinical pharmacologist on the ward. However, most hospitals, despite cost-effect benefits, do not (yet?) employ clinical pharmacologists (Barolin, 2006), and only little is known about how clinical pharmacologists would be perceived and accepted by physicians on the ward.

Other recommendations, for example the use of silver-alloy coated urinary catheters to prevent urinary tract infections (opportunity 5 in the above list), at first appear to be non-clinical management decisions. However, considering the extra cost, even though cost-benefit may amortize those initial costs, could again cause conflict with physicians, when funds/resources are taken from them.
(Shojania et al., 2001). Nevertheless, it becomes clear through the above list that some suggestions are more “clinical” than others, and therefore that implementation of some of those recommendations will depend more on the support of clinicians than others.

Last but not least, the recommendation on improved hand-washing compliance (opportunity 12 in the above list) is a reminder how difficult diffusion of innovation in health care and implementation of best practices can be. Established medical practice, in the West often synonymous with the scientific methods, is difficult to change, even when empirical evidence clearly indicates the need for change. History provides numerous examples, whether in England around the work of Sir Thomas Percival (1740-1804), whose work on internal regulation of hospital practice and a professional code of conduct was first rejected, but became instrumental later during the founding of the American Medical Association in 1847 (Haakonssen, 1997; AMA, 2011; Darr, 2007); in the United States William Halsted (1852-1922) reported of the benefits of disinfecting surgical instruments. There was so much resistance from his colleagues that he even was forced to perform surgery in a tent outside the main hospital building (Holleb, 1986; Darr, 2007).

Because the present study takes place in Austria, Vienna it may be mentioned here that opportunity 12 on hand washing actually originated in Vienna. Faced with the problem of an often fatal bacterial infection among newly delivered women the Viennese doctor Ignaz Semmelweis found in 1847 that washing of hands and instruments in carbolic acid (a solution of chlorinated lime) stopped spreading of the puerperal fever (childbed fever). He instructed doctors on his ward to wash their hands after they had participated in autopsies and before examining the next patient on the clinical round. Although this rather simple but effective procedure virtually eliminated puerperal fever on his ward overnight, and Semmelweis even used mortality statistics to back up his findings, his
medical colleagues rejected his findings and eventually ridiculed him out of Vienna (Young, 1988; Darr, 2007). Semmelweis later published a book describing his findings. However, it was not until 1862, when a French bacteriologist demonstrated the germ theory of disease, that the findings were finally accepted (Best and Neuhauser, 2004; Darr, 2007). As the recommendation in the list above (opportunity 12), which is from the year 2001, as well as many other, more recent, programs on hand-washing procedures in hospitals demonstrate, even today Semmelweis’ findings are still not being fully applied, and 150 years after Semmelweis newly (re)discovered as one of the top opportunities for research in improving safety in health care.

4.2.3. Discussion

High reliability organisations, in comparison to most health care organisations, are much more experienced with a system approach to error. They use well defined methods and tools for the detection, prevention and mitigation of errors. Learning from accidents and near misses is a long established practice and a cornerstone to safety and improvement in high reliability organisations outside health care (Vincent, 2003; ICS, 2006). In aviation for example incidents and accidents are exhaustively investigated. Lessons learned are disseminated widely, and important changes are made mandatory by regulatory authorities (Vincent, 2003). More than three decades ago the Aviation Safety Reporting System was launched to collect, analyse and respond to voluntarily submitted aviation safety incident reports (ICS, 2006). In health care this is different. This became apparent at the US NPSF workshop in 1997, which is regarded by many as the starting point for the patient safety movement in the US. People had to rely on a number of ‘celebrated’ newspaper articles cases from newspaper articles. This is considerably different to safety discussions in other domains. For example in the National Transportation Safety Board (NTSB) aviation accidents are followed by independent investigations of the sequence
of events and contributors to the outcome. Hence system analyses, and the subsequent support for patient and staff, should be an absolute priority in any risk-management and safety strategy, including those in health care (Vincent, 2003). However, health care organisations have been criticised for not giving adequate attention to systemic and thoughtful investigation of incidents and the learning and organisational change that can follow (Vincent, 2003). Progress has been made since, but applying the system approach in health care proofs a challenging task with still many worrying gaps (Wachter, 2010; Vincent et al., 2008). In particular CIRS are still under-utilised in health care systems (Mahajan, 2010).

This section aimed to provide a stronger context of where health care currently stands in terms of safe systems design and where it ought to go. In has done so with the use of a few simple examples but without giving reference to statistical comparisons of the average rate of exposure to catastrophe in health care and other industries, such as Amalberti et al. (2005), because in light of chapter 2 of this thesis such explicit referrals in quantitative terms seem inappropriate / unreliable. The concept of evidence based medicine has been added to demonstrate that, in a world of limited resources, the new patient safety strand of pursuing a system approach is not the only one. If it is to be successful it will also have to stand up against other strands of improvement that themselves have fought a long battle in order to gain acceptance. The next section will introduce the concept of critical incident reporting systems.

4.3. Incident Reporting

The principles of safe systems design can be summarised as: to make wrong actions more difficult, to make incorrect actions correct, and to make it easier to discover errors (NPSA, 2005b). Key to all these three principles for change and
improvement is acquiring information about the behaviour of a system. Experiences in high reliability industries have shown that the systematic collection of critical incidents, as for example the US Aviation Safety Reporting System demonstrates since its inception in 1976 (ICS, 2006), constitutes an important part of a safety and learning culture (Kaufmann et al., 2002). It has been argued that this is one of the weak spots of health systems and that it is a lack of reliable information on safety and quality of care that is hindering improvement in safety (Landrigan et al., 2010; Vincent, 2010; Vincent et al. 2008). Because high reliability industries benefit from well developed reporting systems, in regards to limiting human, environmental and financial threats (ICS, 2006), the establishment of local and national reporting systems has also become a principal approach to patient safety in the UK, the US, and many other countries (Mahajan, 2010; Vincent, 2010). Reporting systems provide a medium for sharing lessons learned and opportunities for improvement and can prevent the reoccurrence of same or similar events in the future (CPSI, 2007).

The idea of collecting data itself is not new. Codman (1869-1940) already recognised the interactions of different factors - clinical care, technology, and methods - in the early 1900s and established a practice called “outcomes management” or “end-result idea” in health care. In his own words “the end-result idea merely demands that the results shall be constantly analysed and possible methods of improvement constantly considered. Bad results may be due to incorrect diagnoses, to lack of equipment, to errors of care, or judgement, or of skill. The end-result idea implies that the hospital should be conscious of its shortcomings, and constantly on the watch to improve its equipment and method.” (Codman, 1924:34 cited in Darr, 2007:37)

Codman was the first physician to hold mortality and morbidity conferences, where cases are discussed openly amongst a care team for the purpose of learning about the care received by a patient and whether or not that care
contributed to a good result (Darr, 2007). Mortality and morbidity conferences are now standard practice in hospitals. A core element of all his endeavours was to learn from previous mistakes so that services may be improved for future patients. However, Codman’s idea of learning from mistakes received similar rejection as did Percival, Halsted, or Semmelweis works and, in order to perform safely, he was forced to open his own hospital. His proposal to publicise end results of care was too startling and intimidating for clinicians and hospital staff as they feared embarrassment as well as political and economical consequences for their hospitals (Darr, 2007). The end result system broke the unwritten rules for tolerance and no open criticism considered necessary in the surgical world (Reverby, 1981), and threatened to turn the surgical auditor into a ‘policeman’ rather than a ‘teacher’ (McColl, 1976).

In light of the relatively recent instigation of the NPSA and the National Reporting and Learning System in the UK it comes somewhat as a surprise to find that a formal guidance on incident reporting in health care was already issued by the Ministry of Health in 1955 (HM, 1955). However, this guidance did not develop into a universally accepted process within the NHS for identifying and reporting critical incidents (ICS, 2006). There were other ‘systems’ or procedures that captured incidents as a by-product, such as the Confidential Enquiries into Perioperative deaths and Maternal Mortality, Audit Commission reports and the NHS complaints procedure, but it was not their primary aim (ICS, 2006).

In response to the alleged unacceptable high rates of medical injuries and preventable deaths and in order to make health care safer around the world the World Health Organization (WHO) launched a global effort in 2004, the World Alliance for Patient Safety (WAPS), to create or adapt and launch incident reporting systems for medical near misses (for example CPSI, 2007; ICS, 2006; Pateisky 2005; NPSA 2005; Battles et al., 1998; Kaplan et al., 1998). In the UK
it was the inception of the National Reporting and Learning System in 2004, an anonymous mandatory reporting system, which saw a first systematic approach to collecting data on critical incidents and near misses. Despite this progress the general documentation of health care processes and the lack of attention given to measurement of safety still present one of the biggest problems in providing safe health services (Vincent, personal email conversation 2011). While the new patient safety movement aims to tackle this problem, in contrast to international developments to introduce CIRS on national levels Austria does not have a national incident reporting system for near misses. In response to what could be seen as a lack of government initiative the Austrian Society for Gynaecology and Obstetrics launched a program that enables Women hospitals in Austria to participate in the international anonymous voluntary online reporting system CIRSmedical. The purpose of Critical Incident Reporting Systems will be explained in more detail in the next section.

4.3.1. The purpose of reporting systems

In order to counteract the apparent failure of health care systems to learn from their mistakes, to advise other organisations when a mishap occurs, or to share with others what lessons have been learnt in dealing with errors so that the same mistakes do not recur repeatedly in many settings and continue to expose patients to unnecessary risk, health care organisations have started to use incident reporting systems (WHO, 2005a). Some believe that effective reporting is the cornerstone of safe practice (WHO, 2005a). Importantly however CIRS are not systems for the measurement of safety (Vincent, 2010). There is agreement however that frequent use of CIRS is an indication of a prevalent safety culture (for example AHRQ, 2011; CPSI, 2007; NPSA, 2005; DOH, 2001; IOM 2000).

Critical incident reporting systems invite reporting of unspecified safety incidents with the aim of learning lessons and feeding back the findings into the system
(Vincent, 2010). Hence the goal of incident reporting systems is not to merely count errors, also because it has been found that reporting systems do not effectively detect adverse events (Vincent et al., 2008), but to acquire information that leads to understanding the error-root and contributing factors (IOM, 2000). In a comparison of different detection methods Sari et al. (2006) found that reporting systems detected only about six percent of adverse events as compared to systematic record reviews. Reporting systems are thus seen as a valuable component of a safety system, but essentially they are systems for warning and communication inside an organisation. If employed on large scale they might be valuable in detecting rare events that are not easily detected by other means.

There are different kinds of reporting systems, with a principal difference that they are either voluntary or mandatory, and either confidential or completely anonymous. Systems that place more emphasis on accountability are usually mandatory reporting systems. In mandatory reporting systems reports are compelled by law, policy/regulation, or other formal means (CPSI, 2007). Often they are run by governmental or regulatory bodies that have the authority to investigate specific cases and to issue penalties and fines for wrongdoing. Some reporting systems may include penalty clauses for failure of compliance with the regulations. The state of Florida for example can fine hospitals up to 250,000 USD for violations of the mandatory reporting system in place (Williams et al., 2003). Nakajima et al. (2005) report of Japanese hospitals that are penalised in form of a reduction of government funding of approximately 1 USD per patient per hospital day when found to violate the reporting agreement. The purpose of these mandatory systems is to ensure that the most serious incidents are reported, investigated and followed up. In addition, in order to avoid penalties and fines, they provide an incentive for organisations to invest in safety (IOM, 2000). Findings from Williams et al. (2003) and Nakajima et al.
(2005) suggest that these (financially) punitive measures have helped to improve compliance with reporting requirements.

The purpose of voluntary reporting systems on the other hand has been described to be more focused on general safety improvement. Voluntary reporting systems, as the one investigated in this study, focus on events that caused no or almost no harm (IOM, 2000). This is based various concepts, mainly derived from Heinrich’s ratio in 1941 (for example NPSA, 2005, see figure 4.1) which asserts that there is a fixed ratio between major (organisational) accidents, minor incidents, and no harm incidents. For every one major accident there may be ten incidents that cause severe harm, 100 incidents that cause minor to moderate harm, and 1000 incidents that were prevented and/or caused no harm (NPSA, 2005). This means that systemic changes may be initiated on the basis of no harm or prevented events, without the need for an accident that actually caused harm. The focus is therefore moved away from low frequency and high consequence events to the analysis of high frequency and prevented, near miss or medium to moderate harm events (Johnson, 2003). Although these kind of reporting systems are a passive form of surveillance for near misses and are different to more active methods such as retrospective chart reviews or direct observations (AHRQ, 2011) they present an additional proactive approach to safety. Events are shared freely and without compulsion from external authorities (CPSI, 2007).
Anonymous reporting systems do not include any identifiable details of the patient, reporter, or reporting institution. Therefore information contained in anonymous reporting systems is often less complete than in confidential reporting systems (CIPS, 2007). Confidential reporting systems on the other hand do include identifiable details of those involved in an incident, but this data is kept confidential. The advantage of confidential reporting systems is that the analysing institution can contact the reporter for follow up and clarification of the incident. Therefore information contained in confidential reporting systems is often more complete than in anonymous reporting systems. This also allows pinpointed feedback to the reporter. Once it is determined that sufficient detail on an incident has been supplied the identifying details are stripped from the report (CIPS, 2007).

Incidents reported in any of the above described types of reporting systems may include errors, injuries, non-harmful errors, equipment malfunctions or...
process failures (WHO, 2005b). Mostly however they focus on incidents that were prevented, for example when a doctor writes a drug on his treatment chart but a nurse notices that the patient was allergic to it and contacted the doctor, or where an incident happened but caused no harm, such as when a drug had mistakenly been given to the wrong patient but caused no adverse effects (NPSA, 2005). When different drugs are held in bottles with identical tops and are stored next to each other and one is in a hurry it is possible to accidentally swap two bottles around (NPSA, 2005). This can lead to classic ‘look a like’ or ‘sound a like’ incidents. Under normal conditions a concentrated member of the clinical team would not mix those up. But in a hurry look a like drugs with overpowering branding and poor information layout can lead to medication errors (NPSA, 2005).

An example is provided in the below figure 4.2, which shows two almost identical looking infusion bags. The picture on the left is water for injections; the picture on the right is lignocaine, a common local anaesthetic with an anti-arrhythmic effect. Although the content and effect of these two infusion bags is very different they have the same packaging, same labelling and small font. This makes it easy for someone in a hurry to pick up and administer the wrong one. If something like this is detected by a clinician it would still be very difficult to initiate effective changes, such as a change in design of the packaging. If however this is reported in a CIRS and is found to be a problem affecting a number of organisations then the analysing body, in the UK for example the NPSA, can then work at a national level to exert influence on pharmaceutical companies. This can result in effective ways to preventing problems, in this case a redesign of the packaging, and makes it harder to individuals to err (NPSA, 2005).
Figure 4.2: Two similar looking infusion bags:

the picture on the left is water for injections, the picture on the right is lignocaine, a common local anaesthetic with an anti-arrhythmic effect;

Source: NPSA (2005c)

CIRS can lead to several ways of learning and improvement safety. It can generate far reaching alerts regarding when significant new hazards are found, for example complications in the use of a new drug. In such a case even a small number of reports can provide experts with sufficient data to recognise a new hazard and issue an alert. Medication alerts are usually reported in separate medication reporting systems. Results of investigations can be disseminated through the CIRS feedback function so that not every organisation has to make and learn from one and the same mistake. Data from large datasets can also be classified and statistical correlations can generate insights into the overall system of care (WHO, 2005b).

The next section will discuss some of the characteristics of good incident reporting systems.
4.3.2. Characteristics of good incident reporting systems

The WHO World Alliance for Patient Safety (2005a) and the Council of Europe (2006), as well as speciality agencies, such as the UK Intensive Care Unit (ICS, 2006), the NPSA (2005), the US AHRQ (2011), the IOM (2000) and the QuIC (2000), and the German Coalition for Patient Safety (2006 and 2007) published guidelines for adverse event reporting and learning systems. Most of those recommendations are based on experience from outside health care (for example Barach and Small, 2000) and more recent publications, such as the WHO World Alliance for Patient Safety (2005a) and the Council of Europe (2006) are largely based on and summarise those earlier reports without providing any additional insight from the still relatively new medical reporting systems. These recommendations are summarised below. A notable exception, introducing new insight from health care reporting systems, is the work of Evans et al. (2006 and 2007) and this will conclude this section.

Based on findings from the Aviation Safety Reporting System, it became clear that for a CIRS to be successful there must be first, a demonstrated, widely agreed upon and tangible need for more and better information. Secondly, a highly respected body, independent from the influences of other stakeholders in the ‘system’, must be in place to collect, analyse data and disseminate findings (Billings, 1998). These are two key principles that must be met (Billings, 1998; CPSI, 2007). Furthermore experience from reporting systems outside health care shows that there are certain characteristics that make up good reporting systems. Importantly they focus on near misses, provide incentives for voluntary reporting, ensure confidentiality and emphasise a system approach to error analysis (Barach and Small, 2000). The WHO (2005a) describes the ultimate measure for CIRS as to whether the information yielded through CIRS is appropriately used to improve safety. Therefore successful reporting systems have also been described as analysis and feedback systems. Although
reporting itself is believed to have a positive learning effect on the reporter the analysis and feedback of reports are key elements. Successful systems should therefore show both, a highly visible ability to properly analyse cases, and recommend changes to those who have the authority to implement them (QuIC, 2000). Providing feedback, ‘closing the feedback loop’, is important. Reporters need to be provided with timely and usable feedback, as well as indications on how they may use the feedback (QuIC, 2000). Reporting systems without adequate resources for analysis and follow up action are not useful. They may even be counterproductive in that it weakens support for constructive responses and is viewed as a waste of time (IOM, 2000).

Barach and Small (2000), who conducted a study of 25 non health care adverse event reporting systems, contend that for reporting systems to be successful there must be a perceived incentive for professionals to report and that those incentives must outweigh any perceived barriers to reporting. Reporting systems must demonstrate an ability to prevent, detect, and mitigate the effect of undesirable combinations of design, performance, and circumstances that lead to adverse events (CPSI, 2007). Accountability should be balanced with transparency and protection for reporters, and the reporting community should be actively involved with the oversight of the system (Barach and Small, 2000; CPSI, 2007). In a wider sense this also applies to the future generation of potential reporters and thus it is consistently argued that successful reporting systems in the future also depend on a reformation of the current education system, training and educating scholars in the various health care professions in the use of CIRS (for example Beverly, 2001).

Based on publications from the AHRQ (2011), the APS (2007), the ICS (2006); the WHO (2005a), Runciman (2003), Leape (2002), , Gaynes et al. (2001), the QuIC (2000), Barach and Small (2000), Cohen (2000a and 2000b) and Billings (1998) characteristics of ideal reporting systems may be summarised as:
• Perceived need: a demonstrated, widely agreed upon and tangible need for more and better information

• Leadership Support: active leadership support throughout all levels

• Training and Incentives: Provision of training for those with reporting responsibilities; provision of free software and generic data to aid internal analysis; incentives must outweigh any perceived barriers to reporting

• Testing: Pilot testing and prototyping of the system takes place before large scale roll-out occurs

• Confidential: Institutions must have a supportive environment for event reporting that protects the privacy of staff who report occurrences; reports are confidential and identifying information has been removed; identities of patient, reporter and institution are never revealed

• Non-punitive: Reports are used for prevention, not punishment; reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting, this therefore requires an

• Independent body: The system is independent of any authority with power to punish the reporter

• Disambiguate: The intent and goal of the reporting system are clear to all interested parties; the system uses common, agreed standards and terminology; a single, clinically useful classification for things that go wrong

• Open: Reports are accepted from all interested parties and should be received from a broad range of personnel

• Easy: Reporting is easy to do and captures rich detail
• Expert Analysis: Reports are analysed by technically expert peers, from multiple perspectives; these experts understand the clinical circumstances and are trained to recognise underlying system causes; this should be a highly respected body, independent from the influences of other stakeholders in the ‘system’

• Timely feedback: Reports are analysed promptly, prioritised at local, national and international level, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified; reporters and larger interested communities receive timely feedback; summaries of reported events must be disseminated in a timely fashion

• Responsive: A structured mechanism must be in place for reviewing reports and developing action plans; the report receiving agency must be capable of disseminating recommendations and must demonstrate an ability to prevent, detect, and mitigate the effect of undesirable combinations of design, performance, and circumstances that lead to adverse events; mechanisms for setting priorities at local, national and international levels; participating organisations commit to implementing recommendations whenever possible

• Systems oriented: Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance; mechanisms for involving and informing all stakeholders

In 2007 Evans et al. studied the reporting habits in ten intervention and ten control units in hospitals in Australia (Evans et al., 2007). They found additional characteristics, or confirmed recommendations from the above list, of those units with an improved incident reporting frequency, thus providing rare
evidence - not merely recommendations based on a non health care context - of how reporting systems in health care might actually succeed. Because the above described characteristics of good reporting systems are mainly derived from non health care reporting systems Evans et al. findings are presented separately. These features are (Evans et al., 2007:175):

- Medical line managers attended root cause analysis training specifically designed to teach systems approach in error management
- the initial education captured the majority of doctors
- departmental education sessions were held at least every ten weeks, with discussion of incidents conducted for at least 20 minutes
- feedback provided clinically relevant incidents for discussion
- posters and manuals were clearly displayed in clinical areas, describing what types of incidents staff should report
- proficient call centre nurses captured reports in a timely manner
- online reporting was not offered

Probably the most striking difference in the above findings from Evans et al. (2007) is the last item in the list, namely that online reporting was not offered. This is interesting because review of the literature clearly points to a move toward online incident reporting. However, Evans et al’s finding is similar to Schuerer et al. (2006) who found a nineteen-fold increase in reporting in surgical intensive care units when they moved from an online reporting system to a paper based system, using a brief card with checkboxes and text fields. Experience shows that useful reporting systems require adequate technology. It
may well be that where this is not possible, for example due to financial restrains, a paper based system is better than a technically inadequate online system.

Last but not least it is important what kind of data is collected in the reporting system and there is agreement that any CIRS should consist of a minimum data set. This should ensure a basic analysis as well as, to some extent, comparison of data between different reporting systems. Usually this basic data set should contain the following information (CPSI, 2007:21 citing Liple, 2001:11):

- What happened (description, severity of actual or potential harm, people and equipment involved)
- Where it happened (location/specialty)
- When it happened (date/time)
- How it happened (immediate causes)
- Why it happened (underlying causes)
- What action taken or proposed (immediate and longer term)
- Impact of event (harm to the organization, patient, other)
- Factors that did, or could have, minimized impact

In addition to this minimum data set through standardised data input fields reporting systems may contain a free text passage where the reporter can describe the event in his own words and in the detail he feels is necessary. It has been argued that the advantage of a system that only allows the input of structured data, such as check boxes or drop down menus), is that data can be
entered more quickly and is easier to analyse. However, users have also expressed a preference for a system with a free text passage because it gives the reporter more freedom in providing contextual information, hence a richer account of what happened (Holzmueller et al., 2005; CPSI, 2007). The free text however demands from the user the ability to structure the event, whereas the structured form already provides structure and consistency for the content of reports (CPSI, 2007).

The next section will discuss barriers to incident reporting.

4.3.3. Barriers to incident reporting

Reporting systems are considered a key component of patient safety efforts. It may be argued that not appreciating any one of the above characteristics when implementing a CIRS may inhibit success of the system. This section will discuss those barriers that are commonly associated with CIRS in health care.

It has been argued that all health care reporting systems, whether officially mandatory or voluntary, are essentially voluntary - because they require the cooperation of staff to bring the information forward. Hence reporting systems depend upon the voluntary reporting of users (Billings, 1998). Various contributors have marked out several cultural, legal, regulatory, and financial barriers as inflicting reporting of adverse events and underreporting presents a significant concern in any CIRS (Billings, 1998). A study by Barach and Small in 2000 reported that underreporting of adverse events in the US was between 50 and 96 percent. More recent evidence from studies comparing incident reporting with other adverse event detection techniques suggests that this still presents a considerable problem in any CIRS and that many incidents are not reported (Evans et al., 2007). Health care providers may not use a CIRS for a number of reasons. This section discusses some of the most important barriers to incident reporting.
Similarly to the last section a lot of the literature on barriers in CIRS stems from findings in non-healthcare industries. Notably Billings (1998), based on his experience in aviation reporting systems, contends that underreporting may occur in three ways: (1) an event is not noticed (2) an event is noticed but it is not clear whether or not reporting is required (3) an event is noticed but deliberately not reported. Key to the acceptance of a CIRS seems to create an understanding amongst staff, what error scientists and patient safety experts refer to as a safety culture, that CIRS is one part of an improvement process and not a mechanism to identify negligence or assign blame (Emmanuel et al., 2008). But this is a delicate issue as an inherent ambivalence of reporting systems is that data gained through the system can be used either for recognising leverage points for improvement or to hold an individual accountable for something (IOM, 2000). The IOM noted in 2000 that the vast majority of errors are not reported, and they are not reported because personnel fear they will be punished (IOM, 2000). Six years later the Council of Europe (2006) reports seven barriers to the use of CIRS, four of which (the following points 1 until 4) are still directly related to staff fearing some kind of ill-effect as a result of reporting in CIRS. Staff might not use CIRS because of a (Council of Europe, 2006):

1. fear of blame, resulting from a lack of open and fair culture

2. fear of the reports being used out of context by the media and others

3. breaches of confidentiality or anonymity leading to ineffective separation of incident reporting systems from disciplinary and regulatory bodies

4. lack of legal protection against using the information for purposes other than learning

5. lack of feedback as to what has changed as a result of the report

no
6. lack of time to report

7. lack of support from the management of the organisation

This fear might create an attitude to only report what is really necessary. Studies show that staff are more likely to report events that actually caused harm, not equally valuable near miss, no harm, or prevented events (Lawton and Parker, 2002; Firth-Cozens, 2002). Lawton and Parker also found differences in reporting behaviour in three different contexts: compliance with a protocol, violation of a protocol, and improvisation where no protocol existed. In compliance with protocols reporting was more common than in instances where no protocols existed or they were not being adhered to. This stresses the importance of protocols for medical practice. A lack of protocols furthers the difficulties a member of staff might have in identifying whether or not an event is reportable, and, in case it is perceived reportable, how to classify or code the event.

The study by Lawton and Parker (2002) also showed that although a bad outcome usually increased the likelihood of the event being reported this was not the case in those instances where staff had to improvise because no protocols were in place. The willingness to report about those events where one had to improvise was drastically lower, even in events that lead to a poor or bad outcome (Lawton and Parker, 2002). Lawton and Parker (2002) argue that this may be related to the 'use of clinical judgement', where doctors, when there is no protocol in place, have 'professional freedom' to decide what is best for the patient. Furthermore it may be related to the earlier discussed upcoming practice of evidence based medicine, in which 'violation' of a practice is often intentional and therefore also considered more culpable (Lawton and Parker, 2002; Lawton, 1998).
Protocols may also be important for designers of CIRS who are faced with the challenge of creating an input mask that allows clear classification of events. Johnson (2003) criticised that many CIRS in health care suffer both in terms of their engineering and usability. One system for example forced users to enter the date of an incident, using drop down menus entitled date, month, and year. Users were also forced to specify a single time at which the incident occurred. This created difficulties as many didn't know what time to enter in case an event had occurred repeatedly. For example if a repeated misadministration of a drug is detected what date should be reported; the date when the incident first occurred, or the date on which it was identified (Johnson, 2003). Other user related factors may include that electronic CIRS typically have large logos announcing that the user is making a submission to CIRS which can be very off putting for staff when using shared facilities on a busy ward (Johnson, 2003).

Firth-Cozens (2002) and Lawton and Parker (2002) further related the importance of existing protocols to the fact that nurses, who are governed by protocols much stronger than doctors, were much more likely to using the system. Several studies suggest that nurses are more likely to report than doctors, and that junior doctors are more likely to report than senior doctors (Vincent et al., 1999; Evans et al., 2006). A national survey of adverse event reporting practices in United States hospitals by Farley et al. (2008) reported that in 86 percent of the 1.652 surveyed hospitals physicians did not report at all or only reported very little. It should be considered though that the study was based on asking risk managers in telephone and email interviews, not acquiring information directly from incident report data. In addition the authors of the study (Farley et al, 2008) note that participation of physicians in CIRS might be higher because they may have asked nursing staff to report the incident for them. This confirms earlier findings, for example by Lawton and Parker (2002), which found that health care professionals, especially doctors, are reluctant to report adverse events, especially to superiors.
Another study by Evans et al. (2006) of six Australian hospitals and in diverse medical settings, surveying 186 doctors and 587 nurses, identified 19 self-perceived barriers to reporting. The top four answers were “I never get any feedback on what action is taken”, that “the incident form takes too long to fill out and I just don’t have the time”, “the incident was too trivial”, “when the ward is busy I forget to make a report”. Those top four answers received about 50 percent agreement from both doctors and nurses. Other identified barriers included not knowing whose responsibility it is to report, feeling that reporting was meaningless, fear of litigation, confidentiality and anonymity breaches. While there was a general agreement amongst respondents that events should be reported more clarification was needed on what should be reported, the reporting process should be simplified, and timely feedback should be given (Evans et al., 2006).

An earlier study by Vincent et al. (1999), which largely served as a basis for Evans’s study (2006), found similar reasons for not reporting, high workload, a belief that reporting was not necessary, and fears that junior staff might be blamed. The study in 1999 already recommended clarifying what should be reported, simplifying reporting methods, better informing staff about the nature and purposes of reporting, providing timely feedback, and having designated staff for reporting as busyness presented one of the main reasons for not reporting (Vincent et al., 1999). Still, in 2008 Shojania reports about the “frustrating case of incident reporting systems” where staff were initially enthusiastic about reporting and over a period of two months or so reported a number of important events - ‘important medications not administered’, ‘inattention to orders for stat blood work’, and the like. However, as one intern remarked: “Last month we submitted a bunch of incident reports, but nobody seemed to care, so we stopped bothering” (Shojania, 2008:400). As a consequence staff became inattentive and lost interest in CIRS. They were less likely to take the time to report and administrators of the system consequentially
regarded CIRS as not producing any useful data (Shojania, 2008). Not only that (the concept of) CIRS doesn’t seem to learn from its own failures the above example may also lead to misinterpretation of statistical data. The system statistics for the unit first showed an upward tick in the frequency of various events in the beginning (when staff for enthusiastic) and then a return to baseline (when staff stopped bothering reporting because of a lack of feedback). However this did not, as some might presume, reflect any change in risk to patients (Shojania, 2008).

Another important barrier related to the design of a CIRS is terminology, a topic that, as earlier sections in Chapters 2 and 3 have demonstrated, presents a challenge throughout patient safety. The WHO (2005b) has commissioned the development of an international taxonomy for patient safety in order to promote greater standardisation of terminology and classification. Similarly, the United States Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has been working on a patient safety event taxonomy to standardise terminology and classify schemata for near misses and adverse events. The JCAHO taxonomy suggests clustering of terms into the five groups: impact, type, domain, cause, and prevention and mitigation. These five groups have 21 subclassifications, which in turn are then subdivided into more than 200 coded categories and an indefinite number of uncoded text fields containing narrative information (Chang et al., 2005). While CIRS in English have at least the possibility to comply with an international taxonomy this is different in German speaking countries. Neither the JCAHO nor the WHO have German as an output language. It is not clear at the moment what effect this will have on patient safety developments in German speaking countries, such as Austria, and how operators of incident reporting systems that are run in German will address this problem of a lack of a standard terminology. The JCAHO classification implies that classifying of events is a highly structured process and therefore will need a strategic overhead. Currently it is not foreseeable which
body in any of the German speaking countries might take on this substantial task.

Last but not least it should be mentioned that running CIRS, also in the increasingly common online way, is not cheap, although this nevertheless seems to be the perception in many health care organisations. More than a decade ago Billings (1998) already stressed that "these systems cannot be run with a couple of clerks and a keypunch operator". At current it is unclear how expensive it actually is to run a CIRS in health care. A review by the CPSI (2007) shows that very little information has been published about the costs associated with the development, implementation and maintenance of CIRS in health care.

Estimations in the UK believe that incident reporting and subsequent system wide changes will result in savings of two billion GBP per year in the NHS, and an additional 400 million GBP savings per year in regards to settled negligence claims (CPSI, 2007). One of the few figures that have been mentioned in regard to actual costs of CIRS in health care is also from the UK. The NHS NPSA operates with a budget of 37 million GBP (NPSA, 2005), of which an estimated five million GBP were allocated for the development and operation of the NRLS for the first three years (Williams and Osborn, 2006). However, if compared to aviation - the aviation safety reporting system spends about three million USD per year to analyse approximately 30,000 reports, equating to about 100 USD per case - the NHS would have to spend 50 million GBP in order to achieve a similar level of analysis for the 850,000 adverse events that the DOH (2000) believes occur each year within the NHS (Johnson, 2003). A lack of adequate funding is problematical because it may well allow the initial collection of incidents but results in the collecting body then being overwhelmed in analysis of events. Aviation reporting systems use a number of specialists for system engineering, software development, storage and information retrieval from large data sets in order to find patterns of common events. Because health care
reporting systems have done relatively little in this respect it may be argued that they are relatively unprepared in handling the amount of data that is expected to come through (Johnson, 2003).

4.4. Conclusion

Incident reporting systems take a valuable role in improving safety in various industries. Good incident reporting systems enable organisations to build safe systems based on near misses and prevented events, without the “need” for a catastrophe to learn from. Within the new patient safety movement incident reporting systems find increasing attention and are expected to make a key contribution to safer health care.

This chapter set out by providing contextual information on CIRS, describing the concept of safe systems design and comparing it to the current state of many health care organisations. Especially the concept of evidence based medicine is on the incline and, while not contrary to patient safety, embodies a kind of intervention that is more embedded in the ‘clinical dimension’. This kind of thinking, based on the scientific method, may find more compliance in frontline operators than some of the new patient safety movement initiatives, like CIRS, that are largely based on findings outside medicine. Hence the introduction of CIRS might not be as straightforward a task as some of the new patient safety literature implies it is. That it is however ‘worth it’ was described in the next section on the purpose of CIRS. The chapter then moved on to discuss characteristics of good CIRS - in essence reporting needs to be safe, simple, and worthwhile. Many of the above recommendations and characteristics on good incident reporting systems are based on experiences outside health care, a fact that does not always come across very clearly in the new patient safety literature. However, this means that, with the exception of Evans et al.’s work
(2007), many of these characteristics of good reporting are to be seen as implications rather than evidence of how systems in health care might work.

As a consequence, and despite the increasingly prominent role of CIRS in health care, there is very little contemporary evidence of how incident reporting systems actually work in health care. First hand accounts on the implementation of CIRS in hospitals are rare, for example what kind of problems hospitals face when trying to apply those good characteristics or how problems have been approached and solved. In which (organisational) circumstances and environments does CIRS foster, which environments make it more difficult for CIRS to work. Can the implementation of CIRS fail, how is its success being measured, and what are the practical outcomes of using CIRS? Answers to these questions are as yet curiously elusive, at the same time expectations into CIRS are, it seems unrealistically, high.

In light of this chapter addressing these questions seems relevant to the success of CIRS, and ultimately to the safety of patients. Leape’s (2002) and Billings’ (1998 and 2003) arguments seem to epitomise that in stating that excellent reporting systems (i.e. existing CIRS in aviation) do not suffer from the barriers to reporting as described in this chapter, but that this is due to a substantial approach to creating a supportive environment to reporting. Although it need be considered that different countries are at different stages in their patient safety endeavours and level of experience with CIRS the literature points to a reoccurring common theme of barriers to reporting, and it appears that these may have not always been adequately considered and addressed in those health care organisations that set out to use CIRS. The lack of literature accounts on the implementation of CIRS may be a further indication that this is a problem that has not yet been substantially addressed.

Apart from this international context no literature could be found on the use of CIRS in Austrian health care institutions. This study will approach this gap in the
literature by studying the implementation of CIRS in a public hospital in Vienna. The review in this chapter has informed the research question, aim and objectives in regard to basic elements of CIRS, “a few golden rules”, on which the observation of CIRS should focus at the outset. Furthermore CIRS presents a complex issue with many unanswered questions regarding its application in a health care context. This suggests it will provide a substantial ground for an in-depth investigation of supportive or inhibitive measures. These however may not be always clearly declared as CIRS issues but may be hidden in daily clinical work or other non-clinical issues which are perceived more important by staff than CIRS. As a consequence the investigation will have to be sufficiently broad at the outset and cling onto relevant issues identified throughout the research process.

As a closing note it should be emphasised that even if all the above barriers were overcome and ideal reporting systems designed and used reporting will always be perceived more purposeful when known threats to safety, whether identified through CIRS or any other technique, are actually removed from the system. Charles Billings (1998), developer of the aviation reporting system and former Chief Scientist at NASA Ames, stresses that:

“...there are enough reports of mishaps with potassium chloride, lidocaine, vincristine and other drugs and devices to have made it very clear that a problem with these exists. The information that these events occur is already present. We may well ask what it is that keeps us from making progress on safety, given that we already know about the existence of these problems. What is added by more formal, elaborate (and expensive) incident reporting?” (Billings, 1998)

Even more so CIRS needs to be seen as one element of a wider systems approach to improving safety in health care. A CIRS alone will not improve safety to the extent that is envisaged by national governments. CIRS can make
a useful contribution to safety but more research is needed on the implementation and use of CIRS to further its development in the still relatively new context of health care. This will hopefully enable the “health care CIRS community” to lead by example, demonstrating how they have learned from their own mistakes.
CHAPTER 5: RESEARCH METHODOLOGY

The purpose of this chapter is to give insight into the philosophical and methodological considerations that have led to the conviction that this is the best way for approaching the research problem and providing reliable and insightful answers to the research question.

5.1. Introduction

This study is an in-depth qualitative exploration of an empirical setting from a critical ethnography stance. The aim in this chapter is to consider how the research question can be answered and to explain why this approach has been adopted. The chapter sets out in section 5.2 on research philosophy. It discusses critical realism as the fundamental philosophical underpinning that informs the methodological choices and design of the study, and explains how the research topic was found in an amalgamation of philosophical stance and the researcher's personal and professional background. Section 5.3 discusses the research methodology employed in this thesis, the overall composition by which data collection and analysis will be conducted. This includes a discussion of qualitative research and critical ethnography, as well as the scope of the study and issues pertaining to research ethics and confidentiality. The first (qualitative) part of this study employed semi-structured interviews and a self administered questionnaire. This is discussed in section 5.4. The second (ethnographic) part of the study used observation and this is discussed in detail throughout section 5.5. Finally section 5.6 discusses claims on data validity and analysis. This chapter is complemented by the ethical approval from Sheffield Hallam University (Appendix A) and the study site hospital (Appendix B).
5.2. Research Philosophy

Researchers are in a long standing debate over how to best conduct research. What all “researchers” have in common, whether they are aware of it or not (Johnson and Duberley, 2000), is that their research is inextricably embedded in commitments to particular values, worldviews or paradigms, and research philosophies (Guba and Lincoln, 1998). Within each philosophy of research are several methodologies, each drawing on a number of methods for data collection and interpretation (Dick, 1993). Accordingly the various research methods or techniques available to the researcher are not valid in themselves but they operate only in a given set of assumptions about truth (Hughes, 1990). Employing one research method means at the same time engaging in a certain conception of the world that allows those instruments to be used for their intended purposes (ibid, 1990). In this section the author’s intention is to give a rationale for his personal research philosophy, not effectively debating which one philosophy is best. The author therein follows Guba and Lincoln’s (1998) contention that no construction of research is incontrovertibly right and that the researcher must rely on its persuasiveness and utility.

The following section introduces critical realism as the philosophy that has most informed this research. Subsequent sections will relate this to finding the research topic as well as the personal and professional background of the researcher, which, as will be discussed later, are an important element in regard to validation of ethnographic research.
5.2.1. Ontological and Epistemological Commitment: Critical Realism

A research process begins with the researcher’s philosophical considerations and assumptions in deciding to undertake qualitative research (Creswell, 2007). Each inquirer brings with him his own worldview, paradigm, or set of beliefs, and these inform the conduct and writing of the study (Creswell, 2007). Johnson and Duberley (2000:9) emphasise this:

"... how we come to ask particular questions, how we assess the relevance and value of different research methodologies so that we can investigate those questions, how we evaluate the outputs of research, all express and vary according to our underlying epistemological commitments" (Johnson and Duberley, 2000:1).

The qualitative inquirer’s philosophical assumptions consist of a stance toward the nature of reality (ontology), how the researcher knows what he knows, i.e. the relationship between the researcher and that being researched (epistemology), the role of values (axiology), the language of research (rhetoric) (Creswell, 2003), and the methods used in course of the research (Creswell, 2007 and 2003; Guba and Lincoln, 1988). These considerations largely reflect Burrell and Morgan’s (1979) metatheoretical assumptions about the nature of social science (see figure 5.1). Based on considerations regarding ontology, epistemology, human nature, and methodology these assumptions enable a “systematic analysis of the overarching structures of thought within a substantive domain so as to specify the conditions under which particular theoretical perspectives are deemed appropriate” (Johnson and Duberley, 2000:77).
Figure 5.1: Burell and Morgan’s metatheoretical assumptions about the nature of social science

<table>
<thead>
<tr>
<th>ONTOLOGY</th>
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<tbody>
<tr>
<td><strong>Realism</strong></td>
</tr>
<tr>
<td>- in essence, social and organizational reality exist independently of human consciousness and cognitions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EPISTEMOLOGY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positivism</strong></td>
</tr>
<tr>
<td>- it is possible to observe the empirical world in a neutral manner though the accumulation of objective sense-data</td>
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</tbody>
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<table>
<thead>
<tr>
<th>HUMAN NATURE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Determinism</strong></td>
</tr>
<tr>
<td>- sees human behaviour as determined by the situation - as necessary responses to external stimuli</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>METHODOLOGY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nomothetic</strong></td>
</tr>
<tr>
<td>- located in the unity of the sciences and applies protocols and procedures derived from the natural sciences</td>
</tr>
</tbody>
</table>

Source: Johnson and Duberley (2000:78)

Critical realism emphasises the importance of a mind-independent reality. At the same time critical realism acknowledges that (knowledge of) reality is never
direct but mediated through individual and cultural perception (Page, 2003). Thus critical realists claim there is only one reality but there may be multiple interpretations of it (Fleetwood, 2005). According to Habermas (Johnson and Duberley, 2000) the goal of critical sciences in general is to facilitate the process of self-reflection, to empower the individual by developing his emancipatory interest and by giving him more control. The unconscious is made conscious and enables self-conscious decision-making. Page (2003:73) puts it like this:

“Critical realism can be said to emphasize the recovery of some form of ontology, an interest in interdisciplinarity (or perhaps more accurately transdisciplinarity—moving from one discipline to another), an interest in wholism, that is, having a total understanding of reality and our perception of reality, an interest in evolution and the evolutionary origins of human knowledge, an interest in unity of method for the social and natural sciences, an acknowledgment of the provisional or incomplete status of our current state of knowledge, and an acknowledgment of the cultural context of human knowledge.”

Critical realism occupies the intellectual space between positivism, with an ontology of observable events, and postmodernism (and poststructuralism), which is often characterised by a strong social constructionist ontology (Fleetwood, 2005). Critical realists believe that social phenomena can be understood, although often only with great difficulty. However, this does not mean that these phenomena can always be meaningfully “measured”. Hence, in order to understand social phenomena critical realists predominantly employ qualitative methods and distant themselves from prediction, quantification and measurement common to positivist approaches (ibid, 2005).

Critical realism seeks to free itself from the shortcomings of positivism and relativism. Although truth is important critical realists are first and foremost

• As the term implies, critical realists emphasize a metaphysical ontology which states that social and natural reality consist of intransitive entities which exist independently of our human knowledge.

• Those entities may not be observable and different people may apprehend different (i.e. transitive) realities according to the varying paradigmatic, metaphorical or discursive conventions deployed through their human agency.

• The perceived epistemic role of human agency means that critical realism rejects the possibility of a theory-neutral observational language and a correspondence theory of truth.

• Critical realists do not see science as being merely a prestigious artefact of conventionally derived self-directed and self-deferential paradigms, or discourses, or language games and so on - instead and despite the pivotal role of its ‘collective unconsciousness’ science is construed as being something other than science itself.

• The model of science propagated by positivism has little bearing upon actual scientific practice save for the manner in which scientists will often explain themselves and their activities to each other.

• Critical realism entails an epistemological defence of causal explanation - causation is not solely expressed through a constant conjunction of events as in positivism. Rather critical realists identify causation by also exploring the mechanisms of cause and effect which underlie regular events, mechanisms which Hume claimed were observable but which critical
realists claim can be shown to be real through their deployment of what Bhaskar calls ‘retroductive’ argument.

The aforementioned key commitments of critical realism are illustrated in figure 5.2.

Figure 5.2: Bhaskar’s synthesis of critical realism

<table>
<thead>
<tr>
<th>Thesis</th>
<th>Synthesis</th>
<th>Antithesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epistemological realism</td>
<td>Metaphysical realism</td>
<td>Epistemological relativism</td>
</tr>
<tr>
<td>Empirical realism</td>
<td>Critical realism</td>
<td>Superidealism</td>
</tr>
</tbody>
</table>

Source: Johnson and Duberley (2000:153)

Based on the above considerations of critical realism and based on Creswell’s (2003) and Burrell and Morgan’s (1979) assumptions about the nature of science (see figure 5.1) this research will proceed from an ontologically objectivist (Realism) and an epistemologically subjectivist (Anti-Positivism) perspective. Using Bhaskar’s (1989, in Johnson and Duberley 2000) synthesis, and as figure 5.2 illustrates, this synthesis of a positivist objectivist ontology and a postmodernist subjectivist epistemology results in critical realism. This critical philosophical commitment as developed by Bhaskar (1986) under the term “critical realism” informs this critical ethnography and the methodological choices to be made in section 5.3.
5.2.2. Focusing on a research topic

Traditional ways of deciding on a focus in research are usually rooted in the academic discipline and emerge from a literature review, coupled with methodological and theoretical concerns. This requires the researcher to have a thorough understanding and be up to date with literature, to possess detailed background knowledge of the relevant discipline, to be technically proficient, and to have at hand adequate time and resources (Robson, 2002). Focusing on a research topic during the opening stages of a thesis may be influenced by a number of other issues. Neuman (1994) suggests issues such as personal values and choosing topics that are of current interest and more likely to be funded. Sometimes ideas come out of discussions with colleagues, others come from direct experiences and observations, which may include prior research or practical experience of the researcher (for example Robson, 2002; Lofland and Lofland, 1995).

Less traditional ways may lead to what Robson (2002) calls ‘real world research’. Such research arises from a desire of wanting to solve a problem of practice, or a concern for change and improvement in a certain real world context. In those instances researchers may already know a lot about a topic prior to commencing the research. In this respect Kirby and McKenna (1989) point out the central role of researchers in the research process, because inevitably they bring with them their own thoughts, aspirations, feelings, ethnicity, race, class, family background and occupation.

Some research traditions are more open to acknowledging those influences than others. Some traditions have connoted personal attributes with research bias, as something that is difficult and best avoided (Maxwell, 2005). However, the above notion of interest and personal attributes is not to be confused with having a closed and pre-judged view of the nature of a phenomenon to be researched and the kind of outcomes to be found (Robson, 2002). There is
growing acceptance, in particular amongst social sciences researchers, of the potential value and benefits that researchers’ personal attributes may have on research projects when their assumptions and values are carefully examined (Maxwell, 2005; Robson, 2002; Kirby and McKenna, 1989).

It has been argued (for example Walker, 1985; Robson, 2002) that in less traditional designs the literature and discipline do not serve so much as a starting point for research, but that they provide a necessary background resource that informs the research. This distinction seems important as it implies to impact the power relationship between researcher and researched, because the agenda is not set in isolation, but in “partnership” with a variety of stakeholders.

Nevertheless, when focusing on a research topic the research is under a set of influences, and he has to develop an understanding where these influences come from and what they mean. As Strauss (1987) notes, insights, hunches, or generative questions about a phenomenon to be studied come from prior experience with a phenomenon, whether personal, more “professionally” from actual exploratory research, or from theoretical sensitivity because of the researcher’s knowledge of technical literature.

Therefore the following paragraphs provide axiological information (Guba and Lincoln, 1988) on how the inquirer might have been influenced in focusing on a topic. These are important considerations in regards to reflexivity throughout this research (see section 5.6.2 reflexivity in note taking and analysis) as “scientists, in order to understand themselves as scientists, first have to become anthropologists, sociologists, psychologists, and historians of themselves” (Zolo, 1990:162, cited in Johnson and Duberley, 2000:177)
5.2.3. Researcher's personal background

The researcher comes from a medical family and literally grew up side by side with patients who visited his parents’ General Practitioner and Dentist Clinic. Impressions were manifold and varied, playing piano for patients in the waiting room during early childhood, selling handmade “ice-cream” to dauntless patients, and later occasionally helping out as a dental assistant or at the front desk. Health and health management topics were a popular topic at the family table and with many befriended medics of the family. Therefore, and of course apart from having the painful experience of being a patient himself, the author is in general familiar with (at least some) clinical settings and the behaviour and language of both medical staff and patients. The author was also coined by an experience where a close family member got into a life-threatening situation, arguably caused by a preventable error in health care. It is therefore inevitable that the author brings with him an array of impressions on how medicine and the organisation of health care does work and could work.

In a very general sense the author’s view may be summarised as that despite the goodwill and effort of clinical staff, errors, especially related to the organisation of work, do happen and that many of these could be prevented. It may well be that small changes in the organisation of health care make a positive impact on the overall service experience of both patients and staff. Conversely supposedly trivial events may result in considerable threats opposing the individual clinicians’ good intentions. While the above claims need to be seen as a reflection of the author’s own, personal, subjective and unsubstantiated impressions they were backed up in informal talks with medics who often shared the author’s view, accompanied it with a long sigh and regarding it as a matter of course.

From those personal impressions stems an interest to study health care organisations from a management perspective.
5.2.4. Researcher’s professional background

The author has previously undertaken academic research in hospitals. He also has experience as a management apprentice in hospitals as well as working (mostly, but not exclusively in management) in various other settings. It would be fair to say that the author was strongly influenced by the work of the Centre for Facilities Management at Salford University, UK during his time as a postgraduate student there. In that regard facilities management is not to be understood as it may be in its ‘classical’ sense of managing facilities but as a distinct discourse and management discipline that is predominantly concerned with the creation of ‘the right social and physical environment’ in organisations (for example Alexander, 1996 and 2003; Alexander et al., 2004; Weicht and Alexander, 2004). Characteristic to this approach is the notion of the ‘internal customer’ and a differentiation between two kinds of activities (for example Becker, 1990; Barrett, 1995); those activities that can be attributed more to the core identity of an organisation, for example an insurance company selling insurances, and those activities that primarily support the core activities, for example managing the car fleet and developing the company dress code to enable the insurance seller to reach the customer and to appear in appropriate clothing. This concept can be transposed to health care organisations (see for example earlier work by the author in 2004). For instance a facilities management organisation can set up and provide a hospital devoid of patients and clinical staff, which can then be populated with its “core personnel”, its natural inhabitants of clinical staff and patients, with continuous support of the facilities management staff.

However, it cannot be denied that while facilities management consists of a lot of (great) ideas (Duffy, 2000; Price, 2002) it nevertheless does not have a strong philosophical underpinning (Grimshaw, 2004) and the above view of a facilities management organisation, although proofed to work in practice, has
not become very popular. As a consequence the initial concern for ‘user needs’ and benefits of a ‘better fit’ that is supposed to link (facilities) management via productivity to strategic planning is in danger of being lost (Fenker, 2004; Grimshaw, 2004), and the discourse remains to be largely driven by the pragmatist perspective of the (property and building) industry. Naturally different perceptions and conceptualisations of what facilities management is are also inherent at universities.

5.3. Research Methodology

5.3.1. Qualitative Research

Qualitative research has had a long tradition in the social sciences (Pope and Mays, 2000), especially in anthropology, history and political science. Over the last two decades more and more researchers from the basic disciplines and applied fields, including organizational studies and health care, have shifted to a more qualitative paradigm (Miles and Huberman, 1994). Smith (1992, cited in Miles and Huberman 1994:1) observes that the terms ethnography, field methods, qualitative inquiry, participant observation, case study, naturalistic methods, and responsive evaluation have become almost synonymous. The qualitative approach is well suited for understanding phenomena within their context, to uncover links among concepts and behaviours, and to generate and refine theory (Glaser and Strauss 1967; Miles and Huberman 1994; Crabtree and Miller 1999; Morse 1999; Bradley et al., 2007).

Also in health services research the qualitative approach is increasingly common (Shortell, 1999; Sofaer, 1999; Bradley et al., 2007). This has led to the study of issues ranging from the diffusion of innovation (IOM, 2000) and general quality improvement (Bradley et al., 2005; Crosson et al., 2005; Bradley et al.,
to physician-patient relationship (Flocke et al., 2002; Gallagher et al., 2003) and culture change in health care (Marshall et al. 2003). It also seems that qualitative research can reap new findings about CI&S, especially given the lack of documentation and the many contextual elements to be considered in its implementation and operation. The qualitative part of this research used semi-structured interviews and a questionnaire, and these investigations prepared grounds for a subsequent ethnographic study.

### 5.3.2. Ethnography

Ethnography can take place in a wide array of social settings. It involves extensive fieldwork, for example direct observation of the activities of the group being studied, communications and interactions with the people being studied, and opportunities for informal and formal interviews (Bogdan and Taylor, 1975; Jorgensen, 1989, Lofland, 1971 in Moustakas 1994, p1). Van Maanen et al. (1982:103-4, cited in Moustakas 1994:2) observed that:

“The result of ethnographic inquiry is cultural description. It is, however, a description of the sort that can emerge only from a lengthy period of intimate study and residence in a given social setting. It calls for the language spoken in that setting, first-hand participation in some of the activities that take place there, and, most critically, a deep reliance on intensive work with a few informants drawn from the setting.”

According to Moustakas (1994) ethnography involves an initial engagement of exploring, planning and getting ready to conduct the study. This includes obtaining permission for observation and participation, exploring the ‘geography’ of the setting, and developing a plan for the scheduling of visits. This has mostly been achieved in the (first) qualitative part of the study. The ethnographic researcher usually comes to know a culture or group through immersion and engagement in the field. This involves extensive fieldwork using methods such
as observation of the activities of the group being studied, communications and interactions with the people, and informal and formal interviews (Bogdan and Taylor, 1975; Jorgensen, 1989, Lofland, 1971, Moustakas 1994). Ethnographers spend substantial time in the field (Burgess, 1984).

Similarly Geertz (1973) argues that at the heart of ethnography is the immersion into everyday life of the subject under study in order to understand how people give social meaning to events, and how this meaning reflects wider social discourses and cultures (McDonald et al., 2005). Studying behaviour in everyday, rather than experimental, settings (McDonald et al., 2005) will lead to good and rich data that can lead to a “thick description” of the phenomenon under investigation (Geertz, 1973; Maanen and Kolb, 1982). McCall and Simmons describe ethnography as a technique that includes “some amount of genuinely social interaction in the field with the subjects of the study, some direct observation of relevant events, some formal and a great deal of informal interviewing, some systematic counting, some collection of documents and artefacts; an open-endedness in the direction the study takes” (McCall and Simmons, 1969:1 cited in Fielding, 2008:157).

As with other research methodologies and methods there is some discussion and disagreement about what counts and what doesn’t count as ethnography (Hammersley, 1990). However, Hammersely (1990) suggests that ethnographic research usually has one of the following features:

- people’s behaviour is studied in everyday context (not in experimental conditions)

- data are gathered from multiple sources, with the bulk of information usually coming from observation and relatively informal conversations
• data are gathered in an unstructured manner (not unsystematic though),
  not following a detailed plan set up at the beginning; initially data are
  collected in as raw a form and on as wide a front as possible, therefore

• research focuses on a single setting and on a small scale, and

• analysis of data involves interpretation, verbal descriptions and
  explanations

There are different forms of ethnography and this study uses critical
ethnography as described by Thomas (1993). Critical ethnography is a way of
applying a subversive worldview to the conventional logic of cultural inquiry.
Critical ethnography is a style of analysis and discourse embedded within
conventional ethnography, however it does offer a more straightforward style of
thinking about relationships among knowledge, society, and political action
(Thomas, 1993). While ethnography often pursues the question “what is this?”
critical ethnography emerges when members of a culture become reflective and
ask “what could this be?”. This reflective process consist of choosing between
conceptual alternatives and making value laden judgements of meaning and
method to challenge research, policy, and other forms of human activity
(Thomas and O’Maolchatha, 1989). In critical ethnography special attention is
given to sustaining a critical perspective and in resisting domestication. The
central premise is that one can be both scientific and critical. Ethnographic
description offers a powerful means of critiquing culture and the role of research
within it (Thomas, 1993). In other words critical ethnography is conventional
ethnography with a purpose. The researcher gives voice to and empowers the
subjects under study; the purpose is to go beyond mere description of
phenomena, invoking social consciousness and societal change, and to using
knowledge for social change. In this respect critical ethnography is
simultaneously hermeneutic and emancipatory (Thomson, 1993).
Critical ethnography is emancipatory in its separation from constraining modes of thinking or acting that limit perception of and action toward realising alternative possibilities. Hence it is different from conventional ethnographers who recognise an impossibility or even undesirability of research that is free of normative and other biases and therefore believes in the “repression of biases”. Critical ethnographers use their work to aid emancipatory goals or to negate repressive influences that lead to social domination (Thomson, 1993). The survival of any society requires repression of some acts. However, not all constraints are equally necessary or beneficial for social harmony and growth. As Schroyer (1975) writes, unnecessary social dominion exists when constraints are built into cultural and social life in ways that promote inequality and give individuals unfair (dis)advantage of social elements of life. It is the hermeneutic element in critical ethnography, the science of understanding - or as some say the prevention of misunderstanding - to not just simply stating a cultural context, but to integrate descriptions of cultural parts into an analysis of the whole that raises the critical implications of the descriptions (Thomas, 1993). Critical ethnographers thus seek “something more”, and attempt to connect the “meanings of the meanings” to broader structures of social power and control (Pfohl and Gordon, 1986).

Perhaps ethnography is situated best to provide the tools for digging below mundane surface appearances of social existence or phenomena and to display a multiplicity of alternate meanings (Thomson, 1993). It is argued therefore that ethnography has the potential to understand the social meaning given to objects, actions, and events, and at the same time to understand how these meanings reflect, reiterate and renegotiate wider social discourses and cultures. Meaning is not static but contextualised, negotiated and sustained with relative sociocultural and historical settings (McDonald et al., 2005). “How people perceive, interpret and make sense of something is shaped by the norms, practices and knowedge(s) within which they emerge” (McDonald et al., 2005:14). As the
ethnographic encounter requires the researcher to become part of the natural setting, learning the ‘language’ in use with its own jargon and dialect and special meanings given to familiar words (Fielding, 2008) he will develop a ‘modicum of understanding’ (Fielding, 2008) which then allows the compilation of fieldnotes. Inspecting and reflecting upon these fieldnotes allows the researcher to begin identifying and discerning patterns of rules which govern behaviour in the setting (Fielding, 2008).

Critical realism has been described as a relatively “young” philosophy without a certain methodology or research design ascribed to it (for example in Hartmann, 2006). Ethnography has found supporters in the critical realist realm (Robson, 2002; Bryman, 2004) and seems well suited in addressing the research question in a setting where different conceptualisations of error, the professional perspective and the new patient safety movement perspective, engage on one and the same phenomenon. The operationalisation of the above elements in the ethnographic part of the study is described in detail throughout section 5.5.

5.3.3. Scope of study

The scope of the study was determined in the preliminary phase of this research, which is described mostly in section 6.2 and 6.3 of this thesis, as the in-depth study of one hospital department. In this preliminary phase the researcher accompanied Expert 1 on his visits to four Women’s Hospitals in Vienna (plus one outside Vienna) and undertook a number of unstructured interviews with department leaders and informal chats with other hospital staff. This phase of the research helped in familiarising with the wider project and possible research environments and deciding on the scope of the study. At first, especially give the promising access to all five visited hospitals, a comparative approach was considered, possibly investigating how different reporting frequencies may correspond to different reporting (department) environments. However as all of these five hospitals had the same low reporting rate it was
considered that rather than following a broader comparative approach, an in-depth investigation of a single hospital would reap better results and make a more valuable overall contribution to knowledge. Another important consideration towards a single site approach was that in-depth ethnographic accounts are extremely rare on this subject.

Analysis of the preliminary observation and interviews did not reveal any major differences between those four departments; they appeared to be fairly similar and were all potentially ‘good’ study sites. The informally observed departments were all fairly similar in size, structure, and in the services they offered, i.e. all five were typical gynaecology and obstetric departments and one of a number of speciality departments at a public hospital. The departments were led by a medic and his deputy, a head nurse and his deputy, with extended leadership including several senior consultants and charge nurses for particular areas. The study site was chosen because access could be negotiated and members of staff claimed a particular interest in being studied. In addition Expert 1, who had initiated contact, held a good relationship with the leadership team of this department. This constituted a research setting that would ensure continuous access to the site which, considering the single site approach, the inductive nature of the study, and the sensitivity of the subject under investigation, was an important prerequisite to the study.

5.3.4. Research ethics and confidentiality

Given the sensitive nature of the subject, medical error, ethical approval was sought from the University where this thesis is being submitted. Once the study site had been selected ethical issues were addressed in writing with the participating hospital department and the hospital’s collegial leadership in order to protect the anonymity and confidentiality of all participants. The researcher met with the hospital's deputy medical director in Vienna to inform him about the intentions of the study and get approval for the study. This also included some
medical tests (lounge X-Ray) the researcher had to undertake. The study was conducted observing all rules of medical confidentiality and stands in fulfillment of the required ethical regulations of both the study site hospital and Sheffield Hallam University. A copy of the (anonymised) ethical approval from Sheffield Hallam University can be found in Appendix A and a copy of the (anonymised) ethical approval from the study site hospital in Vienna, Austria can be found in Appendix B.

A key element in all stages of data collection was to provide respondents and participants the opportunity to remain confidential. This was to unburden their participation in the study. The confidentiality of assessment data was stressed to all respondents and participants before each data collection phase. For the presentation of the thesis all respondents have been anonymised, i.e. they appear in the text as respondents 1,2,...n and are all referred to in the masculine. Most of the professionals observed were medical doctors or nurses. For ease of use in distinguishing between doctors and nurses respondents were marked in the tables as for example “respondent d1” in case of a doctor, or “respondent n7” in case of a nurse. The few other professions, for example an operating department practitioner, were left without prefix, i.e. appear for example as “respondent 18”. Obstetric nurses, although they officially do not belong to the nursing profession anymore since the year 2000, and although in German they carry a distinguishable name that doesn’t contain the word nursing, have still been marked as for example “respondent n14”, because they are still very similar to other observed nurses in regards to the organisation of their work and their interaction (and work schedules) with other staff in the department.

In addition information about the study site was kept to a necessary minimum that would not allow identification of the study site. At the same time it was still carefully considered that omission of data would not alter possible interpretations of the presented research findings. Research of this kind
requires adequate attention of ethical issues and, rather than presenting it in one separate section, was addressed throughout the study, for example in regard to observation, note taking, and anonymising respondent and patient data. Furthermore a considerable difference was found between ethical requirements for studies in the Austrian and the UK health systems. The implications this may have on research more generally is addressed in the conclusions in chapter 8.

5.4. Research methods 1

This thesis addresses the implementation and perception of CIRS from a critical ethnographer perspective. Critical ethnography constitutes an approach to CIRS that advocates engagement in the field, observation of the unfolding of naturally occurring events and the researcher’s reflection on phenomena. This section presents the research methods consistent with the author’s philosophical stance and those methods that are likely to lead to the realisation of the research objective. The qualitative part of the study (research methods 1) used semi-structured interviews and a self-administered questionnaire, and the subsequent ethnography (research methods 2) used fieldwork observation.

5.4.1. Semi-structured interviews

The interview is a common occurrence in social life and there are many different types of interview available to the researcher. Because of the ability of interview techniques to obtain rich and complete data (Easterby-Smith et al., 2002) it was decided that evidence should be collected using the interview technique, in particular the method of semi-structured interview.

The ambition at this stage (outset) of the research was to understand from the department leaders’ perspective why CIRS is was being implemented, as well
as to get a better understanding of the context in which CIRS was about to be used by staff. It was decided that the semi-structured technique would better fit the nature of events in hospitals than a highly structured approach to interviewing. Furthermore the semi-structured interview technique allows the interviewee to include narratives and any other information they feel might be important. Considering the inductive nature of the study it was necessary to give respondents the opportunity to raise issues they felt important. Therefore the interview guide and approach was sufficiently flexible and open to enable participants to talk freely in their own language and terms, giving the interviewees the opportunity to put forward and develop narrative accounts of their work, descriptions of what they saw as important in regards to patient safety and incident reporting, and to elaborate explanatory models of how these events are to be brought about.

An interview guiding sheet was prepared based on the literature, informal conversations with the patient safety expert who initiated the project, and informal talks with other medics who were not participants of the study but who had a general interest in patient safety and incident reporting. Key issues were identified around the implementation of CIRS and the wider managerial context. This was an iterative process until the basic set of questions was determined. In a next step the interview guiding sheet was piloted with befriended medics as well as the deputy head of the department, in a meeting where other arrangements were made for the study, to check for clarity and unambiguous wording of the questions. Using the results of the pilot the interview guiding sheet was refined so that it focused more closely on the key issues. The final interview guiding sheet consisted of 30 questions. A copy of this is attached in the appendix C.

In order to get the department leaders’, a doctor with his deputy representing the medical lead and a nurse with her deputy representing the nursing lead,
view on the CIRS implementation in their department two interviews were conducted. One with the head of the department (respondent d1) and one with the head nurse (respondent n7). Because responses between the pilot interview held with the deputy head of department (respondent 62) and the actual interview with the head of department (respondent d1) largely matched, and there was frequent contact with respondent 62 as the main contact person in the department, it was decided that no additional formal interview needed to be made with respondent 62.

Tape recording of semi-structured interviews was tested during preliminary interviews. However tape recording was not found to be useful as the interviews were repeatedly interrupted by phone calls, other members of staff, patients, or because the interviewee’s attendance was urgently required elsewhere. Starting and stopping a tape seemed to further inhibit the flow of the interview. Sometimes interviews had to progress while walking along the corridor or while changing clothes for the operation theatre. Inevitably other staff and also patients would have been recorded without having their informed consent. Considering these circumstances recording would have been unpractical and may even be considered unethical. Therefore audio recordings were only used in more foreseeable environments and situations, for example in meetings. Notes were taken using prepared space on the interview guiding sheet and a sketchbook. Due to the nature of work in hospitals sufficient time was planned for the interviews. During the pilot study for example the interviewee had to rush to the operating theatre and the entire interview had to be held over a period of four hours. However, in the actual interviews there were less substantial interruptions and interviews could be completed within about 30 minutes.

Interview data were then transcribed and analysed using ethnographic coding. Because of the small number of interviews it became apparent rather quickly that the medical lead and his deputy agreed mostly in their answers and that
they were actively leading the project. On the other hand the nursing lead was informed but didn’t play any proactive role in the project. With these interviews the leaders’ positions regarding CIRS were known and this allowed it to be compared with the views of front line staff. Therefore many of the interview questions were then incorporated in the self-administered questionnaire (see section 5.4.2). This is described in the next section.

5.4.2. Self-administered questionnaire

This study intended to verify information gathered from leadership with front line staff and to get a broader perspective on the CIRS project. Self-administered questionnaires and structured interviews are very similar methods of social science research and therefore self-administered questionnaires seemed a good method of acquiring comparable data from staff. The main difference between the two research tools is that in the questionnaire no interviewer is present, which can be of advantage considering the sensitivity of the subject. It was not clear if staff would have agreed to being interviewed and the anonymised self administered questionnaire gave staff the opportunity to comment on the project out of complete anonymity (even towards the independent researcher). This should provide the researcher with a ‘complete’ impression of how the project is received by frontline staff, without the interference of a gatekeeper or of the researcher himself in selecting respondents. In addition, considering the number of front line staff (70+), the choice of using a questionnaire was a necessary one considering the available resources. Basic design principles, such as described in Newell (2008), Thietart (2001), or Bryman (2004), were acknowledged and incorporated in the design of the questionnaire.

Key issues and potential questions were identified from the preliminary research phase which included a literature review, expert interview, unstructured and informal conversations with staff, as well as observation of CIRS introduction
sessions at other hospitals. After deciding which questions to include a draft questionnaire was developed. Health care staff helped with the wording of questions. The questionnaire was pre-tested on a small scale as suggested for example in Thietart (2001). Using the results of the test the questionnaire was refined so that it focused more closely on the key issues. The finalised questionnaire consisted of 40 questions, 31 of which were multiple choice and nine of which were open-ended questions. The questionnaire took about 20 minutes to complete.

The sample size was determined to include all potential CIRS users in the department. Following the CIRS introduction session at the department the researcher was introduced by Expert 1 and the department’s leadership team as an independent doctoral researcher. The researcher was given the opportunity to introduce the study and the purpose and technicalities of the questionnaire. Each respondent was notified that filling in the questionnaire was voluntary, the deadline for completion, and where to return it (a locked collection drop box in the secretaries’ office). Directly following the CIRS medical introduction session the questionnaire was distributed to staff in person. Where this was not possible, i.e. when staff members did not attend the introduction session, the questionnaire was delivered through their respective group leaders in one of the next scheduled meetings, such as the shift-handover meeting later that day or the next morning meeting. In total 75 questionnaires were given out, 38 of which were returned (51% return rate). The questionnaire is attached in appendix D.

The questionnaire data was important in deciding the next steps of the study. Results showed for example that front-line staff were generally interested in CIRS and welcomed the project. It was not, as could have been assumed considering the low reporting frequency in CIRS, that staff directly opposed CIRS. It also became apparent that many staff who filled in the questionnaires
stated that they either had not heard about or did not have sufficient information for using CIRS. Hence, the questionnaire results brought forward additional and deeper rooted questions. For example, who was right, the department lead, who stated that all staff knew about CIRS and information was provided, or front-line staff, who stated they had not been (sufficiently) informed? Did front-line staff fill provide honest answers? For example, did they really welcome CIRS and were there possibly any other, so far hidden reasons for them not to use it, or did they just provide false answers to “please” the department lead with an anonymous high agreement rate with CIRS and to quickly get rid of an additional and unnecessary (administrative) burden? Results from the questionnaire made apparent that it didn’t provide all the answers and questionnaire data requested more insight. The questions that came up appeared they could not be approached in a questionnaire format but needed a tool that allowed more time, closer engagement with people and environment, and that was sufficiently flexible to follow “leads” that may open up as the research progressed. Reflecting upon this the research evolved into an ethnographic study. Accordingly the decision was made to follow up he quests from interview and questionnaire data by using using fieldwork observation. This is described in the next section.

5.5. Research methods 2: Fieldwork Observation

Since the research aim is to gain in-depth understanding of how a CIRS is implemented in a public hospital in Austria and how it is perceived by staff in a given setting, to collect empirical evidence of supportive measures to the project (objective 4) and to investigate how meaningful it is for staff to use CIRS (objective 5) it was necessary to observe staff within their natural environment. Therefore, and after analysis of interviews and the self administered questionnaire, the researcher began fieldwork observation at the department for
gynaecology and obstetrics of the study site hospital. Like any observational study the aim was to gather firsthand information about social processes in a ‘naturally occurring’ context (Silverman, 2006). The focus was upon what staff actually did in the clinic and what significance CIRS had in their everyday work.

When conducting research the inquirer may be seen as having multiple identities, from a student of organisation and management, to a researcher, researcher-as-subject (Arnaud, 2002; Foucault, 1970), interviewer, observer, and interpreter, and since withdrawing from the field as an author, creator, and narrator of the research text. As such the author subscribes to the view that there are multiple selves within an inquirer (Clarke, 2008) and a need to “respect the fundamental system of thought of the individuals under study, that researchers should fully assume a role of “bringing to light”. (Arnaud, 2002:13).

One of the concerns (traditionally) raised in regards to ethnographic methods is the effect of the researcher on the research environment, something Becker and Geer called “reactivity” (McDonald et al., 2005). However, over recent years commentators have suggested that rather than trying to adopt an unobtrusive approach researchers should consider the extent of impact they may have had on a situation when analysing data (McDonald et al., 2005). Therefore this section considers various aspects of the ‘researcher-research-field’ relationship, during, before and following the observation. These consider: the introduction of the researcher at the department and to various groups of staff; the selection of respondents who would meet the study criteria; duration and time of observation; and a description of how observation took place, when and when not to observe, as well as continuity in observation. Furthermore this section includes a discussion about the role of the researcher as (an almost) complete observer, issues surrounding the credibility of the researcher, as well as a discussion on the possibilities and dangers of the observer taking on the role of a researcher consultant.
5.5.1. Introduction at department

The researcher was first introduced to the department leaders through Expert 1 who functioned as a gate-keeper. As described later in section 6.2 the researcher was then introduced to attendees during the CIRS introduction session where he explained the aims and objectives of the research. On subsequent occasions, for example in order to arrange observation dates with staff who had not attended the introduction session, the researcher was introduced to front line staff through leading personnel or other key people from within the department.

On most occasions the deputy head of department (respondent d2) acted as a gatekeeper and initiated contact with front line staff. In general the acceptance of the researcher by members of staff was good. However, and only naturally, some were more cooperative than others. When staff were cooperative and apparently happy to be observed the gatekeeper’s involvement was kept to a minimum. Sometimes the researcher was just equipped with a name and a location and went to the ward himself in order to arrange a time for the observation directly with the doctor or nurse. On other occasions the gatekeeper’s involvement was more necessary. When someone was apparently reluctant to be observed (or just extremely busy) the gatekeeper helped to ensure that a meeting between the researcher and the person to be observed was actually taking place and in a time consistent with the overall project and observation. However the final decision about whether someone was to be observed or not was left with the very person to be observed, not with the gatekeeper.

5.5.2. Selection of respondents

A meeting was organised with the head of department (respondent d1) and the deputy head of department (respondent d2, the researcher’s main contact
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person in the department) to set forth the basic concept of the observation. They gave their consent and a record of the agreement was made. A copy was sent to the directorate of the hospital. Once directorate consent was acquired respondents were selected.

The selection of the respondents was dependent on several factors, including:

- meeting the study requirement (see below)
- getting agreement from management
- briefing the potential observant about the study
- having an oral agreement with the potential observant to be shadowed for one day
- having written ethical clearance
- conducting observation on normal duty, potential respondents were asked to choose a day that would reflect a common day in their profession

In general the steps involved in the process could be summarised as follows. First the researcher would tell the deputy head of department which group or profession he wanted to observe next. The deputy then briefed the researcher about that group and made suggestions who to approach from within that group, and where and when they could be reached. Subsequently the researcher met with the person to be observed and briefed him about the study and what the observation would be like. When the person agreed to be shadowed for one day a date was arranged for observation.

In order to be eligible for observation respondents had to meet the study criteria. For the observation part of the study this was mostly related to objectives
3. to investigate why CIRS has been implemented from a stakeholder perspective;

4. to collect empirical evidence of supportive measures to the project; and

5. to investigate how meaningful it is for staff to use CIRS.

As CIRS is a “system for everyone” in the department it was important to get the opinion of everyone in the department. Therefore the researcher investigated who actually belonged to the department, differentiating between and excluding people from other departments who would just “visit” the department. Respondents should be selected so that they presented ‘as complete as possible’ view of the department. This meant including respondents from all ranks, leadership and front line staff, and from all kinds of shifts, i.e. day shifts, night shifts, weekend shifts and so on. This resulted in selection of 14 respondents. Table 5.3 provides an overview of the respondents. Not listed in this table are observation days that were focused on topics/meetings and were not targeted at certain professions (OD15, OD16, OD18, OD19, OD20) as well as meetings with people external to the department (OD17 with the hospital’s risk manager, and OD21 with Expert 1).

Table 5.1: Overview of respondents and their functions

<table>
<thead>
<tr>
<th>Observation Day (OD)</th>
<th>respondent (d = doctor, n = nurse)</th>
<th>area/function</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD 1</td>
<td>#d2</td>
<td>deputy head of department (medic)</td>
</tr>
<tr>
<td>OD 2</td>
<td>#n7</td>
<td>head nurse</td>
</tr>
<tr>
<td>OD 3</td>
<td>#n9</td>
<td>deputy head nurse and charge nurse gynaecology ward B</td>
</tr>
<tr>
<td>OD 4</td>
<td>#d2; #d8</td>
<td>deputy head of</td>
</tr>
</tbody>
</table>
Although observation was agreed with and targeted at people as shown in table 5.1 the observation itself was not limited to that one person. The observed person interacts with colleagues and patients, and these are naturally observed and recorded. Some areas, for example the nursery, are very small and “quiet” and although the targeted person was the charge nurse of the nursery the researcher communicated all day with the three or so other staff in the nursery. Obviously the observation was also not limited to a certain area and the researcher followed the respondent wherever he went, whether that meant visiting a patient on the ward, meeting with other nurses, physicians, head of department, people external to the department, or going to the cafeteria.

5.5.3. Duration and time of observation

The aim was to cover the complete work-day experience of the worker. The observer should experience the day in exactly (as much as possible) the way
the person to be observed would do. Hence, rather than following official
timetables the observation started and ended whenever the person came in the
clinic or left it. In general the researcher would meet the person to be observed
regarding to their profession specific schedule and location. Medical doctors
would be met in the morning meeting at 7:45am. Nursing staff would be met at
the hand-over of the shift at 6:45am. Operation theatre staff would be met at the
beginning of their shift at 6:00am. However, because of the reasons explained
above, when the observation would actually start was totally dependent on the
person observed. The researcher wanted to acknowledge that different
individuals have different ways for interpreting their time-schedule. And they
would have their individual ways of acquiring information. Accordingly the study
design was flexible to allow shadowing not only individuals, but indeed the
individuality of their doing.

This was the case for example when observing the deputy head of the
department (respondent d2). Officially his shift started at 7:45am. However, as
was found out during the briefing session, he would be in the clinic already at
6:45am to attend the hand-over meeting of the nursing staff. As he said: “This is
probably the most useful meeting for me to get information about my patients.
Not in the morning meeting with the medical doctors.” (respondent d2)
Accordingly the observation session with respondent d2 also started at 6:45am.

Table 5.2 below illustrates the types of shifts and times of observation. Not
listed in this table are observation days that were focused on topics/meetings
and were not targeted at certain professions (OD15, OD16, OD18, OD19,
OD20), as well as meetings with people external to the department (OD17 with
the hospitals risk manager, and OD21 with Expert 1).
Table 5.2: Overview of respondents, types of shifts, and times when they observed

<table>
<thead>
<tr>
<th>Observation Day (OD)</th>
<th>respondent (d = doctor, n = nurse) /type of shift</th>
<th>time</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD 1</td>
<td>#d2 / dayshift</td>
<td>08:00 - 13:25 (15:29)</td>
</tr>
<tr>
<td>OD 2</td>
<td>#n7 / dayshift</td>
<td>07:45 - 15:06</td>
</tr>
<tr>
<td>OD 3</td>
<td>#n9 / dayshift</td>
<td>06:45 - 15:09</td>
</tr>
<tr>
<td>OD 4</td>
<td>#d2; #d8 / nightshift</td>
<td>06:45 - next day 08:30</td>
</tr>
<tr>
<td>OD 5</td>
<td>#n11; #n12 / weekend</td>
<td>06:45 - 19:00</td>
</tr>
<tr>
<td>OD 6</td>
<td>#13 / dayshift</td>
<td>06:30 - 15:00</td>
</tr>
<tr>
<td>OD 7</td>
<td>various / dayshift</td>
<td>07:00 - 15:00</td>
</tr>
<tr>
<td>OD 8</td>
<td>#n14 / day and evening shift</td>
<td>07:00 - 22:00</td>
</tr>
<tr>
<td>OD 9</td>
<td>#n10 / dayshift</td>
<td>06:45 - 15:40</td>
</tr>
<tr>
<td>OD 10</td>
<td>#n15 / dayshift</td>
<td>06:45 - 15:00</td>
</tr>
<tr>
<td>OD 11</td>
<td>#n16 / dayshift long</td>
<td>06:45 - 19:15</td>
</tr>
<tr>
<td>OD 12</td>
<td>various</td>
<td>07:45 - 12:00</td>
</tr>
<tr>
<td>OD 13</td>
<td>#d17 / dayshift</td>
<td>07:45 - 12:45</td>
</tr>
<tr>
<td>OD 14</td>
<td>#n18 / dayshift</td>
<td>06:30 - 13:30</td>
</tr>
</tbody>
</table>

5.5.4. Observation and different observation environments

Observation of clinical staff at the department can be distinguished between two main groups:

- Observation involving clinical staff only; and
- Observation involving patients
The observer was present in the consulting room at a side angle to both doctors and patient. Patients' consent for the researcher's presence was obtained by the senior doctor for single consultations. Given the presumed sensitivity of the occasion, tape-recording was not attempted. Instead, detailed handwritten notes were kept, using a sketchbook. In other areas (for example in the outpatient department when a patient comes in for a baby screening), the researcher was already in the room with the clinician(s) and patients were called in for consultation. Table 5.3 provides an overview of those different settings.

Table 5.3: Environments in which observations took place

<table>
<thead>
<tr>
<th>Involving clinicians only</th>
<th>Involving patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Morning meeting</td>
<td>• Admissions</td>
</tr>
<tr>
<td>• Midday meeting</td>
<td>• Outpatient Department</td>
</tr>
<tr>
<td>• Handover shift</td>
<td>• Consultation Room</td>
</tr>
<tr>
<td>• Profession specific internal meeting</td>
<td>• Rounds</td>
</tr>
<tr>
<td>• Cross professional meeting - X-Ray review - Oncology conference</td>
<td>• Required /ordered visits to the patients room</td>
</tr>
<tr>
<td>• Information sessions with external consultant</td>
<td>• Operating Theatre</td>
</tr>
<tr>
<td>• Risk meetings</td>
<td>• Presentations (e.g. to future mothers and fathers, birth preparation,...)</td>
</tr>
<tr>
<td>• Informal gathering: Common room, tea kitchen, Cafeteria</td>
<td>• Gym</td>
</tr>
<tr>
<td>• Secretary</td>
<td>• Maternity Room</td>
</tr>
</tbody>
</table>

The observer was equipped with an honorary contract, was wearing a white coat, and therefore appeared to patients as part of the hospital team.
Accordingly there was no need to explain to every single patient why the observer was present. Furthermore it is not unusual in public hospitals in Austria that medics are accompanied by others, for example social workers, a trainee, a medical student or a junior doctor.

In addition, given that the outpatient department was very busy and many patients were seen for very short periods of time, on those occasions it would have been rather cumbersome to acquire consent from every single patient (in general patients also seemed to be more interested in getting medical consultation than being bothered about whether or not a researcher was present). The vantage point of the management of the clinic was that possible benefits of the research would outdo any potential disadvantage to a patient (they could not think of any). Therefore general consent for observation in the outpatient department was given by the management of the clinic. The same applied to other areas where patients were seen for short periods and where the researcher was “just one of many people in the room”. This was the case for example when the researcher attended medical rounds.

Another methodical question at the beginning (and also during) the observation, and one that only concerned the researcher, was how structured and how directly focused on CIRS the observation should be. The aim of the observation was to be as objective and independent as possible and not to take any more influence on the scene than absolutely necessary. Medical error is a sensitive issue and the researcher had many warnings about possible resentment staff may have in being observed. The researcher did not want to give staff the feeling that he was only waiting for an error to happen and then, following the alleged ‘blame culture’ in hospitals, to point a finger at individuals.

Accordingly the observation was accompanied by an attitude of ‘not to scare people off’. There was an inherent danger that if one professional refused observation that others would follow (loyalty within a group or department is
bigger than towards an external researcher who will exit the field soon again). Such an effect would be threatening to the entire research project, as gaining rich insight into the department, with all its individual groups, identities, characteristics and activities, is largely dependent on individuals’ willingness to be observed. Likewise the researcher did not want to influence staff in a ‘positive’ way, that they would use CIRS ‘for’ the researcher. The observation should capture what people, independent of the researcher, would do with CIRS in their day to day activities and the researcher did not prompt or ask staff ‘to do something with CIRS’.

5.5.5. When and when not to observe

Whether or not the researcher’s attendance was appropriate in a given situation was the final decision of the observed member of staff. For example on one occasion the observer was asked by the deputy head of department to wait outside the consultation room because the patient was a foreign woman in her mid-fifties. Due to the patient’s cultural and religious background it would have been inappropriate for the researcher, or indeed any other male, to observe the consultation. Another such occasion was when forensic evidence was taken off a 16 year old female patient that had been gang-raped. Some parts of the consultation were taken in an extra room. In order to give the patient as much privacy and dignity as possible the senior doctor conducted the required tests alone, while other members of the team (together with the researcher) waited outside.

In addition to scheduled observation days the researcher was invited to join any of the scheduled meetings without prior notice and could just ‘hang around’ at the department. These occasions were also used for respondent validation. All of this was facilitated by the fact that the researcher was wearing a doctor’s coat, was given a personal locker to store his belongings, and was allowed to use the department’s secretary office and canteen.
5.5.6. Continuity in observation

As can be seen from the above examples occasions where the observer was excluded from a situation had nothing to do with the observed person trying to "hide something" from the researcher. They are probably even a manifestation of the acceptance of the researcher as part of the team. As such he is expected to comply with the unwritten rules of the team and to do what is sensible. There was one other occasion where observation was interrupted. This was when respondent d17 (a senior doctor and smoker) wanted to go for a cigarette in his "secret place" and just wished to be left in peace with his cigarette (the observer already knew of this secret place from another observation where he was not asked to leave; when respondent d17 returned from his cigarette and the observer already knew where he had been this was commented on by the respondent with a sympathetic laugh).

On those few occasions when the observation was interrupted the observation re-commenced at the nearest possible time. This was more about protecting the patient than disguising what the observant did, and usually the observed person was willing to talk about what happened during those few moments. That the observed person always had the power to ask the researcher to leave also ensured, at least in theory, that he could anonymously and unobservedly use CIRS.

Although it was challenging the researcher tried his best to keep up with the observed person and to record every minute of the shift. This included (literally) running around the building, chasing patients and colleagues, and quickly changing into operation theatre clothes a number of times. Strictly following the observed person also meant not to eat or drink for extended periods of time. Although that came rather unexpected and was at times unpleasant it gave the researcher additional information on “what is going on” and how an alleged
interest in CIRS might have to be seen in relation to other, more basic needs of staff.

5.5.7. The researcher as complete observer

A lot of the discussion surrounding the role of the ethnographer in observation is concerned with the extent of participation of the researcher in a situation. One widely used scheme to differentiate a degree of participation is Gold’s (1985) classification of participant observer roles. It presents a continuum from complete participant, to participant as observer, to observer as participant, to complete observer (Bryman, 2004) (see figure 5.3).

Figure 5.3: Gold’s classification of participant observer roles

\[
\begin{array}{cccc}
\text{Involvement} & \leftarrow & \text{Complete participant} & \text{Participant-as-observer} & \text{Observer-as-participant} & \rightarrow \text{Detachment} & \text{Complete observer} \\
\end{array}
\]

Source: Bryman (2004:301)

While authors have argued at lengths which type of observation is most useful, in the present study the very nature of the phenomena and area under investigation determined the degree of participation to a large extent. Several facts had to be taken into account:

- The researcher is not a clinician
- The researcher is a male and patients are exclusively female
Consultations concern a patient’s most intimate physical and psychological parts; this means that on some occasions even members of the clinical team become “observers” and are not actively involved.

The researcher aims to document phenomena as it appears without directly influencing it.

Thus the role of (an almost) complete observer seems justifiable for this research. This also seems to go in hand with Geest and Finkler’s (2004) observation that researchers, when doing fieldwork in hospitals, can basically take on three roles: those of joining staff, patients or visitors. They (ibid, 2004) observed that most researchers present the point of view from a professional’s perspective and join staff. They might do so in putting on a white coat “to be regarded as ‘one of them’” (for example Frisby, 1998; Pool, 2000; or Geest and Finkler, 2004). Thus, in this present research the observer, through putting on the white coat in many respects became ‘one of them’, at the same time not actively taking part in any of the activities and “merely” remaining in the role as complete observer.

The credibility of the researcher as complete observer as well as the potentials and dangers of taking on a role of a consultant researcher are aspects that are related to the above discussion. They are discussed in the next paragraphs.

5.5.8. Credibility of the observer

During the observation when shadowing staff the researcher became part of a multidisciplinary team. To a large extent staff at the department were aware of the research and the role of the researcher. However, due to the amount of time spent in the setting and the teaching nature of the hospital, which meant that the department often had outsiders as visitors, it seems likely that general hospital staff were not unduly conscious of the observer.
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The presence of the researcher was, with very few exceptions, accepted in that he was fulfilling his role in his discipline of research. It seemed therefore not necessary to legitimise the presence of the researcher any further, as stressed for example in Robson’s (2002) or Bryman’s (2004) discussion on the role of the researcher as complete observer. Accordingly “actions of showing some credibility” were held to a minimum. One example of such an occasion was when the head of department was desperately looking for an up to date operation theatre timetable and the researcher, who was the only one around who had one, gladly handed it over.

During the observation the researcher’s credibility was mostly unchallenged. Where the researcher was challenged or staff tried to avoid being observed this is mentioned as it appears in the text.

5.5.9. The researcher as consultant

One issue that became apparent during the observation was that, probably due to the lack of government policies on CIRS and lack of a national CIRS, the researcher arguably had more knowledge of CIRS than the people observed. On various occasions the researcher was asked to provide information on CIRS. For example even the head of department acquired the password for CIRS through the researcher. Some staff referred to the researcher as “Mr. CIRS” (a group of surgical nurses who, through the head surgical nurse, had successfully avoided being directly observed; they were still observed however when the researcher was in the operating theatre “officially” observing one of the other personnel), implying that he had a personal interest that staff would use CIRS and that he was acting as some kind of ‘CIRS policeman’.

To avoid drifting into the role of a consultant the researcher kept faithful to the aim of the research in documenting phenomena, not actively changing them. It seems important from the researcher’s perspective that problems in health care
are documented in order to bring attention to them and not to offer a “quick fix” and go into describing “solutions”. The literature on observations also contains warnings about a researcher taking on the role of a “research consultant”. Wolff (2004) warns the researcher who promises a “real” and direct contribution to the field under investigation. While in some cases there is a need “to buy-in access” Wolff (2004:96) suggests that in most cases the biggest advantage for hospital staff would be “an interruption of their boring every day routine, a possibility to share worries and claims with someone or to do something good”.

If gatekeepers offer the researcher to take on a consultant role or that of a critical evaluator there are many dangers. Not only that fulfilling such a role could ask too much of the researcher, he sees a diffusion of the researcher’s roles in meeting individual interests and the (new) demands of the professional field. The lay researcher should be able to use his naivety (may it be pretended or real) methodologically as long and as much as possible, which could be difficult as in a consultant role he also has to show at least some degree of expertise to be taken sincere by the field (Wolff, 2004; Robson, 2002).

The next section of this chapter will discuss validity claims and issues of analysis of the thesis.

5.6. Data Validity and Analysis

Using research designs that are largely based on methods generating qualitative data have become increasingly respectable and acceptable across the realm of social research (Robson, 2002). However all field work done by a single field-worker still invites the question “Why should we believe it?” (Maxwell, 2002 citing Bosk, 1979:193). Therefore data need to be analysed and researchers need to prove that results are valid.
The literature suggests many ways for validating and analysing qualitative data. Lincoln and Guba (1985) and Guba and Lincoln (1994) for example propose two primary criteria for assessing qualitative studies: trustworthiness and authenticity. Trustworthiness refers to the credibility (internal validity), transferability (external validity), dependability (reliability) and confirmability (objectivity) of qualitative research (Lincoln and Guba, 1985; Guba and Lincoln, 1994). Thus trustworthiness is oriented more towards methods common in quantitative research (Bryman, 2004). Authenticity criteria on the other hand, provoking but less influential, are more controversial and mark a way towards validity independent from quantitative research (Bryman, 2004).

Manifestations of both trustworthiness and authenticity criteria can be found throughout the study although these cannot always be separated clearly in the presentation. Therefore this section starts with describing one of the key activities during the research, namely note taking. It then moves on to discuss issues of reflexivity (5.6.2), internal validity (5.6.3), external reliability and validity (5.6.4), analysing qualitative data (5.6.5), and analysis and translation (5.6.6).

5.6.1. Taking notes

Robson (2002) points out that one of the main threats to providing a valid description of a qualitative encounter is inaccuracy or incompleteness of data. Accordingly taking notes is one of the essential elements during and after the observation. Note taking largely followed directions found in Patton (1990), for example taking descriptive field notes and gathering a variety of information from different perspectives, including direct quotations from respondents. Data were cross validated and triangulated, clearly differentiating between field notes and the researcher’s own interpretations. The researcher was involved as much as possible in the field, at the same time aware and sensitive to the research environment and the researched. In writing up the report the researcher’s own
experiences, feelings and thoughts were included as they represent an important element of the empirical account. In total 15 professions were observed. Detailed and descriptive records of observations, conversations and interpretations in the field were made using a sketchbook research diary. Detailed and descriptive records of observations, conversations and interpretations in the field were made using a standard A4 sketchbook which the researcher always carried with him. The researcher took as many notes as possible in order to allow interpretation of data as close to reality as possible. These notes included personal impressions, direct quotes, information on context in which the information was taken, i.e. detailed information about date, time (to ten second intervals), location, description of the physical environment in which the observation took place, the number and profession of those present, the kind of interaction they had with the observed person (e.g. if they were on the commanding or receiving end), whether the event was planned or unplanned, number and cause of people interrupting a situation, number of contact and duration of contact with patients, and if the patient had been seen before during this shift (continuous patient numbering), contact with superiors; furthermore diagrams were made, time-schedules and other possibly relevant documents collected and noted, sketches of locations made, use of computer or other technical equipment noted, number and duration of phone calls, any experienced complications or problems, as well as further contextual notes to aid the researcher’s understanding of the context, i.e. explanations of technical terms and abbreviations commonly used in conversations (for example LNR for ‘last normal period’).

At the end of each observation shift the field researcher systematically reviewed the observational records made during that shift, rewrote them in electronic format and archived and listed collected documents. Reflections, interpretations and methodological decisions were also made during this process and were also recorded in the personal reflective research diary. These reflections helped
making preparations for the next observation shift. Preparations included getting hold of all protocols pertaining to the activities to be undertaken in the department that day first thing in the morning from the chief secretary. These items included things like the staff list and the operation theatre timetable for the observation day. This helped to understand how a day was originally planned and allowed, for example, to recognise spontaneous changes as such. Other preparations were more curious. For example hospital staff (usually doctors) often asked to borrow the researcher’s pen, then wondered off with it before the researcher could realise it, or started operating on the patient. The researcher at times ran danger of being left without a pen, leaving him unable to take any notes. As a consequence several pens were carried during the observation, some for “lending out” while one “master pen” was kept that would never be given away. The researcher also learned to equip himself with essential things such as muesli bars in order to endure long periods of observation without a break.

This accumulated to more than 130 hours of observation and collection and review of around 40 documentary files (for example job descriptions, guidelines, welcome brochures for new staff, work schedules, minutes, critical incident video, etc.). Notes that were taken during the observation in handwriting as well as mental notes from the observation that could not be documented on the spot were transcribed using a word processor. This accumulated to about 50,000 words of raw observational data.

Audio recording was not attempted during fieldwork observation. However personal notes and comments were sometimes spoken into the dictaphone rather than recorded in writing on those occasions where it was appropriate and a fast alternative to writing notes down. This accumulated to about 30 audio mp3 recordings. Although not all of these recordings were transcribed in full the audio files, with their background noises, cuts, sighs, notions of exhaustion etc.
provided a useful and important tool during the analysis as they have the ability to take the researcher back into a situation, even more realistically than a written document could do.

5.6.2. Reflexivity

As has been stated above in section 5.2 on research philosophy any researcher will interpret findings within a framework which reflects his own beliefs, values, biases, experiences, presence in a situation and methods used (Bryman, 2004; McDonald et al., 2005; Pink, 2001). Therefore it is important for the researcher to reflect on his experiences and interpretations of data in his research diary, something that has become known as reflexivity (Hammond, 1964; Bell and Newby, 1977; Bell and Roberts, 1984; Van Maanen, 1988) in social sciences research. As early accounts of reflexivity (for example Hammond, 1964) show reflexivity largely predates postmodernity, although the postmodern influence has put greater attention on the role of the researcher as part of the construction of knowledge (Bryman, 2004). Therefore in addition to the detailed and descriptive observations recorded in the sketchbook the author of this study maintained a personal reflective research diary in which he recorded his reflections on the process, asked whether there might have been other possible interpretations of the data, as well as questioning the methodology being used for any inadequacies.

Critical introspection was important to this research during data collection and analysis as taken for granted assumptions, statements, observations, as well as personal thoughts, were continuously questioned, challenged and rethought. Although it is accepted that such a perspective might be more commonly associated with Habermas’ understanding of critical theory, it resounds his more general notion (in Johnson and Duberley, 2000) that the goal of critical sciences
should be facilitation of processes of self-reflection and developing one's emancipatory interest.

Ahern (1999) argues that to “put aside personal feelings and preconceptions (1999:408)” is not as question of how “objective” one is, but how reflexive one is - as it is impossible for researchers to set aside things about which they are not aware. Reflexivity was oriented towards Ahern’s (1999) ten tips for reflexive bracketing. Various other contributors (for example Fielding, 2008; Robson, 2002; Lofland and Lofland, 1984; Bruyn, 1966) have stressed the importance for researchers to be self-critical. These were also considered and data were tested for error and bias using several tactics. These included Lofland and Lofland’s seven ways of evaluating the quality of observation (as described in Fielding, 2008:166), Bruyn’s six criteria of subjective adequacy after writing each set of fieldnotes (as described in Fielding 2008:166-167), as well as Robson’s (2002) characteristics for good flexible research designs and general skills for flexible design investigators.

Reflexivity was also facilitated by the opportunities given to / created by the researcher. For example the researcher was given a personal locker to store his belongings and a doctor’s coat to mark him as being “one of the team”. He was also shown where to dispose of and get a new coat if needed, without having to ask anyone. The researcher was given the amenities of using the secretaries’ office (which included free use of copy machines, telephone and computer), canteen, social rooms, cafeteria, and even shower rooms at any time (24/7). The researcher was also invited to join any of the scheduled meetings without prior notice or to “just hang around” the department whenever he wanted. Good examples of these are observation day 7 and observation day 12 where the researcher spent a few hours in the wards’ secretary, as this was the department’s hot spot where people from all ranks would (for example) meet, bump into each other, ask for information, leave notes, use a computer or had
informal talks. On many of these occasions the researcher would get involved in ad-hoc conversations with all different kind of members of staff and this greatly contributed to the breadth of perspective in the observation. These occasions were also used to double check data and interpretations of and thus contributed to respondent validation.

5.6.3. Internal Validity

Using more than one method can have substantial advantages and reduce ‘inappropriate certainty’ (Robson, 2002). Following Yin’s (2003) and Remenyi’s (1998) notion of six sources of evidence this study made use of various sources including documents, archival records, interviews, observations and physical artefacts. This use of multiple sources permitted triangulation of data.

Data source triangulation was necessary to adequately address the latter part of the research question “…how is it [CIRS] perceived by staff” and in particular objective 3 of the thesis, “to investigate why CIRS has been implemented from a stakeholder perspective”. Stakeholders investigated included the department leadership, front line staff, people external to the department but from within the hospital, as well as experts from outside the hospital. Therefore information was sought from a variety of groups or sources.

Methodological triangulation was used in using different data collection tools. These were predominantly interviews, questionnaire and observation. However the latter also included the collection and review of archival records and documentary data from the hospital. For example apart from “operative items” to facilitate observation, such as work schedules, also staff profiles were reviewed in order to broaden the researcher’s understanding of who worked in the department and to identify any further respondents. Also the staff intranet
has been searched for patient safety relevant information and information pertaining to CIRS.

5.6.4. External reliability and validity

Fielding (2008:164) acknowledges that “making critical assessments of the reality of some unknown area of social life places a heavy responsibility on ethnographers”. Ethnography is a method of discovery and ethnographers must make sense of something that will remain unknown to most of their readers (Fielding, 2008). This makes it unlikely that readers have any direct way of validating the researcher's claims. The “subjective ethnographer”, while making public his descriptions and conclusions about a phenomenon, arrives at them through introspective knowledge (Fielding, 2008). LeCompte and Goetz (1982) recognise that social settings and the circumstances of an initial study cannot be “frozen” to allow replication in the same way as it may be achieved in laboratory experiments. However, they (ibid, 1982) suggest that ethnographers can adopt similar social roles as adopted by the original researcher. It is therefore important to include details in the ethnographic account on how data were collected so that, when a researcher communicates characteristics of the observation to colleagues, they too would become members of the group (Fielding, 2008), and what they hear and see would be comparable to what the original researcher had observed (LeCompte and Goetz, 1982). This is usually referred to as external reliability (Bryman, 2004). It is similar to the concept of external validity, how generalisable findings are across social settings. Attempts have been made in this thesis to provide sufficient detail on the personal and professional background of the researcher (see sections 5.2.3 and 5.2.4), information on the relationship with gatekeepers and the documentation of observations.

Generalisations about the present study are arguably limited due to its single site approach. However, as chapter 6 will show, findings of the preliminary
research in five hospitals and when focusing the research to one hospital did not make apparent any major differences in those departments. It may be argued both ways, that narrowing down the study from five hospitals to one, did or did not affect the external validity of the study. While more sites present a larger scope the similarity between the five observed departments and the fact that underreporting was present in all five departments may also be interpreted as that narrowing down the study, while adding richness to the account, did not significantly affect (decrease) its external validity. Future research may address this issue further.

5.6.5. Analysing Qualitative Data

It is the promise of ethnographic methods that immersion into everyday life of the subject will provide rich data. Data collected in this immersion process needs to be analysed. Usually this happens in an iterative process in which “cultural ideas that arise during active involvement in the field are transformed, translated, or represented in a written document” in order to generate conclusions about what is happening and why (Thorne, 2000). Geertz (1973), an early influential proponent of interpretative ethnography, sees the defining element of ethnographic work not so much in the research methods employed in a study but emphasises the underlying intellectual effort of the study which he calls “thick description”.

A “thick description” (Geertz, 1973; Van Maanen, 1982) does not come about merely by engaging with people but through connecting data to existing theories. In building a thick description both background and detail are important. The researcher strives to explain people’s pattern of life by describing the patterns of meaning that inform their actions. In this way they become accessible and logical for the researcher (and the researcher’s audience). These patterns of meanings are another expression for “culture”. In ethnography cultural frameworks are discovered through analysis of structure and content. This
creates a basis for explaining a particular social phenomenon. In this respect a thick description is both an 'analytical' and 'theoretical' description of social process and systems of meaning (Liamputtong and Ezzy, 2005). However, as Hammersley (1992:12) points out, "these descriptions must remain close to the concrete reality of particular events, but at the same time reveal general features of human social life". In addition Geertz (1973) emphasises that cultures can never be finally mapped out. They will always be partial and incomplete guesses at explanations (Atkinson et al., 2001; Silverman 2006).

It appears that authors, although using divergent terms such as codes/variables, categories/patterns, themes/factors, have identified steps that are common to most qualitative data analyses (for example Miles and Huberman, 1994; Green et al., 2007; Pope et al., 2000; Bradley et al., 2007). Green et al. (2007) suggest that data analysis involves four key steps: immersion in the collected data; coding; creating categories; and identification of themes. Miles and Huberman (1994) found similarities in the analytic practices of different qualitative research types, they are (1994:9):

• Affixing codes to a set of field notes drawn from observation or interviews
• Noting reflections or other remarks in the margins
• Sorting and sifting through these materials to identify similar phrases, relationships between variables, patterns, themes, distinct differences between subgroups, and common sequences
• Isolating these patterns and processes, commonalities, and differences, and taking them out to the field in the next wave of data collection
• Gradually elaborating a small set of generalizations that cover the consistencies discerned in the database
• Confronting those generalisations with a formalised body of knowledge in the form of constructs or theories
As the coding process presents the first major step of data fragmentation it will be given a little more attention here. Anecdotal evidence suggests that it is this first stage of data fragmentation that is the most difficult and can leave researchers puzzled for a long time, not knowing where to start. Arguably it is this element of the research process, overcoming this first hurdle of coding from fieldnotes, where a researcher really becomes an ethnographer - rather than a mere observer. Authors, for example McDonald et al (2005) or Fielding (2008) characterise the ethnographer as someone who can perceive, interpret, and make sense of something that is shaped by norms, practices and knowledges (McDonald et al., 2005) and as someone who will develop a modicum of understanding through learning the language in use and in becoming part of the natural setting. However, the literature provides little guidance on how a researcher may develop such a modicum of understanding, especially in environments that are new to him. It may not come as a surprise that in the present study the researcher was at first 'overwhelmed' with the amount of fieldnotes and transcripts, and the literature provided little answers as to how to overcome this challenge. The above described four key steps of data fragmentation (for example Green et al. 2007) served as a framework for developing a data fragmentation model that gives more detailed attention to the coding process. The below presented figure 5.4, which has been amended from Green et al. (2007), splits the coding process into two individual processes, descriptive coding and conceptual coding. Hence the final model consists of five key steps: (1) immersion into original data, (2) descriptive coding, (3) conceptual coding, (4) creating of categories, and (5) identifying of themes. This is illustrated in figure 5.4.
Figure 5.4: Five steps of qualitative data analysis
The novelty in this model is the notion of two different kinds of codes, descriptive codes and conceptual codes. Descriptive codes on one hand allow the researcher as novice to develop an understanding of the daily routines, the right sequences and duration of events, and the general research environment. These descriptive codes may be complemented by other descriptors such as time-task protocols. Descriptive codes allow the researcher to understand what is going on. Not only do they provide an important prerequisite for the next steps of data analysis but they also provide the researcher with a viable opportunity of engagement and familiarisation with the data. Conceptual codes on the other hand should provide answers to why things are happening. While descriptive codes are rather 'sterile' the contextual codes can already have a more particular research focus. They can also serve to add meaning to descriptive codes. Contextual codes may relate to a group of descriptive codes, but this is not a necessity. Contextual codes may then be merged into categories, which in a final stage leads to the identification of themes.

During and after the observation the researcher was constantly sorting and sifting through material to identify relationships, similarities or distinct differences, looking for reoccurring instances, issues that could be either related to the field (ongoing observation), existing fieldnote transcripts or the literature. This search for 'codes' that could be affixed to new occurrences or existing sets of fieldnotes was an iterative process that included validating respondent information, reading and re-reading fieldnote transcripts, reflecting, and making new observations. Overall there were four stages of data fragmentation, descriptive coding (first stage, small, 134 'descriptive codes'), contextual coding (second stage, small, 71 'contextual codes'), emerging categories (third stage, medium, 14 categories), and emerging themes (final stage, large, 4 themes). This is illustrated in figure 5.5 on codes, categories and themes and the individual sections are explained in more detail below.
Descriptive codes: The first stage of data fragmentation resulted, over time, in 134 ‘descriptive codes’. As a first stage these 134 codes were descriptive rather than interpretive to allow loose grouping and re-grouping as analysis and data collection went on. These descriptive codes were for example ‘CIRS codes’, such as ‘critical’, ‘unwanted’, ‘CIRS missed opportunity’; or ‘meeting’, ‘unplanned meeting’, ‘scheduled meeting’, ‘nurse meeting’, ‘team meeting’, ‘morning meeting’, ‘post meeting’, ‘shift handover’, ‘round’, ‘late in meeting’ and so on - which suggested to group these codes under a common theme ‘CIRS’ or ‘meeting’ respectively. Other loose groups consisted of codes referring to, for example, other forms of communication as in ‘staff communication through file’,
Figure 5.5: Codes, categories and themes
‘staff interact admin’, ‘staff interact nurse’, ‘staff interact doctor’, ‘telephone’, telephone out’, ‘dictaphone’, ‘documents’, ‘sign’, ‘admin’, ‘interrupt’, ‘new staff. Other loose groups referred to non clinical work (with codes such as ‘food’, ‘facilities’, ‘space’, ‘I.T.’), structural and hierarchical codes (such as ‘hierarchy’, ‘leadership’, ‘collegiality’, ‘command’, ‘shifted responsibility’, ‘known problem not solved’), patient related codes (for example ‘patient consultation’, ‘patient contact’, ‘patient care’, ‘patient contact ad hoc’, ‘new patient’, ‘mobility’, ‘discharge’), more emotional codes (such as ‘end of life decision’, psychological emotional stress’, ‘stress’, ‘psychiatric service’), privacy and ethics (for example ‘privacy’, ‘ethics’, ‘privileged treatment’), social codes (for example ‘coffee break’, ‘smoke’, ‘private chat’, ‘gossip’), cultural codes (for example ‘culture’, ‘change’, ‘conflict’, ‘dissatisfaction’, ‘attitude’, ‘trust’), research environment descriptive codes (for example ‘department environment’, ‘hospital environment’), or researcher related codes (such as ‘research design’, ‘sketch’, ‘free observation’, ‘resistance’). In addition to these codes additional descriptors aided making sense of data, for example a detailed time-task protocol that was maintained throughout the study and that provided detail on duration of events, sometimes down to ten-second intervals. Descriptive codes were only loosely grouped and not distinctively named until a second stage of data fragmentation.

This first stage of data fragmentation allowed the ‘researcher as novice’ or ‘outsider’ to understand ‘what was going on’ and in what sequence. However in order to understand ‘why’ things were happening the way they did required a further stage of data fragmentation that went deeper, adding ‘meaning’ to codes, relating them to each other, and in particular trying to relate them stronger to CIRS.

**Contextual codes:** In order to relate codes stronger to CIRS a keyword search was made in fieldwork transcripts, comments and reflexive notes for the term ‘CIRS’ (also abbreviations and alterations of) using the ‘find option’ (Ctrl+F) in
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MS Word. The keyword ‘CIRS’ appeared 106 times in the fieldnotes and another 175 times in the comments and reflexive notes, a total of 281 times. This allowed identification of overlaps between CIRS descriptors and other events. Events that were not strongly related to CIRS were dropped, although on occasions a relation only became apparent later on in the process and the code was ‘reactivated’ and possibly renamed. Using this technique and repeatedly going through the material eventually led to 71 ‘contextual codes’. These codes were more interpretive than the foregone descriptive codes and (with exceptions) connected a number of descriptive codes and events, different observation days and different personnel with each other, and they had a stronger connection to CIRS. Contextual codes were usually termed using a short phrase (not a single word as in the previous descriptive codes) to allow the researcher recalling what exactly they meant (without always having to look at the text) and in order to differentiate them from or relate them to each other. Contextual codes were for example ‘wrong patient instruction’ (T32), ‘wrong patient birth date through telephone’ (T46), ‘patient file transfer’ (T40), bypassing of regulations (T25), ‘knowledge of password’ (T10), ‘willingness to report’ (T23), ‘availability of computers to report’ (T67), ‘light management in operation theatre’ (T17), ‘ordering drugs using in-house computer network’ (T61).

Categories: This process of differentiating and relating contextual codes with each other led to the emergence of 14 categories (the bullet points are a reference to the ‘themes’ that will be introduced in the next section ‘themes’):

1. Clinical issues, communication issues, documentation issues, other issues
2. little awareness of and information about CIRS as barriers to reporting (little awareness), low priority of CIRS as a barrier to reporting (low priority), other barriers to reporting
3. facilities, IT, processes, culture
4. integration of existing documentation, integration of staff, integration of organisational issues

Themes: In a similar process to the building of categories from contextual codes, differentiating and relating them with each other, the above mentioned 14 categories then led to the emergence of four themes:

1. possible reports to CIRS (these will be discussed in more detail in the finding chapter in section 7.4)
2. barriers to reporting (these will be discussed in more detail in the finding chapter in section 7.5)
3. organisational issues with the potential of compromising safety at the department (organisational threats) (these will be discussed in more detail in the finding chapter in section 7.6)
4. practical implications for the use of CIRS at the department (these will be discussed in more detail in the finding chapter in section 7.7)

The above fragmentation of ethnographic data serves as a framework for the development of a patient safety framework. This will be presented in chapter 7, and the discussion in chapter 7 is focused upon the above identified categories and themes.
5.6.6. Analysis and Translation

As the clinic where this study was conducted is in Austria one major element in conducting this study was the translation of data into English. A principal question was whether to translate data before or after analysis. The downside when analysing data before translation is that it inhibits, to a certain degree, the feedback process with supervisors and colleagues. For example a list of preliminary codes or text cannot easily be forwarded for feedback. Another issue inherent in qualitative research, and in particular ethnography, is the question when analysis and interpretation is ‘complete’, hence when ‘results’ should be translated for review. As a consequence analysis and translation of results is never as clear cut as it might first seem. The following paragraphs detail some of the issues that came up in the analysis and translation process.

In this study it was aimed to overcome these problems, sometimes through ‘trial and error’, but eventually finding a middle way with interview and questionnaire data first analysed in German and most of the observational data analysed in English. This allowed the ‘development’ of early ‘translation unbiased’ hunches and a general familiarity with the topic in its natural language before allowing it to evolve, adding the observational data in English, into the present work.

Interview data and questionnaire data were first analysed in German and then translated into English. When feedback asked for additional insight the original German data were consulted. This was done to ‘protect’ data from researcher manipulation as the translation process unavoidably is linked with data-manipulation and -loss of some kind. For example in the analysis of the self-administered questionnaire a translation prior to analysis would bear the danger of translating exactly same German words into different English words, thus artificially and falsely creating a possibility for new codes (this does however not rule out another issue, when respondents might have used the same word but meant different things, and ‘vice versa’). Answers to open questions in the self-
administered questionnaire were also found to bear more information than the mere words that were used in giving an answer. For example it was apparent that a few questionnaires used exactly the same formulations in the open questions. As was found later in the observation it is possible that this was a group of nurses sitting together over afternoon coffee and filling in questionnaires together. Such a scenario leaves space for speculations. It may be that filling in questionnaires was “led” by one particular individual, who “invited” peers to give non-diverging answers in order to demonstrate (false) solidarity on the topic. Another possibility is that the work climate in a particular group is exceptionally good and therefore nothing would speak against filling in a questionnaire together. While these interpretations point to different cultures and subcultures amongst different work groups in the department it leaves unanswered if those unwritten codes of conduct on how to fill in a questionnaire and what kind of answers to provide would also be applied to reporting critical incidents. The way self-administered questionnaires were filled in at least points to such a possibility.

Another issue concerned with language in the open answers was the fact that some responses were written using poor grammar and spelling mistakes. The question was if this represents important information and should therefore be transposed into English (and how?) or if such information should be regarded as unimportant and be left out altogether? Taking the example of the poor German in the written responses it turned out later in the analysis that they indeed revealed something about the respondent. For instance, poor written German is an indication that it is highly unlikely for the respondent to be a medical doctor. It is also unlikely that the respondent is from the operation theatre, which is considered a high reliability environment with highly trained staff, where spelling mistakes are not be tolerated due to their enormous potential for contribution to disastrous outcomes. It may be concluded therefore that spelling mistakes of this extent (which were not mere “typos”) are more
likely to be found amongst nurses or support workers who work in environments with lower reliability, for example on the ward which has many foreign workers.

Indeed, such information can be useful to verify statements that were made by staff and to give meaning to some of the actions of staff. For example during the observation of the head nurse the researcher wondered about the time she spent collecting dirty laundry, packing and labelling them so they could be sent to the laundry. Although the head nurse, when asked by the researcher why not one of the nurses would do this, answered: “well, they can’t do it because they can’t write German” (respondent n7) the researcher could just not believe that. How was this message to be understood? Was it merely defaming foreign nurses because of a personal dislike against foreigners (the department employs quite a few nurses and support workers from Eastern European countries and from the former Yugoslavia - this is not unusual for a hospital in Vienna) and to be seen as a pejorative comment, or was there something (more changeable) behind this? The experience with the poor German on questionnaires verified the head nurse’s comment that it was indeed a language issue, an honest and true reflection of his daily experience at his workplace, and not just a personal comment. This had effect on the iterative coding process. Without the information from the open answers in the self-administered questionnaire the event where he collected and labelled laundry might have been coded ‘work that someone else can do’. With the information in mind the more appropriate code was to be ‘language’, shifting the attention from what might be a ‘personal and attitudinal problem’ to a societal and cultural issue of the correct use of German.

Caution also had to be taken when translating technical terms from German into English and vice versa. While the English literature employs the term ‘safety culture’ the German equivalent would be ‘Fehlerkultur’, which literally translated means ‘error culture’. It may therefore be argued that in the English language
there is a more positive connotation with the term, i.e. the word safety, something that is desirable by all, while in German there is more of a negative connotation by using the word ‘error’, which is something people want to avoid or have nothing to do with. The term ‘Fehlerkultur - error culture’ still dominates the German literature on patient safety, while the German word ‘Sicherheitskultur - safety culture’ seems to slowly gain popularity. Throughout this thesis the term safety culture was used, regardless of which term was used in German. However, future observations might reveal a connection between change in language (use of safety culture rather than error culture) in departments and attitude towards reporting.

Analysing the observational data in English was also facilitated as this happened through marginal notes in the word processed notes document. Affixing codes to a set of field notes was a task mostly independent from the observed and therefore this could be done straight away in English. Direct quotations were translated, trying to keep the originality alive, for example in the use of slang or rather rude expressions. Again, it is believed that all translation processes (also those from originally English information to how it appears in English in a final report by the researcher) is inherently coupled with some sort of ‘researcher bias’ or loss of information. To keep this to a minimum the German quotes were kept at hand and doubled checked in their original form when a particular quote was being used.

Overall the translation process highlighted the fact that the new patient safety movement is driven by English speaking countries (US, UK, Australia, Canada) and that this is reflected in the literature, as the bulk of patient safety literature is in English. Working with English data somehow facilitates relating information with the existing body of knowledge. Many English patient safety terms do not (yet?) exist in German, something that also became apparent in the fieldwork, when patient safety knowledgeable staff used known English terms rather than
German terms. This relates to the issue of a standardised taxonomy. The problems associated with this, for example the WHO's development of such a taxonomy that will not come forth in German because it is not an official WHO language, have already been discussed in chapter 4 (section 4.3.3).

The above mentioned issues are not only relevant in regard to translation but to the validity of the interpretation process in general. It emphasises how important it is to take comprehensive notes on how information was interpreted, coded and categorised. It stresses how important it is to retain copies of original notes to be able to return to the original data and to be able to recall the context in which information was taken. This was aided by making further marginal notes on a copy of the original document. Originals were kept in original form and at hand during the analysis process so they could be returned to when necessary.

5.7. Summary

This chapter began with a discussion of the epistemological and ontological commitments that this study is based on. The chapter discussed how a research topic may be chosen and provided details on the researcher's personal and professional background. The chapter then moved on to look at the research strategy aimed at answering the research question. A qualitative approach using a combination of interview, questionnaire and observation data was deemed appropriate. The individual methods were introduced in light of the research experience and claims on data validity and analysis made.

The following chapters outline the results of putting this research strategy into practice. Chapter 6 goes into the field and presents contextual information on the OEGGG project as well as analysis of the study's results pertaining to leadership interviews and a staff questionnaire. Chapter 7 presents the results
of the fieldwork observation at the department. Chapter 8 uses this information as a basis for discussion of the results, conclusion and pointing out areas for future research.
CHAPTER 6: RESEARCH ANALYSIS AND FINDINGS I

The purpose of this chapter is to provide insight into the CIRS project at the hospital. It shows how reflecting upon the results in this chapter the study evolved into an ethnographic study.

6.1. Introduction

This chapter is the first of two chapters on research findings. Following this introduction section 6.2 provides contextual information pertaining quality management in hospitals in Austria in general and CIRS in the Vienna City Hospital Association in particular. Section 6.3 discusses observations at the CIRS training session at the department. Section 6.4 presents findings from interviews, which aimed to identify the medical lead- and the nursing lead-perspective on the CIRS implementation at the department. Section 6.5 presents findings from the self-administered questionnaire that sought to capture the general safety attitude and perception of CIRS from front line staff. Appendix G presents more details from the questionnaire findings.

6.2. Research context

Information pertaining CIRS in Austria was and is to date curiously elusive. As a member of the European Union and the WHO Austria principally subscribes to recommendations issued by those organisations. This includes the promotion and/or development of a reporting system for patient safety incidents (for example Council of Europe, 2006, 2008a and 2009; WHO, 2002 and 2005a). At
the same time however these recommendations stress that ‘the problem of patient safety’, hence the development and implementation of patient safety strategies, is primarily the responsibility of Member States (Council of Europe, 2008a). In Austria the Austrian Health Care Quality Act (BMG, 2005a and 2005b) ascertained that no pan-Austrian quality system was in place and that provisions on quality and/or quality assurance were isolated and scattered throughout the Austrian health care system (BMG, 2005b). At the same time it circumscribed (or one might say justified) the absence of a ‘systemic quality management system/model’ as “supporting the providers’ flexibility in their quality work and to allow unobstructed competition”. Although one of the objectives of the Health Care Quality Act was to intensify quality work and to implement a quality system (BMG, 2005b) progress has been slow and brought only few tangible results. For example the report stressed in 2005 that nationwide Austrian quality reporting (in a general sense, not to be confused with reporting of critical incidents which presents only one element in this) was to be established, with the objective of preparing an annual, comprehensive quality report, and that such a report was ‘currently being installed’. However, the publication of the first quality report did not come forth until May 2011 (see report BMG, 2011b) and until after completion of fieldwork for the present study. This shortly circumscribes the context in which this study set out to investigate CIRS in Austria.

Similarly to the above described overall situation pertaining to a systemic approach to quality in the Austrian health care system was the situation regarding CIRS in Austria. Unlike other countries, for example the UK with the NHS NPSA which has an operating budget of 37 million GBP (NPSA, 2005), of which an estimated five million GBP were allocated for the development and operation of the NRLS for the first three years (Williams and Osborn, 2006), Austria did not, until July 2007, have a Federal Institute for Quality in the Health Care System (BIQG) and still does not have a national reporting system.
Moreover health care institutions are not legally required to report incidents that did not harm patients or to implement a CIRS. While it was a ‘known secret’ amongst health care professionals that were consulted at the outset of the study that the WKAV was ‘developing’ a CIRS there was no documentation about any possible progress or the direction in which WKAV was heading (see the above issue of forthcoming reports that took years to be published; or a blank BIQG website stating that information will soon be available, which to the knowledge of the author did not happen until very recently). While the research was already in progress the European Union Network for Patient Safety was launched in 2008. They stated that Austria has two CIRS already in place, one of which was described as the WKAV CIRS system “Working with CIRS”, a governmental run voluntary and confidential near miss reporting system, launched in 2006, on a regional level for hospitals of the Vienna City Hospital Association (i.e. WKAV), for all health care workers, with no public disclosure of individual reports (EUNetPas, 2011). However, EUNetPas obtained their information through the means of a three page self-evaluation questionnaire and information should thus be handled with care. The CIRS that EUNetPas was referring to was the ‘secret CIRS’ staff had been talking about. This ‘secret CIRS’ was a pilot phase CIRS and, again referring to the self evaluation questionnaire, being adopted at 26 of a total of 63 high risk wards, with an expected roll out completion in 2013. It thus represents only a fraction of the entirety of WKAV which is one of the biggest health care institutions in the world and consists of 12 hospitals (one of which, the Vienna General Hospital, is the largest hospital in Europe and the second largest hospital in the World), eleven geriatric centres, and two residential care facilities for the elderly, and employs over 30,000 staff. While government officials continue to stress that ‘we [Austrians] have a CIRS’ the investigation shows that public hospitals in Vienna in general do not have access to a CIRS and that only a small number of departments had been officially enrolled in a pilot phase. A first (contrary to the announcement made in 2005 not very substantial) report on results of this pilot CIRS from May 2011
Chapter 6: Research Analysis and Findings

(BMG, 2011a) shows little acceptance of CIRS and suggests that there is a long way to go, both in the BIQG organising, running, monitoring, and disseminating results of a CIRS and in hospital staff using CIRS. The report does not conclude if the CIRS project will be continued or not.

Hence, information on quality in the Austrian Health Care System and the Vienna City Hospital Association, in particular in regards to CIRS, is scattered and inconclusive. Most importantly, from a researcher's point of view, only very little is documented about quality management in WKAV and this makes it difficult to verify and formulate a (research) problem that is worth addressing. From a practical practitioner perspective hospitals in Austria did not have the chance to partake in a nationwide CIRS, neither were there any instructions or recommendations on what stance a health care organisation should take towards quality and CIRS, which stands in stark contrast to the international patient safety development in other countries. It was under these conditions that the Austrian Society for Gynaecology and Obstetrics (OEGGG) initiated the OEGGG CIRS project to enable all Women Hospitals in Austria to participate in an existing international voluntary and anonymous CIRS.

It is not clear neither is it documented how this puzzling situation pertaining quality and CIRS in public hospitals in Austria impacts health care organisations and what the implications may be at the ‘sharp end’. What is the perception of CIRS at the frontline and what benefit do staff expect when voluntarily partaking in a CIRS. What possible alternative ways do staff find in their endeavours to providing safe(r) services? This present study aims to contribute to closing this gap through providing an in-depth account of the OEGGG CIRS project at a public Women Hospital in Vienna.
6.3. CIRS training session

The training sessions by Expert 1 at participating hospitals invariably followed a common scheme and were delivered in a consistent way. After a ‘compact morning meeting’ Expert 1 was introduced by the head of department to the rest of staff. Expert 1 then had about 20 (at a maximum 30) minutes to deliver his presentation, which included a question and answer session. Also at the study site the training session was part of the daily morning meeting. The meeting was attended by medical staff and the charge nurses, in total 32 people. Notably the deputy head of the department and researcher’s main contact at the department (respondent d2) who had previously informally promoted CIRS at the department, in particular the OEGGG project, decided not to partake in this training session. He did not want to give staff the impression that this was “his project” and that he, as a superior, would from now on “monitor” how staff responded to it (respondent d2). The head of department (respondent d1) quickly lead through the morning meeting before he turned the attention to the OEGGG CIRS initiative and introduced Expert 1 and briefly the researcher as an independent social scientist who would accompany the project as an observer. The head of department (respondent d1) emphasised that the OEGGG CIRS initiative was not connected to the Vienna City Hospital Association (WKAV) in any way but that Expert 1 had been invited directly from the department as an independent patient safety expert who, based on his own experience at another department for gynaecology and obstetrics in a public hospital in Vienna and his expertise as a consultant, will be able to support the department in providing safe care.

Respondent d1 also stressed that the work at the department was already good and safe but that never enough could be done for the safety of patients. This was to be seen as an additional and proactive way for ensuring safety at the department. He elaborated that the international trend clearly pointed towards
the use of CIRS. However, he warned that for CIRS to be meaningful it needed to meet certain criteria, in particular in regards to voluntariness, anonymisation of patient, reporter and the reporting institution, and external data maintenance. In line with the OEGGG round letter he argued that, as the WKAV did not offer this 'meaningful context', the OEGGG project had been consulted. He encouraged staff to use the system as one of the available alternatives in handling critical incidents (respondent d1).

The presentations were delivered using Microsoft Power Point, video clips, and examples of safe systems design in aviation and its applicability in health care. The content of the presentation focused on encouraging staff to think differently about safety and risk in their work. In particular attendees were encouraged not to see “errors” and problems as individual in nature but the product of complex organisational and inter-personal relationships. An elementary part of the presentation was to describe how CIRSmedical works and to discuss the issue of confidentiality and protection of reporters. The core concept and purpose of incident reporting in medicine was described with making comparisons to aviation. The delivery of the presentation was slick and practiced and Expert 1 showed good familiarity with the material. However, the delivery and discussion was clearly time constrained and on many occasions felt rushed to ensure that all of the core information was delivered, but within the given timeframe in a somewhat summary fashion. For example the actual CIRSmedical website was not opened and hence the online reporting form not discussed in a “real-life” context.

Staff seemed generally interested in CIRS and participated in the question and answer session. Compared with four other departments where CIRS training sessions by Expert 1 had been observed at the outset of the study the most questions or comments, a total of 14, were asked/given in the study site department. The comparatively high number of responses may have been due
to the endeavours of the deputy of the head of department, respondent d2, who had tried to raise awareness about CIRS beforehand, mentioning and talking about it at the department. The questions and comments from the study site are summarised in table 6.1.

Table 6.1: Questions and comments at the training session at the study site

<table>
<thead>
<tr>
<th>Questions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. will personal feedback be provided</td>
<td>7. there is not enough money for an external CIRS trustee</td>
</tr>
<tr>
<td>2. how will feedback be provided</td>
<td>8. the CIRS trustee is the weak point in the system</td>
</tr>
<tr>
<td>3. are reports clustered into categories (i.e. for search and statistical analysis)</td>
<td>9. the idea of an internal CIRS trustee turns to whole idea of anonymity upside down</td>
</tr>
<tr>
<td>4. does the use of CIRS show any improvement in other countries</td>
<td>10. we should not only report incidents in CIRS but discuss them in the department</td>
</tr>
<tr>
<td>5. there are only three other people in the department who could make a particular mistake, how can this be anonymised</td>
<td>11. if I was to use CIRS I could as well just talk about it in the department, which was countered in the next comment</td>
</tr>
<tr>
<td>6. would it be possible to have an external CIRS trustee</td>
<td>12. through CIRS young staff would have a channel to voice their problems, which they don't do now</td>
</tr>
<tr>
<td>7. there is not enough money for an external CIRS trustee</td>
<td>13. we should start reporting simple things</td>
</tr>
<tr>
<td>8. the CIRS trustee is the weak point in the system</td>
<td>14. patient safety and quality related issues like CIRS should already be taught to medical students at I University</td>
</tr>
</tbody>
</table>

The discussion focused on feedback (questions 1-4), anonymity (questions 5 and 10-13), and the CIRS trustee (questions 6-9). The given timeframe did not allow a thorough discussion of all these issues but Expert 1 did his best to address questions as well as possible. While some questions were more
straightforward to answer, for example that personal feedback is not provided in an anonymous CIRS (question 1), that the kind of feedback provided also depends on the reports submitted (question 2) and that the minimum data set entry form already categorises reports to some extent (question 3), others were, as the discussion in chapter 4 already suggests, more difficult to answer (question 4). In regards to question 4 Expert 1 referred to general system improvements in health care and (due to a lack of clear evidence in health care) to CIRS only in relation to experiences in aviation.

One participant raised the concern that in his job there were only two other people who could make a certain mistake, how could such an event be anonymised (question 5)? This question brought out a very real and practical problem in the use of CIRS. While in theory a high number of reports from many different hospitals and from different geographical regions should obscure where a report comes from in practice this is dependent on a high number of reports and presupposes that staff trust the system enough to and do submit many reports. That CIRS are known to have low reporting rates in the beginning does not work in favour for this particular problem and the respondent did not seem convinced. Comment 13, to start reporting with simple things, came as a logical suggestion to approach this problem and to familiarise with CIRS and to establish trust. Some saw the anonymity of CIRS as a chance for giving voice to junior staff (comment 12), while others suggested to discuss incidents also more openly in the department (comments 10 and 11).

One of the prerequisites for CIRS to become operational at the department was to elect an internal CIRS trustee during the training session. The earlier presented figure E.1 in appendix E (background info on the OEGGG CIRS project) shows that this role is a key element of the OEGGG CIRS. The idea is that an individual is elected from within the department with the function to double check, and if necessary, further de-identify reports before they are put
on the system. It appeared that staff were critical towards the idea of an internal trustee and some quickly marked this out as the weak spot in the system that turned the whole issue of anonymity upside down (question 6, comments 8 and 9). As a result no internal CIRS trustee was elected in this meeting. As this was a necessary precondition for CIRS to become operational Expert 1 suggested to become their external CIRS trustee for the start-up period, anticipating that over time there will be growing acceptance of CIRS and hence also a willingness amongst staff to take on this role, and this was welcomed by everyone. With this agreement the discussion closed.

Following the discussion the researcher was given the opportunity to briefly introduce his study and to distribute questionnaires (see more detail in the methodology chapter in section 5.4.2). Staff were given two weeks to submit responses. During this time interviews were held with the department leadership to determine their view of CIRS. This is presented in the next section, before turning to the results of the questionnaire.

6.4. Leaders’ Perspective (Interview)

Based on experiences in the preliminary phase of the research as described throughout section 6.2 and the literature review a guiding sheet for semi-structured interviews with the department leaders was prepared. The head of department (respondent d1) is a practicing gynaecologist and obstetrician and has been in this position at the department for a number of years. The head nurse (respondent n7) had been in the hospital for over 40 years, working at several different departments in the hospital, and was looking forward to his retirement over the next couple of years. The head of department together with his deputy (respondent d2), who has also been at the department for some time, were the project initiators for CIRSmedical at the department. The head nurse
(respondent n7) was informed about and supporting the project, however, his involvement was not as proactive as from the medical lead.

### 6.4.1. Introduction

While awaiting the return of questionnaires two formal semi-structured interviews were held with the leadership of the department: one with the head of department (respondent d1) and one with the head nurse (respondent n7). In addition information was obtained from the deputy head of department (respondent d2) when testing the interview guiding sheet and the questionnaire, and from the frequent informal conversations with him as the researcher’s main contact person at the department. However, this was not counted as a formal interview. The interview guiding sheet can be found in appendix C.

### 6.4.2. Interview Objectives

Interviews were targeted at objectives

3. to investigate why CIRS has been implemented from a stakeholder perspective; and
4. to collect empirical evidence of supportive measures or otherwise barriers to CIRS.

The context of the implementation was different to other countries in that it did not follow a new national policy on reporting, such as in the UK, but that the department proactively implemented CIRS as a response to a lack of a new policy on CIRS. The intention of the interviews was therefore to get the department leaders’ perspective on the implementation of CIRS at the department. What are the leaders’ motives to join the network; their expectations; how did they think to overcome the (known) barriers to incident reporting; what financial considerations had been made; how good was their
own knowledge of CIRSmedical and possible alternative CIRS in health care; did staff have any experience with reporting procedures and quality improvement initiatives prior to this one - in short: to find out the leaders strategy to successfully implement CIRSmedical in the department.

This can be summarised as follows:

1. Why: why is CIRS implemented, is it imposed on staff by management or is it staffs’ wish
2. Knowledge: managements knowledge about CIRSmedical and other CIRS
3. Experience & training: do staff have any experience with CIRS and other quality improvement initiatives
4. Benefits: what are the expected benefits from using CIRSmedical
5. Progress report: leaders estimation of the overall process and staffs’ ability to change
6. Barriers: are leaders aware of some of the known problems in using CIRS and how do they hope to overcome these in their own department
7. Accountability: is anyone in particular in the department responsible for the implementation
8. Assessment: will there be any assessment of the project

6.4.3. Medical lead perspective

The CIRSmedical initiative at the study site hospital has its roots in the enthusiasm of the head of department (respondent d1) and his deputy (respondent d2), and the professional and personal relationship to Expert 1. The 'story' started with a joint skiing-holiday between Expert 1 and the deputy head of department (respondent d2) and a visit of both department leaders (respondent d1 and d2) and Expert 1 at a Gynaecology and Obstetrics Conference in Basel, Switzerland (where CIRSmedical was developed) in late
2004. According to the deputy head of department their post-skiing and post-conference conversations turned to talking about patient safety and CIRS. The department leaders had become increasingly interested in CIRS and it was “only a matter of time to formally invite Expert 1 to the clinic and to try applying some of these patient safety techniques at the department” (respondents d1 and d2). The department had been showing interest in CIRS for some time and wanted to be amongst the first departments in Austria to join the OEGGG project. An earlier (about 18 months ago) approach to implement CIRS was turned down by the Vienna City Hospital Association (WKAV) due to a lack of funds (they decided to promote the development of their own system). However, under the benefited conditions of the OEGGG project the hospital’s collegial leadership had signalled to agreeing to pay the annual administration fee (of 350 Euros).

The head of department and his deputy initiated the OEGGG project at the department and invited Expert 1. They initially informed staff and the hospital’s collegial leadership about CIRSmedical and the benefits for an independent reporting system, hoping that word-of-mouth would increase acceptance and interest at the department. They also conversed with their peers in other Women Hospitals to see how they pursued patient safety, how the acceptance was within the department, and how it was received by the hospitals’ collegial leadership. The OEGGG round letter was the final kick-off signal and an opportunity to join under benefited conditions (fee waver). The project is entirely independent of the hospital’s collegial leadership. It has been approved from the hospital board but they are not involved in it in any way.

The head of department (respondent d1) opted for the product CIRSmedical as it is the only system he (currently) knows of and he trusts the expertise of his colleagues, both his deputy (respondent d2) and the (external) Expert 1, and the OEGGG recommendation. The head of department stated that there was
“no alternative” and that CIRS medical seemed to him “a good system” (respondent d1) although he had to admit that he himself had actually never used a CIRS. When asked about his experiences with critical incidents and errors he admitted that he had both caused and observed them. Reflecting on them he thinks that he would have reported at least some of them had a CIRS been in place. His knowledge about CIRS is limited but he doesn’t see that as critical as he isn’t the “CIRS Master”. CIRS is something for everyone at the department.

The head of department described the culture in his department as “pretty good”, with an atmosphere among staff where most errors can be discussed, with a staff that is change friendly, and willing and able to learn. He believes that severe errors are reported (through already existing channels). The general problem to be tackled with CIRS is to reduce less severe errors and incidents which he believes are not always reported in his department. On one hand out of a fundamental fear of staff towards superiors and respective consequences, on the other hand due to a general desire to protect the alleged “irreproachable reputation of the medical profession” (respondent d1). He did not know whether any particular staff had training or expertise on CIRS before they came to this department but thought the possibilities of that being rather small. No training had been offered at the department.

He continuously encourages staff to talk openly about incidents and errors directly with him, or if staff prefer to talk with someone else about it with someone other than him. ‘It’s not that I need to know every little detail about who did what and what might have gone wrong but it is important that staff talk about it and find a constructive way of dealing with it. If this can be further shared in a CIRS that would be even better’ (respondent 1). Therefore he sees it as his responsibility to offer such a system to his staff and appreciates the possibility of anonymous reporting. He feels it is important to raise awareness
amongst staff about the etymology of organisational accidents and from an error science perspective the implementation of CIRSmedical just makes sense”. The main purpose in implementing CIRS is to foster learning.

What could create problems in his opinion is a lack of trust in the system. He also points out that less severe incidents could be interpreted by potential reporters as “not important enough to report”. Reporting could also be too cumbersome in that too much work effort would be needed or it was just too difficult to write a report. Less educated staff may have problems with the free text passage, to formulate an experience in a clear and precise manner. According to the head of department there are enough PC stations, which also provide the required privacy for reporting. He expects staff to submit two to five reports every week.

The head of department pointed out the “alleged simplicity” of the system and explained the pyramid learning system to spread knowledge about how to use CIRSmedical. The pyramid system, as the name suggests, works like a pyramid, with Expert 1 and the deputy head of department (respondent d2) on top. One of them explains the reporting process to two members of staff, who then explain it to another two, who explain it to the next two and so on. A group of three people (one teacher, two novices) should allow enough time for questions. Explaining CIRSmedical to someone else also helps in a way that the “teacher” has the opportunity to prove if he really understood how CIRSmedical works, after the motto “you only understand what you are able to explain”. Apart from the pyramid system there is no other training planned and there will be no acclaimed project champion in the department. This is also linked to the budget which, at first, is limited to the annual administration cost (of 350 Euros per year payable to OEGGG). He himself is not and will not be the “CIRS-Master” and no other person in the department had been installed as a project champion.
If the endeavour taken for CIRSmedical is sufficient time will show. There are no defined parameters to measure a success with CIRSmedical, as CIRSmedical ‘cannot be measured with hard and heavy parameters’. Time will show what it does for the department and possible success can be expressed through personal experience of staff with the system or probably to some extend also with the number of reports coming in. The ambition or goal is to reduce minor mistakes and no harm events should occur less often.

The department leader’s view (respondent d1) may be summarised as:

1. Why: CIRS makes sense; it is in line with recent developments in patient safety and promoted by the OEGGG; department wanted to implement CIRS for a while; staff need and want CIRS in their department; it was a democratic decision to implement CIRSmedical and presents staff with an additional way of dealing with error; the project is independent, the hospital leadership has approved it but is not involved

2. Knowledge: Leader’s knowledge on CIRSmedical is limited, which he doesn’t see as being critical as it is not his role to be the CIRS master

3. Experience & training: Experience of staff with CIRS and any other of the new patient safety movement tools is limited; no training had been offered or conducted at the department and no training is planned other than through the pyramid system and word of mouth; the system is ‘easy to use’

4. Benefits: Minor errors and critical incidents are expected to occur less often with the help ofCIRSmedical; staff can, in addition to conversing more formally at the department, share incidents on CIRS

5. Progress report: Staff is change friendly and will adopt to CIRSmedical, with 2-5 reports being submitted per week; no formal progress report planned as CIRS ‘can’t be measured’
6. Barriers: Expected problems are lack of trust in the system, general fear of staff towards superiors; a general desire to keep up the alleged “irreproachable reputation of the medical profession” and one’s own performance; too much work effort for reporting; problems in formulating the free text passage for less educated staff; difficulty in estimating/understanding the importance of minor incidents and therefore underreporting (but still 2-5 reports weekly)

7. Accountability: No project champion in the department; CIRS will be promoted through the pyramid system with Expert 1 or the deputy head of department at the top and word of mouth; its simple to use

8. Assessment: No formal assessment of the project; time will show success or failure

6.4.4. Nursing lead perspective

Interview number two with the head nurse (respondent n7) was an entirely different experience. As it turned out that the OEGGG project at the department was initiated by two medics, the head of department (respondent d1) and the deputy head of department (respondent d2), and that the head nurse was informed about the project and supported it, but was not proactively involved he provided a more critical and almost ‘outsider perspective’ on the implementation of CIRS at the department. Interviewing the head nurse was also important as it brought in the entire nursing perspective. Nurses are naturally different to doctors; for example their job at the department is their only job and they spend more time there (they do not rush off to their private practices at lunch time). The nursing job is heavy labour and not always as well respected as the work of doctors. When the head nurse started working at this hospital 40 years ago ‘doctors were Gods and nurses were nothing’. A lot has changed since and
especially at this department all staff are encouraged by the head of department (respondent d1) to actively partake in discussions and to speak out. However, there is sometimes friction between the two professions when doctors do not share all the information with nurses, or when doctors expect nurses to run after them in order to comply with regulations for example regarding the prescription or administration of drugs, or obtaining signatures for patient records.

The head nurse had first heard about CIRS in one of the department’s (doctors’) morning meetings a couple of months ago where the idea was introduced by the medical lead and generally well perceived by the attending medical staff and with enthusiasm. The medical lead encouraged staff to ‘ponder about it’, ‘if it was something for our department’. However, the head nurse had underestimated the importance of CIRS, given the attention it was given now, and was somewhat taken by surprise by the implementation, already *having forgotten what that [CIRS] was all about* (respondent n7). CIRS is something that is currently not offered or promoted by the Vienna City Hospital Association (WKAV) and therefore it is implemented independently at the department. However, it is something desirable but not something that would be necessary. Although he has no experience whatsoever with CIRS he knows about the complexity of such implementations. He made the painstaking experience of implementing the IT system which finally took 15(!) years to be implemented. The Vienna City Hospital Association (WKAV), which this hospital belongs to, is *an organisation whose mills grind very slowly*. Considering his own upcoming retirement over the next years he was not keen on getting actively involved in CIRS, although stressing that he was not against it or planning to inhibit it in any way.

The head nurse emphasised that ‘quality’ (the term quality rather than safety was often used by respondents) at the department was high and that already a lot was being done. Compared to the medical lead the head nurse could also
point to a number of individuals in speciality subgroups in the department who were his contact people regarding quality. However this was not due to special qualification or training staff had received but that they were the leaders of respective subgroups and thus ultimately ‘responsible’ for quality in their area. Asked about a main contact person for quality and safety, such as a risk manager, he could name an individual from the directorate (i.e. the hospital’s risk manager) but at the same time stressed that ‘this isn’t really a contact person, we really don’t have anything to do with him’ (respondent n7). Like the medical lead the head nurse stated that staff had no knowledge of or had received any training in CIRS or error science. Apart from the half-hour training session with Expert 1, the pyramid system, and word of mouth no further training or promotion of the project was planned. At the time of the interview frontline staff [they were not present at the training session] didn’t know anything about CIRS and didn’t even know when this is about to start (it had already started with the training session).

Knowing about the complexity of implementations his expectations in CIRS were limited. He saw it as something that would require substantial effort and as he was not proactively involved in it could not tell how much would be done in that respect. He gave an example from a problematical situation long time ago where a CIRS might have helped finding out about a problem. However, he himself was not sure if he had or would use CIRS for reporting concerns. He also expected that in the first month almost no reports would be submitted. In general the proposed start up time of three months in which Expert 1 would act as the CIRS trustee was seen as being too short and he would estimate that at least double that time (six months) would be needed. The pyramid system and word of mouth could work in some areas but not all. He mentioned the situation of a high number of part time staff, some of which he didn’t even see for a month. In general the one training session was not enough and front line staff at
the moment did not know anything about CIRS. More information and meetings or talks between staff would be necessary.

He also verified that although CIRS was initiated by the medical lead they were not ‘leading’ it. There was no ‘CIRS Master’ at the department and ‘accountability was hanging in the air’. However he had a few individuals in mind at the department who could at least ‘officially’ be appointed as leaders. This however wouldn’t mean that they were actually qualified to do so. Due to his limited knowledge of CIRS he also wouldn’t know how to assess the project and answered more philosophically with the question ‘how do you measure success?’.

However he assumed that success may be measured to some extent through the number of reports submitted on CIRS.

The head nurse’s view (respondent n7) may be summarised as:

1. **Why:** initiated by medical lead; the Vienna City Hospital Association does not offer CIRS and therefore CIRS is being implemented independently at the department; CIRS wasn’t perceived by him as something so important; the CIRS implementation is desirable but not a necessity

2. **Knowledge:** no knowledge about and experience with CIRS; his experience is that such implementations take very long and knowing about the complexity of these things and considering his upcoming retirement he is, although not against CIRS, not putting any heart sweat in it

3. **Experience & training:** nursing staff did not have any training; nobody from the nursing staff knows more about CIRS than he does; no training or promotion of CIRS planned other than through the pyramid system and word of mouth

4. **Benefits:** limited expectations, nurses should communicate their problems in CIRS but if this is about to result in improvements it will require proper
evaluation and workup; at the moment front line staff know nothing about CIRS

5. Progress report: no formal progress report planned but there should be a report and feedback; first month no reports expected but staff 'not against it'

6. Barriers: a start up phase of three months with Expert 1 is too short; evaluation, workup and feedback will be necessary; fear of blame; doctors do not want to admit when they made mistakes; implementations always take very long, the mills of the Vienna City Hospital Association grind very slowly; more information necessary; staff need pressure otherwise there will be no result

7. Accountability: No project champion in the department; the accountability ‘hangs in the air’ although certain medical subgroup leaders could in his opinion potentially take the lead

8. Assessment: difficult to measure success; probably through the number of incoming reports

6.4.5. Discussion

Interviews with medical and nursing lead showed that the OEGGG CIRS project at the department was initiated from the medical side. The OEGGG CIRS was being implemented at the department because the Vienna City Hospital Association (WKAV) did not offer a CIRS. The OEGGG CIRS was implemented independently from the rest of the hospital. As a non WKAV project the OEGGG CIRS was a no, or a low, budget project with only the annual administration fee of 350 Euros being budgeted for. However this was not explicitly voiced by
either of the two interviewees to be a problem. Nevertheless their perception of the project differed in several other ways. The medical side saw CIRS in a very positive light and with great enthusiasm. CIRS was ‘easy to use’, didn’t require a lot of resources and was expected to be carried by staff who would perceive it as an additional opportunity for meaningful engagement with error. CIRS was perceived by the medical lead as something ‘external’, a system that already existed and that needed very little additional input from within the department. According to the medical lead communication at the department was already very good and CIRS just an additional opportunity for sharing incidents anonymous and with a wider group; incidents which - so the implication - had already been discussed within the department. In that way the department as a whole could both contribute to and benefit from lessons learned across the entire network of participating hospitals. There was clearly some excitement amongst the medical lead to becoming one of the first Women Hospitals in Austria to use CIRS.

The nursing lead on the other hand was a little more reserved and didn’t resemble the medical leads’ excitement of becoming one of the first hospitals in Austria to use CIRS. CIRS had been initiated from the medical lead and the head nurse was not proactively involved in it. The head nurse also expressed that he would not get involved too much in CIRS until his upcoming retirement. This suggests that he saw the implementation as something quite complex and substantial as his retirement was still about two years ahead. This fits in with his other comments which suggested he saw CIRS more as developing into an ‘internal system’ that needed incorporating into the existing organisation and that this would take time. To his knowledge there was no active resentment at the department against CIRS but he expected that nurses would perceive CIRS as additional workload. If it was to have any effect more information and training would be required and feedback to the reports would be essential. His
experience was also that staff ‘needed to be pushed a little’, otherwise there would be no results.

In summary there was a perception amongst the medical lead that CIRS will be rather easy while amongst the nursing lead the perception was that if it was to have any effect it would require additional resources and time. Strikingly both the head of department (respondent d1) and the head nurse (respondent n7) did not base their statements on experience with CIRS. They had no experience with CIRS and appeared to know fairly little about the concept. They also had not, not even once, logged on to CIRSmedical - not before, during, or after the training session. It was the researcher, who had already acquired a username and password from the deputy head of department (respondent d2), who passed on login details to the head of department following the interview. Together with the researcher the head of department took his very first look at CIRSmedical (this was already after the official implementation and training session at the department). His first experience with CIRS was that he did not understand some of the requests on the input form and he was surprised that he could only choose one option in the multiple choice menu. Furthermore, when looking at the existing reports he wondered why nobody had commented on them. He then wrote a comment himself but wondered why it didn’t appear on the system immediately. This shows just how much he had relied on and trusted Expert 1 and his deputy (respondent d2). His first experience with CIRS as a user was probably quite different to how he might have first anticipated it (and had already promoted and recommended to his staff).

The following section presents findings from the questionnaire. The questionnaire was targeted at front line staff and aimed to verify information from the interviews and to get a perspective on CIRS directly from the sharp end.
6.5. Staff perspective (Questionnaire)

After obtaining the department leaders’ view on the implementation of CIRS at the department this part of the study aimed at getting a first hand and anonymous view of the very people that are expected to use CIRS. These frontline staff principally consist of medical and nursing staff who work in one of the following areas at the department: obstetric ward, labour room, nursery, gynaecology and oncology ward, operation theatre, as well as an outpatient department which includes the gynaecology, pregnancy, and hormone ambulance. In total the department employs around 100 staff.

6.5.1. Introduction

Based on the literature and the early familiarisation with the project (see appendix E), in particular observation at the CIRS training sessions and informal talks with potential CIRS users, a staff self-administered questionnaire was developed. The questionnaire consists of 40 questions, 31 of which are multiple choice and nine of which are open ended questions. Completing the questionnaire takes about 20 minutes. In total 75 questionnaires were distributed. According to the gatekeeper respondent d2, the head nurse respondent n7, as well as the chief secretary respondent 13 this covered all potential CIRS users, with the remaining staff being auxiliary staff who ‘would not be able to fill in such a questionnaire’ (for example a cleaner whose German skills are not sufficient). The return rate was 51 percent, with 38 questionnaires being returned to the researcher. The questionnaire can be found in appendix D.

6.5.2. Questionnaire objectives

Observing training sessions at various other departments had already shown that staff were generally interested in CIRS but that this one training session did not provide sufficient time for voicing and addressing numerous issues staff
may have regarding patient safety in general and CIRS in particular. In order to get a general and anonymous overview of how staff made or made not sense of CIRS at this point in time, the very beginning of CIRS use at the study site, a self-administered staff questionnaire was distributed to all potential CIRS users. The questionnaire aimed to capture how staff made sense of the environment in which CIRS was expected to flourish and how they perceived CIRS.

The questionnaire was targeted at objectives:

3. to investigate why CIRS has been implemented from a stakeholder perspective
4. to collect empirical evidence of supportive measures or otherwise barriers to CIRS; and
5. to investigate how meaningful it is for staff to use CIRS

The thesis so far suggested that patient safety is concerned with the entire health care ‘system’ and likewise that CIRS needs to be seen as one element of a wider patient safety concept. Given that this questionnaire was distributed at the beginning of CIRS-use at the department it encompassed a wide range of topics. This should allow identifying those areas that are of particular concern to staff at this department. Due to the general approach of the questionnaire a detailed categorisation of questions did not seem useful as it bore the danger of ‘over-classifying’ the questionnaire and ending up with a category for each barrier and question. Therefore only a principal distinction was made between more general safety attitude questions (‘safety attitude questions’ 1-15) and those more related to the implementation and use of CIRS (‘CIRS’ questions 16-40).

In addition, as questionnaire and semi-structured interviews are very similar research tools (for example Robson, 2002), the questionnaire was designed in
a way to allow comparison between the two. 21 of the 30 questions from leadership interviews were incorporated into the 40-question staff questionnaire. With a few exceptions (C.17-C.19, which were targeted more at personal perceptions) these questions allowed direct verification and/or comparison with information provided by leadership in interviews. With the benefit of hindsight from interview data the analysis also allowed to validate/compare additional questions, such as question C.22 “Do you have access to a computer in order to use CIRSmedical?” or question C.28 “Do you wish to have ongoing support for using CIRSmedical?”. For the mere purpose of presentation these answers to questions are clustered into paragraphs and do not follow the exact sequence of the questionnaire.

6.5.3. Findings

After the initial observations and talks as well as interviews with the medical and nursing lead (section 6.4) this section provided a broader and anonymous view from frontline staff on their attitude to safety and perception of the OEGGG CIRSmedical project. Findings from the questionnaire suggest that staff perceive quality management as something important, yet not something systematic at the department with an overhead to turn to for support. Staff could not reach out for support as 60 percent didn’t know who to turn to regarding quality issues in the department. Likewise they were not being efficiently reached by the hospital risk manager as 37 percent of staff did not even know that the hospital had a risk manager.

The overall stand towards quality management was that it is something every individual is responsible for. This was also manifest in that quality concerns were not always shared with the rest of staff and if, those issues were preferably discussed in the small work group (about three other people). This might be related to the way incidents are currently being dealt with at the department. Respondents pointed to a lack of reaction on critical issues that
were already known in the department. Incidents that had been identified were
often no followed up, the root cause not identified and thus a reoccurrence not
inhibited. Furthermore some staff had experienced negative feedback when
voicing their concerns openly and constructively. Even if this was mostly in an ‘it
doesn’t concern me’ kind of attitude and not in an open ‘blame and shame’
approach it nevertheless caused frustration in the person that had shared the
incident. It is also possible that a lack of reaction to known discrepancies at the
department may have discouraged staff from sharing new incidents because it
would be meaningless if no action followed; something that will also apply to
CIRS. That critical incidents had been discussed in the department but did not
trigger any constructive reaction also points to a lack of a systematic approach
to error management.

The OEGG CIRS project might therefore be seen as a new element in the
department’s (unsystematic) endeavours in improving quality of services. But
how does the implementation happen and how is CIRS perceived by staff? The
results of the questionnaire show an overwhelmingly positive attitude towards
CIRS. Although not everyone had been aware of the upcoming implementation
and some people had still not even heard about CIRS, the idea of implementing
it at the department was positively received. Importantly staff did not fear that
the implementation was a kind of control organ superimposed on them. The fact
that not everyone was aware of the project does not comply fully with the
medical lead stating that CIRS was ‘a wish from staff, but it does corresponded
with the statement of the head nurse that, to his knowledge, at least nobody of
the nurses was against it and that there was some enthusiasm about it.

The idea of a CIRS also seemed relevant considering that about half of the
respondents had experienced critical incidents in their work. However there was
also a group of staff who stated they had never observed or witnessed a critical
incident. According to the patient safety literature this is highly unlikely and
stems from staff being unaware of incidents. That staff do not recognise (all) such incidents as critical incidents that are worth reporting may be related to the fact that almost all staff (92 percent) haven’t had any error management relevant training or otherwise experience with a CIRS. This also became manifest in answers concerning possible barriers to reporting. These answers did not point so much to a problem of the safety culture (i.e. attitude to safety) but to a lack of knowledge about how CIRS works, what and how to report, or how safe it really was in terms of anonymity to use CIRS. About half of the respondents said they did not have enough information about and trust in the system for using it. Likewise they did not trust the CIRS trustee, which was a reminder of the concerns raised about the role of a CIRS trustee during the CIRS training session. At the same time many staff stated that principally they had no problem sharing reports anonymously with a third party, suggesting again that this was rather a matter of being adequately informed and not pure resistance. The majority of staff also explicitly stated that they wished ongoing support with the project. Considering these facts it seems important that adequate training is being organised for staff in order to overcome these barriers to reporting.

Once staff trust the system and know what and how to report CIRS will need to reap some benefits for them. Staff did not formulate a specific kind of feedback they would expect but it was apparent that they expected some kind of visible action following the reports and that this action should ideally result in a reduction of errors at the department and a better and safer work environment.

In summary the idea of having a CIRS at the department was well perceived although staff had some concerns regarding the anonymity of the system. Given the lack of training they had received staff were found to have little knowledge about systematic error management and CIRS and in the need for adequate training. The experiences with critical incidents at the department suggests that
CIRS can be relevant to staff but that due to a lack of response to already identified problems staff may be discouraged to report new incidents in CIRS. Therefore attending to known problems may be another key factor in the success of failure of the CIRS project. So far CIRS is seen as one of many improvement projects and not as a panacea that could potentially help to communicate a number of other (and pending) quality issues. More than half of the staff did not give an estimate of how many reports will be submitted, with the rest expecting 1-5 reports coming in per week. Findings in the questionnaire suggest that a number of issues, from anonymity, to training, or things such as access to computers, will need addressing before people seriously consider using CIRS. Once these barriers are overcome a lot will be dependent on what kind of feedback is being provided and if CIRS can establish itself as a unique and useful patient safety tool or if it will continue to be perceived as just another management trend.

Interestingly, like in the leadership interviews, staff did not base their estimations on any experience with CIRS as at the time of the questionnaire only one respondent had already been to the CIRSm edical online reporting form.

6.6. Summary

CIRS at the department was initiated by the medical lead and through their personal contacts with Expert 1. It was driven by the medical lead with the nursing lead taking no proactive part in the project. The head of department, who himself had little knowledge about CIRS and had never used or visited the CIRSm edical website, took the stance that CIRS was useful, and as it didn’t need any additional resources and was ‘easy to use’ should be offered to staff at the department as an additional way for communicating incidents. There was an expectation that CIRS would run by itself, with no need for a CIRS master or
training other than the training session by Expert 1 and sharing how the system works through word of mouth. There was also no need to systematically analyse or monitor the project - staff would benefit from the system through a learning effect just by using it if they wanted to.

Findings from the questionnaire can probably be epitomised in two statements: first, staff had a generally positive attitude towards CIRS, and secondly staff had very little experience and knowledge in error management and CIRS. Observation at the training session and answers from the questionnaire suggest that frontline staff are in need of additional training and required more guidance in CIRS. Many questions regarding CIRS were still unanswered, either due to a lack of time during the CIRS training session, or due to a lack of a CIRS master or a quality delegate to turn to in the department. To close with the words of the head of department: time will show if CIRS will be a success at the department or not.

The next chapter will present findings from the fieldwork observation of CIRS in use at the department.
CHAPTER 7: RESEARCH FINDINGS AND ANALYSIS II (FIELDWORK OBSERVATION)

7.1. Introduction

This chapter introduces the findings from the fieldwork observation at the department. These findings represent the last stage of data collection, after observation of the training session, interviews with the department leadership about the strategy for CIRS, and the questionnaire with front line staff about their safety attitude and initial perception of the project. This chapter considers ‘CIRS in use’ at the department. The observation took place 18 months after the formal introduction of CIRSmedical at the department (training session), at a time when it was already apparent that staff were using the system very little. Staff from different ranks at the department were observed over a period of five months in 14 non-consecutive observation days, which are referred to as ‘Observation Days’ or OD1,2,3 etc. Staff are referred to in the same way as in previous sections, i.e. respondent d1 (for a doctor) or respondent n7 (for a nurse). Patients are referred to with capital letters (for example patient K). This relates to the consecutive listing of patients during one observation day, for example ‘patient K on OD2’ is not the same person as a ‘patient K on OD7’, and the text might not mention a patient J beforehand. Incidents are described as ‘not being reported’ in those instances where no similar anonymous report could be found in the entries on the CIRSmedical website.23

After this introduction section 7.2 provides information on the reporting frequency to CIRS over the period of the study. The remainder of this chapter is

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23 More information on the methodological intricacies of the fieldwork observation can be found in the methodology chapter throughout section 5.5.
then mainly structured around the patient safety framework, illustrated below in figure 7.1, which was developed from the qualitative analysis of ethnographic data as described in the methodology chapter in section 5.6.5. The patient safety framework consists of four themes and fourteen categories. The individual sections of the patient safety framework are explained in subsequent sections. Sections 7.3 to 7.6 introduce findings of the fieldwork observation according to the four themes ‘possible CIRS reports’ (section 7.3. with the sub-categories ‘clinical issues’, ‘communication issues’, ‘documentation issues’, and ‘other issues’), ‘barriers to reporting’ (section 7.4. with the sub-categories ‘little awareness’, ‘low priority’, and ‘other barriers’), ‘organisational issues’ (section 7.5. with the sub-categories ‘facilities’, ‘I.T.’, ‘processes’, and ‘culture’), and ‘practical implications’ (section 7.6. with the sub-categories ‘documentation’, ‘integration of staff’, and ‘integration of organisational reports’). These findings are complemented with a section on ‘results’ (section 7.7), providing information on the CIRS feedback meeting held by Expert 1 at the department and elaborating some of the consequences of the project, before closing in a discussion in section 7.8.

Figure 7.1: Patient safety framework
7.2. Reporting frequency

An important indication whether or not CIRS is accepted at the department is how frequently CIRS is being used. Despite the early enthusiasm of many of the stakeholders involved, the OEGGG project being a voluntary and proactive move towards safety, it became apparent that CIRS was used infrequently and less than Expert 1 and staff at the department had anticipated. Expert 1, who was receiving incoming reports as the CIRS trustee, stated that only a handful of reports had been coming in. This information was verified by the researcher in visiting regularly the CIRS website which gave insight into the pool of reports from all participating hospitals. After three months there were a total of 57 reports for all of the (at that time five) participating hospitals on the system. Until the start of fieldwork observation all hospitals together had reported a total of 215 reports onto the system. However, the majority of reports came from one hospital that had invested in additional consultation from Expert 1. The other hospitals reported infrequently and were considered by Expert 1 as underreporting. In addition it was also observed that the ‘comment function’ on the CIRS website, supposed to be a lively exchange amongst health care professionals on specific incidents, was little used. To anticipate from the CIRS feedback session by Expert 1, which was held towards the end of the fieldwork observation period and upon leaving the field, the study site department had reported a total of 48 reports over a period of 22 months. The findings from the feedback meeting are presented later in section 7.7.

Because of the low reporting frequency a more in-depth fieldwork observation was necessary and this was targeted mostly at objectives

4. to collect empirical evidence of supportive measures or otherwise barriers to CIRS; and
5. to investigate how meaningful it is for staff to use CIRS.
Those issues relevant to safety and CIRS that became apparent during the fieldwork observation are presented next.

7.3. Possible reports to CIRSmedical

7.3.1. Clinical issues

This section presents the category with contextual codes that were most closely associated with clinical core issues at the department.

T34 incorrect sample taking: On OD14 the theatre nurse (respondent n43) takes samples that were taken during the operation to the central laboratory (another department in the same hospital). The laboratory worker marks out two errors: (1) the sampling method was incorrect (not the tissue itself should be brought but only a liquid in which the tissue was put for a couple of seconds) and (2) the wrong form was used for documenting this type of sample. The theatre nurse (respondent n43) says that this type of sample is taken only every other year. Both the theatre nurse and the laboratory worker could have reported the incident on CIRS but this was not something they considered. However, the theatre nurse (respondent n43) said he will communicate this internally amongst his theatre nursing colleagues. He also mentions “a (theatre) book where I can document this” (respondent n43).

Comment: As the hospital as a whole does not run a CIRS the laboratory worker has actually no access to a CIRS. The theatre nurse wants to share the incident but this only happens internally amongst fellow theatre nurses and in an informal way. He had heard something about CIRS once but then he just has so little information about and knowledge of CIRS in general and the OEGGG project more specifically that this incident (like others presumably) is not perceived as a possible CIRS report. Furthermore it is up to his perception of
the usefulness or severity of the incident to document this incident in the ‘theatre book’, which is a documentation map for theatre nurses. This however is also more of an ‘informal’ way of documentation, there is no requirement to have such a book for theatre nurses itself, nor are there any guidelines or procedures what, when, and how to document incidents in the book.

T36 pain after C-section: On OD9 the charge nurse from the obstetric ward (respondent n9) mentions that since about three weeks patients who had a C-section suffer from and complain about pain in their right shoulder. In the discussion in the morning meeting a causal connection is made between shoulder pain and a new positioning method for patients with C-sections, which had only been introduced about three weeks ago. The head of department wants to follow this up.

Comment: The incident is shared internally but not put on CIRS. Considering that this new positioning method is also used in other Women hospitals this incident could be shared through CIRS to alert others. A search may also be conducted to see whether other Women hospitals had similar problems with the new positioning method and how they approached the problem.

T37 medical strip and spray dressing: In the morning meeting on OD13 respondent d38 (a senior physician) starts a discussion on whether post operative medical strips or spray dressings should be used. He observed that nurses on the gynaecology ward sometimes take them off too early (to check the wound) which sometimes causes irritations and which may increase the risk of post operative wound infections. When discussing what the standard procedure at the department is it turns out that there are actually two different procedures in use, one on the gynaecology ward and one on the obstetric ward. Patients from the gynaecology ward get a medical strip in the operation theatre. After two to three days this strip is replaced by another and watertight medical strip, which allows the patient to take a shower. Patients from the obstetric ward
get a spray dressing in the operation theatre. This spray dressing is more expensive but it does not need to be changed, it is more convenient for the patient (less painful and the patient can shower right away), at the same time it reduces the risk of post operative infections. The head of department suggests using the spray on both wards: “Can anyone tell me what the difference is between a cut on a gynaecology and an obstetric patient? Let’s do that [the spray] with all patients and on the entire department - the pain-free hospital. Do we need to write anything? No... you will communicate that in your morning meetings anyway.”(respondent d1)

Comment: This incident is but one manifestation of a common practice in the department to communicate things internally (also in meetings) but without issuing statements or documenting it. There are also no minutes taken of morning meetings. Better documentation may facilitate dissemination of this new procedure and help ensuring it actually becomes the ‘standard procedure’. Documenting when it was introduced may also allow for causal connections between use of spray for all patients and (possible) improved outcomes, such as a lower post operative infection rate, shorter patient stays, increased patient satisfaction, and ultimately lower costs (no wound infection treatment required).

T32 wrong patient instruction: On OD1 head of department and his deputy (respondents d1 and d2) go to see patient K on the ward in a four-bed room. After caring for patient K and before leaving the room the head of department exchanges a few words with two other patients (patients B and L). He finds out that patient L was wrongly instructed to withhold her urine. Certain procedures require the patient not to urinate for a period of time. In this case however this was the wrong instruction and caused unnecessary discomfort to the patient. The head of department allows patient L to see the bathroom. Once outside the four-bed room the head of department calls all nearby nurses quickly together to a spontaneous group meeting on the ward and addresses them (without
blaming anyone directly): "Whoever told the patient not to urinate, this is wrong and utter nonsense; please pass this on to all the others so it can be avoided in the future; for patients with this clinical pattern withholding urine is very painful and inhibits the healing process", (respondent d1)

Comment: This no harm event caused unnecessary discomfort to the patient. The head of department, who by chance found out about it, was not interested in blaming anyone but in the comfort and safety of the patient, that correct treatment and care are provided and that everyone knows about it so it would not happen again. This may have further been anonymously shared on CIRS. However, nobody in that small group mentioned it as a possible CIRS report and it went unreported.

T56 Hepatitis C patient: The husband of a high risk (Hepatitis C) patient who was together with the patient in the operation theatre during her C-section leaves the theatre area still wearing his operation theatre clothes and slippers. He then enters the delivery room area to go to see the bathroom, changes his clothes there, ‘disposes’ them into one of the open lockers and leaves (to go for a cigarette). One minute later one of the theatre nurses comes looking for him because of a possible infection risk through the (Hepatitis C blood) contaminated theatre clothes he was wearing. As the husband has already left the theatre nurse returns to the operation theatre and does not follow the incident up any further.

Comment: Hepatitis C is transmitted over blood, including dry blood. Although little is known about how long exactly the infection risk is active it is believed that contact with contaminated blood to up to one week presents an infection
risk. It is possible that contaminated material (theatre clothes) might spread and create a safety hazard. This incident was not reported.

T9 surgeons late for operation: On OD14 an operation that is scheduled to be led by two senior surgeons starts with just one as the other one is late. Surgeons who are late for the operation cause substantial problems for the rest of the team as the entire operation plan for the (half-) day needs to be altered. “Unfortunately he is always late. I mean, I don’t care when he comes, but then you can’t write the operation plan like this. At the start of the day we always waste time and then together with the emergencies this all adds up” (respondents n43 and n44).

Comment: The researcher observed that operations started without all staff being present on more than one occasion, also with other doctors, but especially with this particular senior physician. This was further verified in conversations with other staff from various ranks. While other members of the surgical team were ‘not particularly happy’ about it they at least seemed to accept this behaviour: 7 have mentioned it once but what else can I do? He is a doctor and they can just afford to do that and know they can get away with it (respondent n43). Apart from possible negative outcomes in case of an emergency the fact that operations start before everyone is present shows how difficult it would be under the prevailing culture to implement recommended safety standard procedures, such as preoperative safety briefings. Already standard in hospitals that are at the forefront of patient safety surgical teams hold preoperative meetings where, in order to create a climate of improved communication, collaboration, teamwork, and situational awareness, the surgical team reviews together and before an operation starts pertinent information about the patient and the pending procedure using standardised

24 the researcher informed the head obstetric nurse who then called a cleaner to get rid of the clothes and clean up the area
checklists. Research shows that surgical teams that have preoperative safety briefings better work together, communicate well, can quickly detect and more easily avoid errors, and make a substantial contribution to safety (DeFontes and Surbida, 2004).

The observation does not suggest that operations at the study site always started without everyone being there. However, when it happened there was an attitude of accepting it and finding a way around it. Nobody had the time to investigate the root cause of the problem or the ‘guts’ to either bring the entire operation to a halt, waiting until the surgical team was complete, or to report the colleague. A deeper rooted problem is that there actually is (unbelievable as it may sound) no written procedure on the conditions for starting an operation.

The lack of standard procedures allows operations to begin without all members of the surgical team being present. Furthermore, in connection to CIRS, research has found that breaching of procedures increases reporting (see chapter 4). Accordingly where there are no procedures to be broken this will not be reported. If preoperative safety briefings were to be introduced at the department they needed to be made compulsory. A prerequisite would be a procedure under which conditions an operation is allowed to begin. Otherwise a preoperative meeting might be bypassed from staff that are late.

T57 vacuum birth under suboptimal conditions: On OD10 in the nursery nurses and the external paediatrician whisper secretly about a colleague (a doctor) who had performed a vacuum birth despite the fact that the child’s umbilical cord was twice wrapped around the child. The newborn child has some marks on his head which are caused by this type of delivery. They discuss the risks of this certain procedure (one of many procedures) in this particular situation and they appear to agree that this was probably the fastest but not the safest method.

Comment: Although these nurses together with the paediatrician whisper about the incident no comment or feedback is provided to the doctor that performed
the vacuum birth, neither is there a noticeable intention to do so at another point in time. They also discuss the work of another colleague (a doctor) who uses an, as they argue, ‘outdated method’ for deliveries. CIRS may have been used in this instance to make an anonymous and non-blaming report. Apart from the general willingness or unwillingness of staff to report this incident in CIRS there are at least two factors that may inhibit reporting in this particular situation. First, the department does not have its own paediatrician and paediatricians only come in from another nearby hospital as needed. It is unlikely that this paediatrician knows about the CIRS project at the department (considering the power relations it is more likely that in this instance the doctor would have reported about the other doctor, rather than a nurse about the doctor, even anonymously). Secondly, the CIRSmedical website states that reporters should only report incidents that they themselves have caused or observed (no 3rd hand reports). The nurses and paediatrician in this case may understand their position as ‘not directly involved’ and be discouraged from reporting. Another operational question relates to the time of the incident. What time should be reported on the form, the time the incident occurred or when it was first detected?

7.3.2. Communication issues

This section presents the category with contextual codes that were most closely associated with communication issues at the department.

T45 patient not handed over (reported): On OD4 one of the senior physicians (respondent d8) criticises that two patients were not handed over to him. He was in the undesirable situation of suddenly standing in front of two patients he didn’t know. He then had to inquire from the ward nurse about them. It turned out that a junior doctor from the previous shift had been in charge of these two patients, had ‘forgotten’ to hand them over, and had already gone home.
Comment: Respondent d8, an avid supporter of CIRS, submits two reports into CIRS (one for each patient).

T47 patient information for transfer patient too vague: On OD4 a patient is transferred from another hospital with a clinical report that reads “globulaere Neoplasie”.

Comment: The senior physician (respondent d2) finds this information too vague as this can refer to a great spectrum of symptoms, from simple pimples to severe health issues. This is not detailed enough a report and not an adequate for a transfer patient. Respondent d2 calls the hospital that sent the patient to inquire about him. This results in loss of time, delayed treatment, and patient dissatisfaction as he has to provide information on his medical history again.

T43 same patient name: On OD2 the outpatient department brings patient files for patients that will be admitted the next day. The head nurse (respondent n7) notices that two patients have the same surname and a similar age. On OD5 patients with very similar (and foreign) surnames share the same room. On OD8 two patients with the same surname are on the operation theatre list. On OD10 two patients with same first and last name and the same birth year are on the operation theatre list.

Comment: In a conversation on OD8 with respondent d27, an anaesthetist that works at multiple other departments, he confirms that same patient names are indeed a frequent occurrence. According to respondent d27 it is not uncommon that two patients have the same first and last name, same birth year, are in the same department but in different areas, and may have a very similar patient record with only marginal differences. Mistaking one patient for another is a constant threat at the hospital. No information is provided of how often patients are actually mistaken. What becomes clear however is that there is no
systematic procedure, let alone a digital patient identification (barcode) to prevent a mix up of patients, to issue a warning and raise alertness amongst staff that there are two patients that can be potentially mistaken. Some staff at the department try to work around this issue and recommend highlighting patients with same names with a marker. As a constant potential threat this could be reported on CIRS.

T46 wrong patient birth date through telephone: During an X-Ray meeting on OD4 it is found that one of the patient's birth date is incorrect. Apparently this happened because the birth date had been given over the phone.

Comment: A lack of standardised communication, as is common practice for example in aviation where pilots use only standardised English terms in a command and control language, was a contributory factor to this incident. The observed senior doctor who is notified of this incident is already more than 24hrs on duty. Although he describes this as a perfect example for a CIRS report, at the end of a long shift the incident goes unreported (at least for the time being, he might have reported the incident later on). The respondent also shows signs of fatigue, for example he accidentally and without noticing reopens and starts discussing a patient file that had just been discussed.

T55 high risk patient: On OD8 a C-section is done with a patient that has Hepatitis C. The doctor performing the intervention only finds out after the operation that he was operating a Hepatitis C patient. The doctor complains to the head midwife that he should have pointed out again that this was a high risk patient.

Comment: Although it was mentioned in the morning that the patient suffers from Hepatitis C the doctor overheard this. The doctor and the head midwife discuss how difficult it is to understand others during the meeting referring to colleagues who 'mumble something in their hand', 'sit in a corner of the room
where nobody can hear him’ or ‘somebody is telling a joke at the same time’. There is no standard procedure that would mark out high risk patients.

T24 department specific abbreviations: On OD10 the ward physician on the gynaecology ward (respondent d34) told the researcher how frustrated he was with the way junior doctors and ward physicians were introduced to their tasks at the department. Junior doctors usually only spend a couple of months at the department and they are not familiar with many of the terms and abbreviations used at the department (a problem the researcher can sympathise with due to the difficulties he experienced at the beginning of his observation). Therefore respondent d34 was in the process of putting together a list of abbreviations “that nobody knows, for example LNR - German: Letzte Normale Regel - which stands for ‘last regular period’” (respondent d34).

Comment: When reviewing archive material and folders in the preparation for the observation the researcher came across a list of abbreviations for the obstetric ward. This is another case where information desperately sought by one worker in the department already existed (at least in parts) in another part of the department. Imperfect communication (also from the ward physician who did not know who to approach with his problem) and imperfect sharing of information led to this situation. A standardised list that is easily visible, accessible or distributed to all could also be in the interest of other hospital staff that are not at the department on a permanent basis, such as paediatricians from other hospitals, anaesthetists, psychologists, pharmacologists, or radiologists. Respondent d34 could have shared the problem with abbreviations and possible implications on CIRS.

25 The researcher gave respondent d34 a copy of his list of abbreviations.
7.3.3. Documentation issues

This section presents the category with contextual codes that were most closely associated with documentation issues at the department.

T31 editing of clinical report: On OD 1 respondent d2 notes, as he has noted previously, that some colleagues, especially new to the station or young colleagues, write (two specific elements of) the clinical report on separate sheets. However the house policy is to have all information on one single page as it is possible to overlook something with two pages. Familiar with the house rule a senior doctor who has to verify the report expects a one page report, reads the first page and verifies the entire report of what actually is a multiple page report. According to respondent d2 this is a reoccurring problem.

Comment: The colleague who wrote the multiple page report is currently on holiday. Respondent d2 leaves a handwritten note for this colleague. Although respondent d2 feels this would make an ideal CIRS report he does not, on this occasion, use CIRS. However, he states that he may report it later ‘if there is enough time’ (respondent d2).

T41 patient records not verified: Patient records need to be verified by senior physicians. On OD6 the head secretary (respondent 13) finds out that one senior physician had apparently forgotten to verify ‘his’ records, as there are 35 records pending. The head secretary informs the senior physician so he can work through this before anyone else finds out.

Comment: What the head secretary does not mention is that one of the consequences of unverified (pending) records is that they cannot be transferred back to the outpatient department. All patient records of discharged patients should be transferred back to the outpatient department within 24 hours because of the possibility of re-admissions. In case of a re-admission the immediate patient history from this hospital is highly relevant. The incident is not
shared with anyone else and there is no investigation how ‘the system’ allows 35 ‘pending’ records.

T40 patient file transfer: On OD2 the head nurse controls admissions and dismissals and finds that some patient files had not been transferred back to the outpatient department within 24 hours, sometimes with considerable delays.

Comment: Once a patient is dismissed the patient file is ‘closed’ by a doctor and should then be transferred back to the outpatient department within 24 hours in case of a re-admission. In practice however the head nurse finds a one week old file that the doctor has not yet closed. The head nurse says that he wants to write a note to all doctors to double check their dismissals at the end of their shift to prevent this from happening. As a reoccurring problem this could be anonymously shared on CIRS.

T58 birth register: On OD10 staff in the nursery are not sure whether to record the number of pregnancies or deliveries of a patient.

Comment: It is unclear if other staff and in other documents might also mix this up. At least for now the incident is not followed up any further by staff.

7.3.4. Other issues

T35 substantial cost increase of one drug: On OD8 In the morning meeting the ward physician (respondent d30) notifies staff of a certain frequently used product which price has, literally overnight, increased by 500 Euros. He suggests a cheaper alternative drug.

Comment: Sharing this on CIRS could disseminate this information further, warn other Women hospitals and help save costs across the entire hospital (network).
T42 disposal of hazardous items: At the end of the observation on OD2 (it is already 2:30 pm, after the head nurse’s official shift end and already quiet at the department) the clerk passes by the open door of the head nurse. He assumes that a still originally packed 5kg container of soda lime had been accidentally binned and shows it to the head nurse. It turns out that the product is expired and had been binned (according to surgical staff correctly) by surgical support staff. However, soda lime consists of 75 percent calcium hydroxide which can cause skin irritations and blindness, so it is not completely unproblematic to just leave it on the hallway for the clerk to collect it. Especially considering, as the head nurse emphasises, previous events where individuals had been found searching the hospital waste. In another department one doctor was known to place expired eye drops visibly on the ward in a simple nylon bag “that was practically for the patients to take away, that was normal there” (respondent n7).

The head nurse decides that this item should not end up in the domestic waste as it could cause harm. The incident worries the head nurse as only a little while ago there was a major clear out of the operation theatre area where this product (it can’t be used in any of the machines that are in use at the department) should have been detected. “Why did nobody find it then? This is what worries me!” (respondent n7) He composes a handwritten note to the chief surgical nurse to prevent this from happening again.

Comment: Although this incident is not reported in CIRS it is discussed the next day in the nurses’ morning meeting. The incident is further followed up on OD3 and according to the pharmacy the correct handling for the soda lime is to (a) if originally packed send back to pharmacy, or otherwise (b) dispose of in the hospital’s special waste. Although the incident has been investigated and the correct handling is now known to the head nurse and the charge nurse, who

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26 A chemical mixture used in anaesthesia to remove carbon dioxide from breathing gases to prevent CO2 retention and carbon dioxide poisoning
want to share it with other nurses in respective meetings, it could have further
been shared on CIRS. A number of reports on expired drugs (soda lime, eye
drops, etc.) could point to a management issue of drugs, questioning why
expensive drugs are not used up before their due date, and this could
potentially save costs.

7.4. Barriers to reporting

7.4.1. Little awareness of CIRS

This section presents the category with contextual codes that were most closely
associated with little awareness of CIRS at the department.

T5 junior doctors and medical student apprentices don't know CIRS: OD1
Respondent d22 is a junior doctor\textsuperscript{27} who already had been at the department for
several weeks. During this time respondent d22 had completed his introduction
training and had already ‘made himself a name’ as someone who brings up
issues and likes to call things by their name. Although the doctor responsible for
the junior doctors’ training (respondent d20) may be considered ‘pro-CIRS’ the
junior doctor (respondent d22) was completely unaware of the possibility to use
CIRS at the department. CIRS hadn’t even been mentioned in the training.
Respondent d22 also stated he had not heard about CIRS from anyone else at
the department. He insisted that he had not received any kind of written
information about CIRS, although he would be interested. When the researcher
told him more about CIRS the junior doctor’s reaction was that “it can’t work
when it is anonymous” (respondent d22). It wouldn’t be useful to do this
anonymously as every patient is unique and has a unique problem that occurs

\textsuperscript{27} junior doctor or house office refer to the same position of a doctor in medical training
only in a certain situation. An observed error is a subjective perception and therefore not a true assessment of right and wrong. In addition respondent d22 stated he was convinced that he would not be allowed to use a CIRS and over the remaining two months of his service at the department.

The information given by the junior doctor (respondent d22) that CIRS had not been mentioned in their training was verified through interviewing other junior doctors. It turned out they all hadn't heard about CIRS. This was equally true for medical student apprentices as for example respondent d41, a student apprentice from Germany, who had already been at the department for three weeks and was actively involved in many of the medical activities, something that cannot be taken for granted, verified on OD13. He had never heard about CIRS. It is unlikely that he did hear something about it in his remaining time at the department (apprentices usually spend one month at the department).

Comment: The researcher then asked the deputy head of the department (respondent d2) why junior doctors were not allowed to use CIRS. He replied: "Of course all junior doctors are trained. They receive a folder with information but they just don't read it; it doesn't matter if you put it on a piece of paper or a disk - in the end it is them who have to sit down and read it, they just don't do it; also the four eye principle doesn't work, it is a disaster" (respondent d2). However, the statement that junior doctors are trained on CIRS is an exaggeration in itself because basically training on CIRS does not exist in the department. A look at the file for newly appointed staff and junior doctors (accessed through the head secretary) revealed that indeed the junior doctor was right and that the information folder does not contain any information on CIRS - CIRS is not mentioned in even one word. It is not clear where the mistake is and who would be responsible for informing them about CIRS. As a matter of fact junior staff and medical student apprentices do not know about CIRS.
T65 interdisciplinary ward team doesn’t know CIRS: On another occasion on OD13 the gynaecology ward, a joint coffee break and loose discussion, an entire interdisciplinary team, consisting of ward physician, nurses and nurse trainees, was found not to know anything about CIRS.

Comment: It appears as if the previous charge nurse of this particular ward had actively suppressed and not passed on information about CIRS (see also T12 ‘information about CIRS deliberately not shared’).

T7 interdisciplinary weekend ward team can’t find info about CIRS: Upon request of the researcher (it is a quiet evening during a weekend shift on OD5) a senior physician (respondent d25) together with nurses from the checkpoint try to find information about CIRS or risk management in the hospital. Together they search the electronic information system and can’t find anything, no information about CIRS medical or any other information on CIRS.

Comment: The researcher already knows that there is some general information about CIRS on the system. It appears as if they have never searched for this information, or used it, before.

T6 head nurse has no info on CIRS and T66 charge nurse has no info on CIRS: That there was little documentation of CIRS was further verified on OD3. When observing the head nurse (respondent n7) it became apparent that although he appeared generally very well organised (everything was neatly arranged in folders that occupied the entire wall of the office) and seemed to have a folder or document about almost anything he did not have a specific CIRS folder or even any kind of information on CIRS. There was also nothing such as a ‘quality management folder’. It was a similar experience when inquiring information about CIRS from the charge nurse of the obstetric ward, who is also the deputy head nurse of the department (respondent n9) (T66 charge nurse has no info on CIRS, OD3). He too seemed to have a folder for about everything and when
asked about CIRS literally jumped off his feet, looking through the folders, only not finding anything, saying “ah, it must be somewhere here, below there; maybe someone took the folder away, everything is open here” (respondent n9). He promises the researcher to look for it. In the end he finds something about the WKAV system, not the OEGGG project (also not noting a difference), in the PC. It appears as if he saw this for the first time and is clearly not familiar with it. It is somewhat surprising that he doesn’t even know whether or not there is some information about CIRS.

Comment: Surprisingly it was found on that the young ward secretaries (respondent 35), compared to clinical front line staff and the head secretary, knew comparatively much about CIRS (OD10). As they are familiar with the in-house computer system and always searched for new things they knew there was (some basic) information about the WKAV CIRS (not the OEGGG project) on the system. However, they had never been asked about it nor did they have to provide any of this information about CIRS to clinical staff. On the other hand one of the senior physicians (respondent d25) who officially holds the title ‘quality delegate’ from WKAV is not involved in CIRS and doesn’t have this information.

T10 knowledge of password: Fundamental for using CIRS is knowledge of username and password. It was observed that many of the staff who had at least heard about CIRS did not know the password. The obstetric ward tried to counter that by placing a small sticker on the PC which had the username and password on it. Still however staff were observed not making a connection between CIRS and this little sticker. Staff from the obstetric ward repeatedly stated they wouldn’t know the password.

Comment: While the idea of a sticker with username and password may be considered a good idea, especially given the general lack of information about CIRS, there was in impression that staff who claimed they didn’t know the
password expected a more formal presentation of username and password, not just being expected to obtain this information by themselves from the sticker. As it is a shared computer at the ward checkpoint it was not clear who had left the sticker there and who was supposed (allowed) using it. The perception was that the sticker better should have been accompanied by a more formal and personal introduction. Other than that it was observed that the PC at the obstetric ward checkpoint was the only one with such a sticker and that other PCs could have been labelled, especially in the senior physicians’ rooms. Senior physicians spend a lot of time there when not on the ward, for example when writing patient records, sleeping or resting during the night shift. These rooms provide the desirable privacy when reporting in CIRS. The sticker may work as a reminder for staff to use CIRS. Another potential candidate for a CIRS sticker is the computer in the outpatient physician’s office as the room provides some privacy (OD13).

T12 information about CIRS deliberately not shared: During the observation it appears as if more staff on the obstetric ward have at least heard about the OEGGG project (although they generally don’t know anything about CIRS itself) than on the gynaecology ward. One of the nurses on the obstetric ward, respondent n12, for example says that: “All I know about CIRS is that I got this little card with a username and password, I have that in my files, but that’s all I know.” It seems that someone in the department has taken the initiative and printed little (credit card size) cards with username and password information. On the obstetric ward these cards had actually reached frontline staff, for example respondent n12. On the gynaecology ward however, which recently had a new charge nurse, the researcher doesn’t see any of those cards and staff in general appear to know less about the project (for example that it had already started, username and password, etc.). Inquiring about it from the new charge nurse on the gynaecology ward he starts to look for it. It turns out that those cards do exist but had (the new charge nurse supposes deliberately)
been locked away by the old charge nurse who was known to be anti CIRS. When the new charge nurse finds those cards, now long after the project had started, he gets angry about it as he had specifically asked the previous charge nurse if there was any information available on CIRS.

Comment: This incident points out a potential disadvantage of the top down pyramid approach in sharing information about CIRS. If one of the charge nurses (high up in the pyramid) is not interested in CIRS and ‘prefers’ his nurses not to use CIRS he can effectively block out an entire ward from receiving information about and consequently using CIRS. As there was no direct CIRS person at the department to follow this up and the dissemination of information on CIRS was dependent on trust and goodwill of the upper ranks in the department this situation could prevail until it was discovered by chance.

Disseminating information about CIRS using the pyramid system seemed to be not very effective. Over the entire observation period at the department the researcher did not once see this or any other method being used to spread information about CIRS. There was very little written information available on CIRS and no one person overlooking the implementation.

7.4.2. Low priority of CIRS

This section presents the category with contextual codes that were most closely associated with the low priority given to CIRS at the department.

T69 other projects: Largely due to their relative independence and fragmentation into medical specialties staff can instigate or participate in almost any (medical) study they want. Fieldwork observation allowed seeing CIRS in relation to other projects at the department. On OD4 during the nightshift respondent d8, a senior physician, called a 24 hour telephone line (Cyrosafe, it is 4:56 in the morning) to transmit data about the newborn baby. He does that out of his own initiative. He had heard that they were looking for participants
and decided to support the program. The ward physician on the other hand shows little interest and leaves. Observation on OD9 shows the ignition of another project by the charge nurse on the gynaecology ward (respondent n10) who is running, out of his own initiative, a ‘fast track’ project to better and faster mobilise patients after an operation. However, projects do not always have to be related to clinical matters. On OD5 for example information about the department’s ‘activity day’, which was announced only the previous day, was already posted in the nurses’ meeting and social rooms, which had not been the case over the 18 months that CIRS had already been in use at the department.

Comment: The above observations suggest that some staff are highly motivated and interested in improving medical safety and put in a lot of personal effort in setting up projects. It is likely that those staff can also be motivated for other, probably more complex, initiatives such as CIRS. However, it also becomes apparent that participation in any of those projects is voluntary and not documented. In many cases colleagues may not even know about the existence of a project or who is participating in which one. In theory the overall responsibility for participation in these projects lies with the head of department but he does not have the time to overview, coordinate or document them. This may result in redundancies and doesn’t seem to make full use of the inherent learning potential within the department that could be achieved with a better information exchange about these projects. CIRS seems to be a similar ‘victim’ of a lack of an ‘overhead’ and staff are found not to identify with CIRS as much as they do with some of the other projects.

T70 investigation of thefts: OD7 Recently there are increasing thefts at the department. One of the department’s digital cameras had been stolen from one of the senior physicians’ office, a small amount of money, as well as food and drinks were missing in the secretaries’ office. This is discussed during the morning meeting and the head of department says: "I don’t want to shout it out
loud but time has come to hand this over to the professionals [i.e. the police]” (respondent d1).

Comment: It seems very clear here that this isn’t something the department can handle on its own and that external professional help is required. It may be argued that this is equally true in regards to patient safety and CIRS. However, this doesn’t seem so clear to the department. The thefts present a threat that everyone can directly relate to. Thefts are discussed on at least three of the observation days, far more often and intensely than CIRS. Why hasn’t CIRS been followed up so persistently? Is it just because getting help from the police is for free?

T59 technical support and T71 services with feedback are used: Staff, especially nurses, have been observed frequently using the technical support team. Everybody from the nursing team knows the extension and consults their service, whether it is with computer issues, a faulty patient bed alarm or a dripping water tab (OD5 and OD8). Feedback is prompt and the service good. For example during the weekend shift the electrician came quickly to fix the patient bed alarm which the nurse just noticed earlier does not work and also leaves a spare part on the ward checkpoint in case it should fail again.

Comment: The whole work environment seems to be very ad-hoc, with many unplanned events unfolding over the day, asking improvisation from staff and prompt support services. In that light it seems that important issues are associated with prompt feedback. A dripping water tab is undesirable but doesn’t fall exactly under the responsibilities of a nurse. Despite that, and probably due to its good prompt feedback, the technical support service was frequently used. In contrast CIRSmedical did basically not provide any feedback over the past 18 months. It might therefore have been associated with a lower importance and was not frequently used.
T23 willingness to report: Some of the senior physicians, although overtly not against CIRS, seem to have very modest interest reporting in CIRS. They appear quite ‘laid back’ to ‘change that will never happen’ (respondent d17 and d38). They have seen many programs come and go without having any (lasting) effect, so they also ‘take it easy’ on CIRS (ibid). Asked if he would probably use CIRS from home a senior physician is almost insulted, responding “now that would be something; I have never done that and I think it is not even possible...” (respondent d38). One of his colleagues (respondent d17) has a case for CIRS but says “no, I won’t report this now; and I have forgotten how to use it, I will just tell it to the deputy head of department and he will put it in”. Doctoral staff generally seem to lack information about and knowledge of CIRS, coupled with a lack of awareness of what kind of events may be reported to CIRS. Respondent d17 for example states (the very unlikely) that “in the past six to nine months there was nothing I could have reported on CIRS”.

Comment: That many of the doctor staff seem unwilling to report directly in CIRS may also be related to other habits, one may say the culture (see also section 7.5.4), at the department. For example it was observed that one senior physician makes all the itemisation of services (i.e. which procedures had been performed on a patient - for the finance department) for the entire department. In theory every doctor should do this by himself and immediately following an operation but that’s not the case. Maybe this contributed to a perception amongst staff that as long as one person ‘does it’ nobody else has to care anymore. This could explain why CIRS is not indoctrinated into everyone’s everyday activities but more seen as ‘the thing of the deputy head of department’ (respondents d17 and d38).
T21 time windows not used for reporting in CIRS: While staff are generally busy during the morning hours especially in the afternoon there are sometimes time windows where ‘there is nothing to do’. Time that may be used for composing CIRS reports (it takes about 10-15 minutes to report).

Comment: Where these time windows occurred time was used for other things than reporting, an informal chat with a colleague, a coffee break, or searching five minutes for a candle for the birthday surprise cake of another staff member. Although breaks and social contacts are important it shows that CIRS in the department does not have as high a status as acclaimed in the patient safety literature. That more of these time windows were observed in nursing personnel than amongst doctors might be related to the patient safety literature which states that in general nurses report more than doctors.

T33 theatre nurses don’t use CIRS: At the end of OD2 the researcher overhears a lively conversation between the theatre nurses. They are talking loud and full of emotions: “This was clearly a communication error! It’s ok you know, but then talking a lot of bullshit... about it and not admitting that there has been a mistake is absolute bollocks.” (respondent n24)

Comment: This incident is an example of ‘healthy discussions’ at the department. However, this group in particular was not involved very much in CIRS and it is unlikely that this incident was shared any further in CIRSmedical, although it seemed predestined for it.

7.4.3. Other barriers to reporting

This section presents other contextual codes that are associated as barriers to reporting at the department.
The CIRS trustee: The anonymity of the system bears in it that somebody has to de-identify reports. The design of the input mask can already prevent obtaining information that would lead to identification (i.e. not asking for details that could lead to reporter identification). However the free text passage that describes the event and the circumstances under which it occurred in the reporter’s own words, arguably the key part of the report (for example Expert 1, IOM, 2000), still needs to be checked for anonymity. This requires the role of the CIRS trustee, for checking the narrative on details that may lead to identification of any of the parties involved.

Comment: The fact that an internal CIRS trustee (i.e. someone from the department) was required for CIRS to be operational presented a, probably the, major barrier. This was evident by the number of questions and comments concerning the CIRS trustee during the training session (section 6.3) and the fact that nobody in the department volunteered to become the CIRS trustee, not at the beginning of the project and not during the course of the observation until leaving the field. Expert 1 had to ‘volunteer’ to become the department’s CIRS trustee. The same was observed in three out of four hospitals that had been observed at the beginning of the study. Only one hospital elected a CIRS trustee. There are many potential reasons why staff members did not want to become CIRS trustees, such as confidentiality, liability, or fear of rejection by peers. It may also be seen as just additional workload that staff do not really have time for. The department leadership did not clearly position itself on this matter and never communicated if extra time could be made available for executing the role of a CIRS trustee.

Apart from trust and time factors concerning the role of an internal trustee, and considering the (lack of) knowledge staff had about CIRS and patient safety, it is questionable if just any member of staff could have actually stood up to the requirements to this job. Furthermore the observation suggests that there would
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need to be at least two trustees, one for reports from medics and one for reports from nurses.

T13 time to report: On a normal dayshift from 8am until 1:25pm on OD1 with the deputy head of the department (respondent d2) the researcher wondered when respondent d2 would have had time to use CIRS. He was busy every single moment of the shift and worked without a break. Also OD1 showed how busy (this time nursing-) staff are, especially during the morning hours. The observed nurse (respondent n37) worked through her entire shift without taking a single break, only rushing to the toilet once, a stopped 1 minute and 30 seconds. Another nurse, respondent n32, when asked if anything could be improved at the department in terms of quality he responded: “Ah, for that I would need three days! Somebody should just explain to me how they can expect one single person to make three patient admissions, to give out food to everyone on the ward, and to make the requested blood tests, and all this between 8am and 9am. Can you (addressing the researcher) change that?” (respondent n32)

Comment: Both doctors and nurses have been observed to be extremely busy during the morning shift. Just from a time factor it seems unlikely that anyone will report use CIRS in this time period. In general it is considered that reporting an incident in CIRS takes about 10 to 15 minutes, depending on the familiarity of the reporter with the reporting procedure, the complexity of the incident, and his ability to formulate the free text passage (Expert 1). 10 to 15 minutes might not sound very long to ‘outsiders’ but seems very long in the context of the everyday work at the hospital. The time task protocol that was taken throughout observation reveals that physicians spend on average less than two minutes with one patient. Even if reporting one incident would take ten minutes this is already the equivalent to seeing five patients. With the above described low status of CIRS it seems highly unlikely that staff would choose CIRS over the opportunity of spending more time with patients. In addition the time that it takes
to report an incident also has to be seen in context for the very department and in connection with the availability of computers. This suggests that much more time is needed. This discussed in the next code T67.

T67 availability of computers to report: PCs are something precious in the department and especially during the mornings constantly occupied, resulting in other staff and patients having to wait. This is especially a problem on the ward checkpoint when nurses have to put new admissions on the hospital system and doctors want to use the computer at the same time.

Comment: Although CIRS can be used from any computer with an internet connection i.e. also from home, using CIRS in their spare time doesn’t seem to be a popular option amongst staff (for example respondents d38 and d17), and one may add ‘why should it be’? But also using CIRS during staff hours seems to be an issue that needs addressing. Little time, coupled with lack of computers and an unawareness of the importance of near misses and no harm events does not exactly present an environment that fosters reporting. The previously described incident T13 with the deputy head of department (respondent d2) showed that, although as deputy head he probably had more privileges in using a computer, he still only used two computers over the entire shift. One of which, the PC in the operation theatre area, was not connected to CIRS, and the other one was the very crowded PC on the nurse checkpoint with no privacy and literally 4-5 staff and patients constantly around, with direct view of the computer screen. Using the staff computer at the checkpoint would be too obvious as both staff and patients can observe it (they might even start to speculate what and about whom he is reporting30). It is more than likely that he

30 The researcher constantly took fieldnotes during the observation. Staff were generally ‘nosy’ and wanted to look at the notes but didn’t seem to bother too much. On one occasion however a nursing apprentice approached the researcher with the words ‘what did you just report about me!’ and it took quite some convincing talk that nothing negative was reported about her particularly on that instance. On another occasion theatre personnel associated the researcher’s note taking with their immediate activities

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would be interrupted by others (staff or patients) who want to know something, need to ‘quickly use the computer themselves’, or that he’d be called away quickly (which means they would have to abort the message and start from scratch at a later point). If the deputy head of department already finds it difficult to find an appropriate environment for reporting this may be even more difficult for other staff lower down the hierarchy.

In addition it need be considered that is not possible to just ‘quickly use’ any computer at the department for reporting in CIRS. It has been observed (at least at some computers) that in order to report to CIRS staff have to log out of the hospital system first and then log on to the PC with personal username and password, which allows them to access the internet. Apart from the time loss this presents an unnecessary additional barrier and may also have an effect on the perceived anonymity or confidentiality of the system, giving a feeling that one’s report may be traced through the personal log in. Overall, and although the head of department stated in the interview (section 6.4.3) that there were enough computers for reporting, it seems that either there are not enough computers or that work processes need to be reorganised in a way not to allow bottlenecks when many people need to use the computer at the same time. As long as staff cannot fulfil their core duties as a result of this situation it is questionable how much computers will be used for reporting in CIRS (the new charge nurse at the gynaecology department, respondent n10, had inquired about an additional computer).

T18 litigation: OD8 During the morning meeting a patient case is discussed. The patient has been already at the department for two days, yet the head of department wants to wait with an operation and prefers trying a more conservative approach first. Another physician (not from the department) wants (and possible wrongdoing).
to get involved and operate the patient immediately, which creates a bit of a friction around the incident. The head of department mentions that over the course of his career he had been sued many times “once for operating too early, and once for not operating early enough..., however, I was never convicted” (respondent d1).

Comment: Although this is not directly related to CIRS the incident shows that doctors nowadays have to live with a constant fear of being sued (and that there is little emotional and professional support in that respect for them). The woolly statements about reporter protection regarding CIRS in Austria will not help or encourage staff to ‘trust the system’ and report in a carefree manner.

T 68 reporter protection: On OD8 a senior physician (respondent d28) who has experience with CIRS from another hospital attests to the above fears of litigation in connection to CIRS. “It is good to report but with one foot you are in prison. Patients expect us to be completely error free. I know the system but I have not used it myself.” (respondent d28)

Comment: In a press conference on CIRS in the Austrian Health Care System the president of the Austrian Medical Chamber (APM, 2009) listed as the principles of the Austrian government pilot CIRS: anonymity, impunity, learning and participation, suggesting that reporters are legally protected. However other sources (during the observation, especially Expert 1) contradict this and the question is if the president (APM, 2009) promised too much. The recent BMG31 publication (BMG, 2011a) states that according to Austrian the Austrian Health Care act paragraph 54 reporters are under no legal protection when reporting, which is the case for example in Scandinavian health care reporting systems and is considered a key asset of any CIRS in high reliability industries. An attempt to conceal this apparent shortcoming is made by stressing that, despite
a lack of impunity, according to paragraph 78 of the Austrian Code of Criminal Procedure (StPO) the OQMed, which is the operator of CIRS, is not an institution with sovereign right and therefore has no explicit obligation to notify the authorities. Whether this assessment is thorough and reliable is questionable because the BMG as the contracting entity is authorized to issue directives to the OQMed and it may be argued that the OQMed is thus a subgroup of the BMG. What the exact juridical situation is can not be elaborated here. However, it must be stressed that juridical issues have not been addressed adequately by the parties involved in CIRS and that thus no documentation and reliable reference exists to this topic that would make it clear for potential users if they have or have not to fear litigation claims when using CIRS.

T19 online reporting: Some staff were observed to not even try to access CIRS because they ‘knew’ that they wouldn’t have access to the internet with their login. Older nursing staff have been observed having slight difficulties with and avoid using PCs. CIRSmedical is an online only system.

Comment: Some logins have restricted internet access. Although CIRSmedical is one of the few websites that can be accessed using those accounts many staff appeared not to be aware of this. In regards to anonymity it is also questionable if staff would want to use CIRS using their personal account. Considering the log on - log off issues it is also not possible to “just quickly use CIRS” as this is quite a cumbersome time consuming process that does not seem to fit the hectic and ad-hoc core daily (medical/nursing) procedures. In addition there is no alternative to reporting online. A study on improving voluntary incident reporting by Evans et al. (2007) showed that improved reporting rates were achieved in those hospitals where online reporting was not offered. Despite the discussions around the role of a CIRSmedical trustee staff have been observed to bypass the online reporting issue by just passing on
information verbally to the deputy head of department (respondent d2) who
would then put it on CIRS.

T26 CIRS input form: On OD 3 respondent n14, the head midwife, criticises that
his profession does not appear in the CIRS dropdown menu. In general he
seems unhappy with the lack of appreciation of this (new) profession. The only
other direct ‘criticism’ of the input form was made by the head of department
(respondent d1) when he tried out the system himself (together with the
researcher following the interview, see section 6.4.3) for the first time and not
everything appeared a 100 percent clear to him. He was puzzled for example
whether or not the report he submitted had been accepted and why his report
didn’t appear on the website (it first had to pass the CIRS trustee).

7.5. Organisational threats

7.5.1. Facilities

This section presents the category with contextual codes that were most closely
associated with the term ‘facilities’.

T17 light management in operation theatre: On OD13 during the endoscopy the
lights in the operation theatre are dimmed so that surgeons have good visibility
of the screens. As the anaesthetist does not have a separate light he has to
prepare the medication in semi-darkness (he tries to get more visibility by
moving nearer the window, but this doesn’t help a lot). A few minutes later
another theatre nurse joins the procedure and also has to work in semi-
darkness.
Comment: The current lighting conditions foster errors due to bad visibility and are a potential latent threat. In a proactive stance to safety this need be addressed before something happens.

T44 design: On OD3 during the morning meeting the re-arrangement of some consultancy rooms is discussed. Nurses claim that it is necessary that the room will be adapted in a way that patients can be transferred into the consultancy room in their own bed (rather than in a wheelchair and having to be lifted into a consultancy bed). In this context the head of department makes everyone aware of one of the pitfalls inherent in the examination to be performed in this room, that patients should not be examined in a lying position as this results in an ‘allegedly correct but nevertheless false diagnosis’ (respondent d1).

Comment: This incident presents a risk that nurses may accidentally set up a trap for doctors when they position patients wrongly and not all staff are aware of it. The incident points to interface issues between doctors and nurses. The correct procedure for this kind of examination could be shared on CIRS.

T15 meeting room situation: On OD13, a physician (respondent 39), introduces a new therapy during the morning meeting. The current meeting room situation may be described as being less than optimal: 23 staff cramped together in a tiny room with staff sitting on sofa edges, tables, and most of them just leaning against the wall due to inadequate furniture arrangements. The meeting room is mostly devoid of meeting room amenities such as flipchart, blackboard, let alone a video beamer for presentations. Accordingly staff follow respondent’s 39 presentation over two small PC screens. Although the researcher is comparatively good positioned he can barely see anything.

Comment: One of the implications a meeting room situation like this may have can be seen in T55 on OD8. A high risk patient (Hepatitis C) was announced in the morning meeting. It happened that the surgeon who was to perform the
operation later that day, who was present in the morning meeting, did overhear this and operated the patient being unaware of the risk. There were other things that contributed to the situation, for example a changing operation schedule and shorthand changing of surgeons (which may be a result of T9 ‘surgeons late for operation’), no additional reminder to the surgeon that this was a high risk patient, but the meeting room situation was a contributing factor. The surgeon and the head midwife discussed that it was not uncommon that sometimes you just can’t understand others because of the built environment. It is likely that the meeting room situation (and in a wider sense the way meetings are held, people go in and out, no note taking, not adequate basic facilities) contributes to communication errors. Just how potentially severe this is shows OD8 ‘T54 banked blood’. A patient schedule for operation was discussed in the morning meeting and the head of department stated that this patient would require special blood from a blood bank abroad if there were any complications during the operation. This blood needs to be ordered in advance. Due to the missing documentation and alert functions before an operation, as shown in the above incident T55 with the high risk patient, this may be simply ‘forgotten’ or just missed as part of the conversation in the morning meeting. These describe typical cases where nothing bad can happen but in case something goes wrong the consequences are potentially severe.

Adding to ‘facilities issues’ it has to be noted that staff in general complained to the researcher (and from the researcher’s lay perspective was confirmed) about a lack of space, for example to prepare medication, for patients’ admissions using the computer (privacy?), for face to face meetings with staff (employee talks), interviewing new staff, privacy with patient, or general staff meetings. If one can’t even have privacy for a patient or staff talk how realistic is it to expect privacy when reporting in CIRS?
This section presents the category with contextual codes that were most closely associated with ‘I.T.’.

T30 mobile phone settings: The next incident happened during the nightshift on OD4 with the two doctors on duty (respondents d2 and d8). It is customary that one of the two doctors on duty (usually the more senior one) can rest and is called in only as a back up or when otherwise needed. Exactly this is what respondent d8 wanted to do at around 9pm. He was consulting a new patient who had been at the hospital’s outpatient department earlier that day but returned to the hospital at night because of throwback pain. Respondent d8 decided to call his more senior colleague, the deputy head of department respondent d2, for assistance. However, the staff mobile phones, the main mean of communication at the department, did not connect. By chance the researcher, who was also equipped with a staff mobile, pressed a key and the connection is established. It was pure coincidence and without it respondent d2 could not have been reached (this all happened in front of the patient). That same night one of the midwives could not reach respondent d8, who was the main doctor on duty, for the same reason. During another observation on OD6, four days later, the same thing happened to the head nurse during the dayshift. This time the researcher could not ‘help’ as it was a different phone with a different setup.

Comment: It turned out that staff mobile phones have two frequencies but only work in one of them. It is not known why or how the frequencies had changed but it is found that different phones (of the same type though) have different settings of how to change back to the frequency that works, i.e. there is not one universal rule that can be applied to all phones (which would be useful as staff sometimes swap mobiles). Over the next days it becomes apparent that not many people know about these technicalities or how to handle them. Staff that
were directly affected were observed to consult the technical support team. However, the technical support team only provides symptomatic support and does not identify or remove the root cause of the problem, meaning that the same problem can reoccur and to different people. Sharing the incident on CIRS could either make more people aware of the problem or, through the incident being documented, instigate changes. The consequences of not being able to reach physicians, especially during night shifts where one cannot just leave his area to look for someone in person, are potentially severe.

T60 faulty blood pressure meter: On OD13 the ward physician on the gynaecology ward (respondent d42) tells the researcher about an incident that occurred a week ago with the electronic blood pressure meter. The physician suspected that the blood pressure meter measured incorrectly and double checked it with manually measuring the patient’s blood pressure. He suggested that the blood pressure meter was faulty or unreliable. He discussed the incident with one of the nurses but nothing has changed.

Comment: Electric blood pressure meters are sensitive to noise and it could be that this influenced the measurement. To find out the exact reason the blood pressure meter could have been checked by a technician and other possible reasons (for example the influence of noise on measurements) identified through sharing the incident on CIRS. Respondent d42 is not aware of the possibility to using CIRS at the department.

T61 ordering drugs using in-house computer network: On OD9 the charge nurse tries to order a certain drug via the in-house computer drug order system. Products are selected from a drop down menu and the product he wants is not on that list. Only when calling the pharmacy it becomes clear that the product is available but that the system does not list all available products for ease of navigation (listing all drugs would result in an ‘endless’ list).
Comment: The list of products visible to staff could be amended to (all) those drugs relevant to gynaecology and obstetrics or staff using the system should be made aware of the fact that drugs that do not appear in the list might be still available through directly contacting the pharmacy. Possible consequences of the incident are delay, additional effort, possibly higher costs through using a more expensive alternative, or not using the product of choice. As not all frontline staff directly order through the system (usually nurses document what they need in a drug order book and the charge nurse then orders those drugs using the computer system) sharing this incident on CIRS could alert other charge nurses in the hospital.

T20 access to quality related information: On OD8 the head midwife (respondent n14), out of his own initiative, wanted to acquire information about hygiene in one of the nurses PC’s. However, he cannot due to access restrictions.

Comment: If general quality relevant information is already on the system there should be a way that all staff can access it. While this may present a problem that could be addressed in-house a related incident shows the wider dimension of access issues in health care. On another occasion during the nightshift on OD4 respondent d8, a senior physician, consults a patient who had previously been at another hospital and at this hospital’s outpatient department. Respondent d8 tries to access the electronic patient file online but is refused access. Access to patient data is a more general (and hot debated) issue but greater information sharing at least within the hospital or between inpatient and outpatient area is desirable and might be feasible. Access to general quality information, not patient data, seems to present an opportunity for change that should be relatively easy to bring about. As clinical staff do not have time to pursue this it is unlikely that it will soon change. Documenting it in CIRS would
at least provide a statistic on how often staff experience this problem and might call someone with responsibility on duty to attend to this issue.

7.5.3. Processes

This section presents the category with contextual codes that were most closely associated with ‘processes’.

T29 actualisation of telephone numbers: Mobile phones are the main mean of communication at the department. Mobile phone numbers change frequently and the current process is not sufficient in keeping up to date, resulting in situations where staff cannot reach each other. One example where this happened is OD14. The patient was already ‘prepared’ (positioned, narcotised, etc. and on the operation table) and everyone was waiting for the surgeon. After five minutes the theatre nurse tried to call the surgeon but used the old telephone list that was still hanging in the operation theatre (the researcher was with the head secretary a few days prior to this event when the head secretary not only printed out the new list but personally brought it to the operation theatre; however, operation theatre staff have to put up the list themselves as the head secretary cannot enter the operation theatre himself). Staff cannot reach the surgeon and have to wait until he arrives in the operation theatre by himself.

Comment: As not one person is responsible for updating telephone numbers the researcher could observe the co-existence of multiple telephone number lists and with differing information on it. These lists are also devoid of a ‘last update’ date which sometimes results in up to date lists being replaced by older telephone lists. Moreover staff complained that even when the lists in the department are correct the electronic list in the hospital system (for other departments), which is run by the hospital directorate, is not updated. This was a problem that prevailed despite personal intervention of individual physicians. This creates potentially dangerous situations when staff members cannot be
reached in an emergency. The initiative from the head secretary to print and manually distribute up to date telephone lists is desirable but was not appointed one of his core tasks and therefore probably not executed and followed up in the same way as he does with his core duties. The head of department showed a somewhat resigned attitude when the issue was brought up (once more) in the morning meeting. Jokingly he suggested to the physician who had intervened at the directorate: ‘try it once more, if nothing happens we send Mr. Weicht [i.e. the researcher]’ (respondent d1). The incident was not reported in CIRS. Again it is suggested that at least a documentation of the incident could help when discussing the issue with the directorate. It seems to be another issue that no one is ultimately responsible for.

T64 drugs not verified - patient delay: Nurses can suggest certain drugs for patient treatment. These then need to be verified by one of the physicians. During the week this works fine but on weekends drugs are not verified and nurses have to wait until Monday morning for physicians to do so. As no extra time is calculated for the additional workload on Monday it happens that drugs are not verified by 8:30am. Drugs that are not verified and ordered by that time will only be available for the next day, causing delays in treatment and extra costs.

Comment: Reporting this in CIRS reporting could provide statistics on how often this happens.

T63 delayed patient discharge: On OD9 a patient discharge is delayed because the department cannot get an appointment for a final ultrasound examination (at that hospital). This delay means the patient has to stay an additional day at the department causing substantial additional costs and additional logistical effort (change food-order for the day, plan bed capacity etc), discomfort, and an additional infection risk for the patient because of the prolonged stay.
Comment: Reporting this in CIRS reporting could provide statistics on how often this happens.

T62 missing patient consent inhibiting transfer: OD9 It does happen that patients are transferred to the department in a bad general state. Those patients often only require little medical attention and could then be transferred to a nursing home. For the transfer from the ward to the nursing home written consent from the patient is required and staff sometimes have difficulty acquiring it. According to staff there are cases where it is apparent that patients do not want to make ‘the final move’ to a nursing home and try to delay the transfer as long as possible by not giving consent (some patients pretend to be asleep, deaf, or act defiantly). This results in situations where patients stay on the ward for weeks (seven weeks in one recent instance), causing immense costs for the health system, and not receiving the best care.

Comment: The previous charge nurse at the gynaecology ward did not seem to bother too much about this and the new charge nurse now tries to acquire patient consent for a possible transfer to a nursing home right at the admission of those patients. Otherwise the charge nurse is faced with a prevailing problem of a patient not suitable for this ward and blocking a bed. Through using CIRS lessons may be learned how other departments deal with this issue in a meaningful and humane way.

T14 time, patient factors, and organisation - known problem not solved: Section 7.6.3 introduced the contextual code T13 ‘time to report’. How efficiently staff use time is closely linked to the processes in the department. One example is the incident on OD11. It happened that three patients came to the gynaecology ward with the same disease pattern (hence requiring the same examinations and possibly the same treatment). Because of the extent of this particular series of examinations it is important that they are done early in the morning so that all of the possibly required tests can be performed on that same day. Nurses need
to arrange appointments in different parts of the hospital (X-Ray department etc.) in time and also arrange hospitality services such as lunch or a daybed. The particular constellation of same disease pattern and that all three patients were sent to the gynaecology ward at the same time resulted in a disproportional workload, stress, and longer waiting times for patients. One of the patients, a private patient, complained to the head of department about the long wait.

Comment: This incident shows that ‘busyness’ at the department is often the consequence of a mix of patient factors and organisational factors. It is possible that patients have the same disease pattern but appointments could have been made for different times, not to have appoint them all on one and the same day. The head of department was furious that patients had to wait so long because he wanted patients to have a good first impression of the department. In the end it was the nurses, who already knew in the morning how this would end, that were told off. This is a re-occurring problem and although the situation could be improved through better interface management nobody seems to have time to really work on solving this problem. Translating this incident into the world of CIRS it is questionable whether incidents such as this boost staffs motivation to think in a systems concept and use CIRS. Front line staff knew already how this would end. The head of department is the only one with power to actively change this situation. Despite his inactivity, in the end it was the nurses who got the blame (a manifestation that a blame culture is emotionally more rewarding than identifying systemic causes). The negative outcome in this case was ‘only’ an increased waiting time for patients. However, parties involved were not able to discuss the incident constructively and the same incident may occur at any time in the future. How likely is it, in case the patient’s health is affected (however slightly that may be), that the incident will be documented, analysed, so that the underlying conditions are identified and systemic changes made to prevent this from happening again? It is suggested that in order to be credible known problems need to be addressed before staff can be encouraged to report
about new problems (what's the point of reporting something you know will not change?).

There were other problems with interface management, doctors waiting for other doctors, doctors waiting for patients, doctors waiting for patients to be narcotised, patients already narcotised and waiting for the surgeon. However, these were not followed up. They might be recorded in a CIRS (a waiting person should have time to report) to determine and document how often such events occur and can lead to evidence-based discussions on the need to change ‘the system’.

7.5.4. Culture

This section presents the category with contextual codes that were most closely associated with ‘culture’.

T50 bypassing procedure / normalisation of deviance: Nurses in Austria are legally not allowed to administer infusions. The lawful procedure is for nurses to prepare infusions and then for physicians to administer them. In reality however this procedure is often bypassed due to staff shortages. For example during a weekend shift there was only one doctor on the ward and he was too busy to attend to all patients in a timely manner. As a consequence the nurse both prepared and administered the drug, thus bypassing the official procedure. This is against the law and also breaches the four eye principle (one member of staff double checking with the other if it is the right drug, dose, and patient).

Comment: The situation is not uncommon and although perceived undesirable by staff (because of time constraints, stress, against the law) at the same time there is also at least a feeling amongst some staff (doctors and nurses alike) that this is not something a nurse couldn’t do and therefore should also be allowed to do. It regards a wider health policy issue that allows comparison with Germany where nurses are allowed to administer infusions. Because in Austria
this is not so junior doctors, who should learn something in the three months they are at the department, become infusion idiots; administering one infusion after another that nurses have prepared. In the described incident the doctor in charge just happened to come into the room the moment the infusion was connected. The infusion that was connected was one in a row of many (i.e. the nurse was not ‘prescribing’ a new drug but continuing the treatment). The incident happened on a weekend shift with lower staff capacity. However, as long as this procedure is frequently bypassed this presents another ‘normalisation of deviance’ (one of the contributing factors leading to the Challenger disaster) and may extend to other areas and procedures. Reporting the incident on CIRS could again provide statistics on the consequences of staff shortage and policy regulation.

In discussion with one of the senior physicians about this study he attests to the concept of ‘normalisation of deviance’ in that in the first few weeks, when he was still new at the department, he noticed a lot of things for improvement. Over time his sensibility for things that might be potentially improved had decreased. 7 don’t see these things anymore; I suppose I just got used to it’ (respondent d25). His comment is interesting in relation to T5 (see section 7.6.1) and suggests even more that junior doctors and medical student apprentices, who spend just a few weeks or months at the department, should be actively included in CIRS.

T51 bypassing of house rules: The bypassing of official procedures is observed on several occasions. These are not always about clinical procedures (which the observer can only detect to a very limited extent) but more humane things such as smoking on the ward toilet and in the physicians’ room, eating uncollected patient food instead of sending it back (which is a reason to get fired), or parking a bicycle in the office. The bicycle and smoking story was quite amusing as this was actually a deal between three physicians who shared one
office. The two smokers ‘allowed’ the cycling one to park his (rather expensive) bicycle in the office. In exchange the cyclist tolerated the other two would smoke in their shared room, which was a real privilege as there was a smoking ban for the entire house (OD13, respondents d17, d38 and d40).

T52 bypassing procedures / pharmacy control: On OD3 the assistant head nurse and charge nurse of the obstetric ward (respondent n9) receives a call informing her about the exact time and date of the annual control of the department’s pharmacy. He passes on this information to nurses on the ward. This control is actually labelled as “the annual unannounced control” and one of the nurses on the ward says that “officially I don’t know about it, just vaguely, because it’s about the same time each year” (respondent 11). On a later observation day, OD 10, the nurse on the ward then prepares for this annual control, sorting out all expired drugs before the control takes place. A few items are found and disposed of.

Comment: As this happens somewhat secretly the causes of the problem are not identified, for example why drugs have not been disposed of in time, or why they were prepared in a way that they do not have a use by date on them (it turns out that nurses often cut off the required amount of pills from a stripe, thus cutting off the use by date which is imprinted on one end of the stripe). It appears as if not a single error should leak out of the department. By the time of the unannounced annual control the ward pharmacy is in an ‘impeccable state’. It presents an environment where the examiner cannot find anything wrong, thus cannot instigate investigations into the root causes and cannot instigate any systemic changes. Possible lessons learnt cannot be shared on a CIRS. This represents a symptomatic (person) approach rather than an root cause identifying (systems) approach to error.

T53 work schedule and shift times: There was an incident where one doctor took a day off with very short notice, scheduling a colleague to cover his shift
but overlooking that this colleague had already been scheduled for this time to work in the outpatient department. As a result there was a shortage of one doctor for that day. As it happens this particular day was an extremely busy day and staff struggled to get through the day. This incident resulted in a heated discussion between the people involved. As a consequence it was decided by the head of department that the weekly work schedule, which so far had been arranged just before the weekend started (with some people already leaving for the weekend and assuming they don't have to come in for work on Monday - only to be scheduled by someone else for Monday, should be ready by Wednesday. The head secretary comments that this new procedure was ‘desirable but completely unrealistic’ as ‘doctors always change everything a hundred times’ (respondent 13).

Comment: What added to the confusion was the large number of different types of shifts. Doctors and nurses for example have different shift times and also start their shifts at different times of the day. Some shifts start or end 15 minutes earlier or later than other shifts. For an outsider it is difficult to comprehend why this is so and nobody in the department could tell the researcher why so many different shift times co-existed. That it doesn’t make perfect sense seemed to also appear to others, for example the deputy head of department (respondent d2). Although his shift starts with the doctors’ morning meeting at 7:45 he already came in at 6:45am in order to attend the nurses’ morning meeting too. “This is probably the most useful meeting for me to get information about my patients. Not in the morning meeting with the medical doctors.” (respondent d2)

A comment need also be made regarding the length of shifts. It is common practice at the department to have 24 hour shifts and sometimes even 48 hour shifts. In regards to the known correlation between fatigue and performance impairment (Dawson and Reid, 1997) this presents a severe threat to safety. Some staff complained about this, for example respondent d29 who said: “/
have been working for 25hrs in a row now and I have two kids waiting for me at home. This is how this hospital works!” (respondent d29)

One last note on the shift times, the fact that doctors did indeed change their shifts many times and with very short notice also made it difficult at times for the researcher to prepare for the next observation (for example which staff can be expected to be around for respondent validation).

### 7.6. Practical implications

#### 7.6.1 Integration of existing documentation

This section presents the category of contextual codes that were most closely associated with the ‘integration of existing documentation’.

T3 dictaphone: In the entire department doctors use dictaphones (rather than paper forms) to document the patients’ history. This is then word processed by one of the secretaries before it is printed, verified and signed again by doctors, and filed.

Comment: This procedure actually has in it an interface, the secretaries, who are not intensively interested about medical/clinical intricacies but have the required vocabulary to document everything like a doctor. It may be worth considering if the existing dictaphone procedure could be used for reporting incidents in CIRS. Secretaries already use a number of templates for composing clinical reports. A similar template could be set up for CIRS reports. When recording a CIRS message in their dictaphone doctors could use a codeword (for example CIRS) to alert the word processing secretary that what is about to follow is a CIRS report. Secretaries could then forward this separate message, devoid of any staff or patient identification, directly to CIRS (or still
another CIRS trustee). Potentially this would save doctors valuable time, it would solve the problem with lack of computers, the problem with privacy (it is easier to find a quiet place with your personal dictaphone), doctors would not have to get used to a new procedure or technique, and as everyone uses dictaphones it would not be obvious for others that someone is actually ‘talking (reporting) to CIRS’. To some extent this could solve the problem of the CIRS trustee as the CIRS trustee would only have to verify the content of the report but would not have to anonymise it. It could be done without additional resources save for the extra time required by secretaries, a template guiding sheet in the form of a quick checklist (what basic information should be reported and in what order, profession, patient’s age etc.) in every paper patient file, on several places in the department, or as personal handouts. This method could especially be used for no harm events and near misses. In a further stage secretaries may be sent on ‘CIRS categorisation’ training.

T1 and T34 book in operation theatre and incorrect sampling method: An incident on OD14 regarding an incorrect sampling method (see T34 in section 7.5.1) was only communicated internally. However, the theatre nurse involved, respondent 43, also mentioned “a (theatre) book where I can document this” (respondent 43).

Comment: The book mentioned by the theatre nurse could probably be used for CIRS, i.e. events already reported in the book could be anonymised and then put on CIRS and thus shared with a wider community. While the incident may have potentially been communicated amongst the theatre nurse work group it seems as if theatre nurses are the only ones who know about and share information in this book. This is similar to other observations, for example T32 (wrong patient instruction, see section 7.5.1), where information was shared but only on a very small scale.
T2 documentation of speciality council: The department holds weekly oncology councils. These are inter-professional meetings that include staff from in and outside the department and hospital and they last about one hour. The feeling in this meeting is very different to many of the other observed meetings. The meeting room is adequate in size, the atmosphere is very professional (nobody late, no interruptions), everyone takes notes and everything is documented using the dictaphone and another ‘council book’.

Comment: As the meetings mainly discuss what went good and bad in certain cases, and do so from a systems (medical) perspective with different professionals involved, possible incidents in those documented cases could be anonymised and shared on CIRS.

7.6.2. Integration of staff

This section presents the category of observations most closely associated with ‘integration of staff’.

Integration of junior doctors and medical student apprentices: The observation showed that with the junior doctors and medical student apprentices two relatively large and highly fluctuating groups of staff were completely unaware of CIRS.

Comment: It is usual that junior doctors come to the gynaecology and obstetric department at the very end of their two year housemanship. Junior doctors have the latest medical knowledge and have very recent first hand experience of working and learning in many different departments and hospitals. Like the senior doctor (respondent d25) and the ward nurse (respondent n12) mentioned on OD5, amongst others (for example physician respondent d2 and d8),
attesting to their own experience externals or outsiders have the potential to “see” things that internals do not see anymore because they got used to it (related to the concept of ‘normalisation of deviance’, see section 3.4.4). The comparative insight of junior doctors bears potential and could lift their status from ‘syringe idiots’ (respondent d34) to more valuable members of the department. Junior doctors are often naturally curious and inquire about things. As they are at the department only for a predefined period of time it is possible that they would act more fearless in criticising peers as they would not have to live with (fear of possible negative) consequences for their career for very long. This is a point that has been especially mentioned in a comment during the CIRS feedback meeting where respondent d26 stressed that it is especially junior doctors who should be encouraged to report as ‘they are the ones who are still motivated and still think that something can be changed’ (respondent d26).

Medical student apprentices should get to know CIRS and the underlying systems concept early on in their education and this includes the practical training they receive during their time at the department. As the CIRS trustee acts as a controlling interface there is no danger that possibly wrong reports from medical student apprentices (due to their yet incomplete ability of comprehending medical incidents) would end up on CIRS.

There were other groups of staff that potentially could be integrated (better) into CIRS. One of them is the hospital-external paediatrician (see T57 vacuum birth under suboptimal conditions in section 7.5.1). Again, being external he could potentially see what departmental staff already got blind to. The same applies to anaesthetic staff (they don’t belong to one department) or any other visiting staff to the department. In addition it was found that the department secretaries had comparatively good technical knowledge of CIRS and how to access
information and clinical staff could make better use of these secretaries’ hidden skills.

7.6.3. Integration of organisational issues into CIRS

This section presents the category of observations most closely associated with the ‘integration of organisational issues into CIRSmedical’.

Organisational issues: In addition to observations at the department the website of the reporting system was searched for reports, comments, and statistics. After reports had started coming in from the various participating hospitals the research took note of a message that appeared when visiting the website and which concerned the kind of ‘incidents’ staff reported. It appeared that a proportion of reports were non-clinical in nature, for example: “there is so much negative communication between different groups of professionals” 33, “I am constantly so tired, soon something will happen”, “constantly the telephone rings and disturbs me at a task that requires concentration”, “every time when I want to calculate chemo-therapy doses I get called to a patient”, “where I work it is so noisy that I cannot concentrate”. Reporters were asked not to report these incidents but to refer those kind of organisational issues to their superiors directly. Expert 1, who was running the system, stated that “…of course they are related to risk and safety, these are the classical contributing factors. However, they can’t be dealt with through this means/system. We need concrete incidents or almost-incidents” (Expert 1).

Comment: This message shows that there are a number of non-clinical incidents reported in CIRS and suggests that these sorts of incidents appear to staff as important incidents that are relevant to safety. Expert 1 principally agreed but stated that ‘while contributing factors are important’ that limited

33 Source: accessed on 03.03.2009; retrieved from CIRS2
funds, at the start up of his business, and the lack of understanding amongst stakeholders of the importance of contributing factors he could, for the time being, only ‘self real [clinical] incidents that happened (or almost happened) at the sharp end and that were more closely related to clinical events, such as the misadministration of drugs. Under the current management these ‘organisational threats’ as the researcher calls it are not included in CIRS, i.e. they are not being analysed or followed up.

These findings also bear an interesting correlation with another observation made at a NHS Women Hospital in England. During the course of the present study the researcher gauged the possibilities for conducting a comparative study between an Austrian and a NHS Women hospital, an idea that was later put down because of the great differences in ethical requirements in those two countries (this will be elaborated further in the conclusion chapter). During that process the researcher had the opportunity to interview the risk manager and the nursing director of a Women hospital that had been using the NHS National Reporting and Learning System (NRLS) for some time and had a constant reporting frequency of about 200 reports per month. This risk manager had the overall responsibility for the hospital’s risk issues. Reports were submitted non-anonymous and paper based, collected in the in-house database, before being submitted to the NRLS on a weekly basis. In comparison to the CIRS in the study (section 6.2.1) the process of submitting a report involved the following steps: After an incident had occurred a member of staff would complete the incident reporting form, submit it to the ward sister, who passes it on to the matron (overlooking a number of wards), who passes it on to a full time risk lead which could be one person from a group of people bearing titles such as clinical governance manager, risk advisor, risk manager, or risk officer. In addition these people possessed special medical or nursing knowledge of a particular
medical/clinical area, for example plastic surgery, orthopaedics, or pharmacy, and would be from different ranks in the hospital organisation, such as director, matron, charge nurse, ward sister, laboratory manager, or support worker. In this particular NHS hospital trust the hospital employed a total of 14 such full time risk leads that held monthly inter-professional meetings with each other and reported to the trust’s two risk managers. These risk leads therefore were analysts with content experts who can understand and interpret reports (Billings, 1998; IOM, 2000). Although this gave interesting insight on what a budgeted CIRS (as compared to the OEGGG project in the study) can look like there was another interesting correlation in regards to ‘organisational incidents’.

When asked about ‘organisational incidents’ the hospital’s risk manager had to admit that about 50 percent of all submitted reports were non clinical and organisational issues and that those could not be delegated to one of the appointed risk leads, because they were all from the existing ‘clinical organisational structure’. This means that reported contributing factors to patient safety, like in the present study, are not acted upon. This points to a mismatch between patient safety endeavours based on an existing organisational structure and requirements to safety that call for an ‘organisational risk lead’ who can take on those ‘contributing factors’. Without this it seems an important piece of the puzzle is missing in a systemic approach to patient safety. Apart from the perpetuated risk not responding to organisational incident reports may have other untoward effects. Staff who report organisational incidents on CIRS may be discouraged when their non-clinical reports are left unattended and no feedback is provided. It may well be that when time comes for them to report a medical incident they will not report it (at least through this system) because of a negative association with the system.

These observations suggest that CIRS has unrecognised potential for identifying organisational issues. It may be worth investigating if there is a
possible correlation between reporting organisational incidents in CIRS and staffs’ willingness to reporting (the originally sought after) medical incidents to CIRS. It may be that staff find it helpful to report organisational issues first, receiving feedback, experiencing the anonymity and confidentiality of the system, and thus building up trust which is necessary for reporting more sensitive incidents that are more closely related to the clinical core issues at the hospital.

In conclusion it seems as if current risk procedures, in both the Austrian and the UK hospital, are set up in a way to fit existing thinking of the medical/hospital system and do not sufficiently reflect system thinking as brought forward in the high reliability and patient safety literature.

7.7. Results

7.7.1. CIRS feedback meeting

A feedback session to be held by Expert 1 was initially planned to take place soon after the project had started. However it was some 22 months into the project when the first feedback meeting took place. The feedback session was a dedicated ‘CIRS feedback’ meeting with extra time allocated and this time at a more appropriate venue (than morning meetings or the earlier training session), a meeting room in another part of the hospital. The initiators of the project had made some effort, in their own verbal and mostly undocumented way, to promote the event. The deputy head of department (respondent d2) had conversed about it with colleagues. In addition the observer spotted out an A4 computer print-out at one of the nurse checkpoints announcing the event. Work in the operation theatre was put on hold until 10am to allow all staff to attend the meeting. Prior to the feedback meeting was the daily morning meeting at the
department, which had 19 attendees, the lowest attendance in all the observation. Before and after the morning meeting staff rumoured about the feedback meeting “do you know where this is?”, “is this today?” and the meeting was not especially announced in the morning meeting, probably the head of the department just forgot to remind everyone again. As people were leaving the meeting room he remembered and shouted “everyone can come with us” but it seemed too late, a bit like a teacher trying to give out homework after the bell had rung. Some people wandered off, while the researcher joined a group of physicians, led by the head of department, and walked to the meeting room. Upon arrival the head of department (respondent d1), realising that all the nurses had disappeared, said: “I am really annoyed now that all the nurses are gone” (respondent d1), although some of them should reappear later.

The meeting was attended by 23 staff, including the head of department and his deputy, the head nurse, four out of the five charge nurses, 13 physicians, two surgical nurses, and the hospital’s risk manager (two physicians, respondents d25 and d26, only joined for the very last few minutes). The hospital directorate had been invited and agreed to come but had to cancel just a few minutes prior to the meeting. The meeting lasted 1 1/2 hrs (08:15 - 09:45), with half the time taken by the presentation and half the time for discussion. The head of department started the meeting, shortly reflecting on the project, before leaving the stage for Expert 1.

Expert 1 started off with an important change that had been made. He had found that the CIRSmedical entry mask was too complicated. Therefore his company had created a new and simpler online ‘CIRS 2’. All reports had already been transferred onto the new system with username and password for users remaining the same. He gave a short reminder of the purposes of CIRS, using the ‘Heinrich ratio’ which asserts that there is a fixed ratio between major accidents, minor incidents, and no harm incidents (see section 4.3.1) and
stressing the two most important elements of the report: what could have happened and why did it not happen. He stressed the importance of external data management, the anonymity of reporters, that it was not a system for complaints ("those are for the complaints box"), as well as giving more general reference to the need for safe system design in health care, stressing that hospitals should have forcing functions, like a cast in medicine to prevent motion, to prevent people from doing wrong things and to make it easier for them to do the right things.

The presentation then turned to the reports that had been submitted from the department onto CIRS. Over the past 22 months Expert 1 had received a total of 48 reports from the department. These were clustered into:

- areas where they occurred (26 at the ward, seven in the nursery, seven in the outpatient department, six in the operation room, and two in other areas);
- types of error (28 skill based, 12 rule based, four knowledge based, four other), and were
- nature, concerning medication (14), documentation (6), patient records (4), operation theatre order (4), referral (3), patient call (2), additional examination (2), and other (13x1).

Expert 1 admitted that this was not very much and hence that the analysis was not very significant, but that the number of reports was congruent with the literature, emphasising that underreporting is a known problem of any CIRS. It appeared to the researcher that Expert 1 attempted to stick to a CIRS analysis although this might have been questionable considering the (small) amount of reports from this department. The consultant was probably aware that the department was in need of management support and additional risk related training. However, he mostly referred to this in conjunction with a need to
consult his services, which the hospital would have to pay for. Expert 1 recommended conducting a risk training for all staff, introducing special communication techniques, toolkits, and risk manuals in an additional one or two day training session to boost reporting, giving reference to one of his client hospitals where increased reporting had been observed following additional training. According to Expert 1 the cost for this training would amount to roughly 3.000 Euro.

The contribution in the discussion was good (compared to the training session) with a total of 24 comments being made by eight different staff. Some of the comments were directed towards Expert 1 and other comments were directed towards the head of department or were responses to previous comments. However, in general more staff could have attended. The still relatively low attendance, with one representative for each group - the ‘usual suspects’ one might say, showing not more than a very minimum of commitment - seems to suggest that the project was perceived as either ‘another administrative burden’ where one just had to attend or as something that was more for the higher ranked staff. The low attendance may also be related to time and date of the feedback event. Observations showed that the time of the meeting, 8:00 until 9:30, is the busiest time in the department and difficult to attend for all “normal” front line staff, in particular nurses and more junior staff such as ward physicians, junior doctors, or medical student apprentices.

For example one of these front line staff, a nurse on the gynaecology ward respondent n46, would have liked to join the meeting but did not know that she had been ‘invited’, or who could have covered for her shift. Moreover the event took place a few days before Christmas and key people in the department, for example the charge nurse from the gynaecology ward (respondent n10) and the assistant head nurse (respondent n9) were away on holiday. It might have been possible to arrange the meeting at a different time, given that this was the first
(and as yet only) feedback session in two years. On the other hand this date probably tells something about the low priority of CIRS at the department, or even meeting situations more generally, that it cannot be expected to have a large number of staffs and all key people together in a meeting. But it was also apparent that other staff could have attended the meeting but didn’t. As mentioned above the operation theatre had been put on hold until after the meeting. Despite this there was only one representative for all operation theatre staff present in the meeting, the head surgical nurse respondent n21, reinforcing a lack of involvement in CIRS by theatre personnel. It was ostentatious that the discussion was held exclusively amongst physicians. Not one comment was made by the head nurse, charge nurses, theatre nurse, or the hospital’s risk manager.

The discussion itself showed that staff wanted to see some action following the reports and analysis, and the ‘so what’ question dominated the first minutes of the discussion. ‘What do we have to do now, where do we start? I need something [more] concrete’ (respondent d20). ‘We have the analysis, but what can we do with the data now?’ (respondent d25). Some also suggested why it didn’t work, for example respondent d26, a senior physician, added: ‘CIRS only works when all public hospitals participate’ (respondent d26). Another respondent asked for more external support (respondent d20). However, at times the discussion drifted away from CIRS and moved to more general problems, probably because it presented a rare occasion for staff to air some of their problems and concerns. Respondent d47 for example addressed the head of department with his ‘feeling’ that there were ‘comparatively few procedures, regulations or checklists at the department’. For work in some sensitive areas, for example the outpatient department, there was basically no information (respondent d47). Hence the ‘organisation’ of the hospital /department and the ‘structure’ of and processes was questioned. One respondent asked ‘how safe is good enough’; referring to certain medical procedures that ‘can either be
done in ten minutes when there is time, if you are alone and it is busy you do it in three minutes’ (respondent d26). While participants made interesting remarks the discussion seemed to turn into an endless quest with participants finding all kinds of ‘reasons’ why things didn’t work. The head of department was thankful for comments and suggestions but didn’t know ‘where to take the time to implement any of these suggestions for changes’ (respondent d1).

The meeting ended at the scheduled time because everyone had to return to their ‘core commitments’. Many questions, whether or not, and under which conditions to continue with CIRS were kept pending. The department still had not appointed an internal CIRS trustee (Expert 1 had voluntarily continued to fulfil this function). The head of department arranged to keep in touch with Expert 1. In the daily lunchtime shift handover meeting later that day it was unusual that only eight people attended. It might be that staff were busy catching up with the 90 minutes they had ‘lost’ in the morning. The CIRS feedback session was not mentioned in one word.

### 7.7.2. Consequences

The meeting provided a first feedback on the OEGGG CIRS project at the department. In addition it presented staff with the rare opportunity to voice their concerns on quality in the department more generally. However due to the unclear funding situation, the small number of reports and, inherent with the lack of CIRS training, lack of knowledge about CIRS and patient safety the meeting did not sufficiently focus on strategy improvements and did not present any constructive steps on how to continue with CIRS (the new CIRS2) or patient safety more generally. The head nurse (respondent n7), who was not proactively involved in the project, commented later: ‘If that is all the feedback we get then I am not surprised nobody is using it [CIRS]’ (respondent n7).
One of the practical outcomes of the meeting was that the head of department and the hospital's risk manager met for the first time and arranged to meet in the near future. The researcher joined this meeting between the head of department (respondent d1), his deputy (respondent d2), the new head nurse (respondent n33) and the hospital's risk manager (respondent 19), as well as one other follow up meeting, both of which took place within four weeks of the CIRS feedback meeting.

These meetings gave opportunity to get to know each other and to exchange perspectives. The head of department started addressing the risk manager: ‘Who are you, I don’t know you or anything about what you do. Are you from the Vienna City Hospital Association, from the Directorate, in-house?’ (respondent d1) After a first introduction the head of department then described how the department had come to start the OEGG project, the progress so far, and that he definitely wanted to continue with CIRS. He only was not sure how to bring this about. He also appeared to grasp the wider context of CIRS and hence the need to document processes in building a risk management strategy for the department. The head of department emphasised again his perception that work at the department was ‘good, very good, in many areas; we just need to write down what we are doing; ideally we should be in a position where, when we hit a problem, we can say - this is how we did it last time and this is how we can approach this problem now’ (respondent d1). The head of department appeared to understand the cause of problems at the department but admitted he continually got stuck in the implementation due to a lack of time and resources. ‘The current solutions are not systemic, only symptomatic, and we would need time for each work group to sit down for 1 1/2 hours without any interruptions, no operations, no interruptions, no mobiles, and to talk about how to document our processes. At the moment when we find a solution...once everything works fine again everybody just forgets about it within three weeks’ (respondent d1).
The risk manager, not a common position in public hospitals in Austria, who was not involved in the CIRS project talked about his work and that he had been conceptualising his own risk management model over the past two years. He informed the meeting about the (theoretical) possibility of joining the Vienna City Hospital Association (WKAV) pilot CIRS, which was being tested at another department of the hospital and which the head of department did not know about. At the same time he stated that the resources were very limited and the chances of being included in the pilot were very little. The pilot CIRS was estimated to need about three years to work. The risk manager then moved away from CIRS specifically and started to introduce his own wider risk management model. Although the model was still in its conceptualisation phase it was principally agreed between the risk manager and the head of department that this model could be tested at the gynaecology and obstetric department. The risk manager would provide a layout for describing the core processes at the department and the department would have to invest staff time in documenting those core processes.

While the risk manager and the head of department appeared to find some synergies and common interests in their conceptualisations this did not seem to fit the expectations of the other two participants. The deputy head of department wanted to pursue the OEGGG CIRS project, stating that ‘we should stick with what we have and not start all over again’ (respondent d2), believing that the CIRS with Expert 1 was ‘the only truly anonymous CIRS available’ (respondent d2). This however did not fit with the head of department’s considerations that ‘while reporting in CIRS with Expert 1 is for free we need the feedback and this is not for free’ (respondent d1). The new head nurse (respondent n33), which was overlooking a number of departments, had ideas with another external expert who would provide an analysis of all processes, which could be used as a basis for process management’ (respondent n33).
The parties involved in the discussion appeared to have substantial conceptual differences of how quality and safety at the department may be achieved. Although the talks between risk manager and head of department were promising an incident involving the researcher should reveal how difficult collaboration between the two potentially is, and also partly explain why the risk manager and the department have not had collaborated on earlier occasions. In addition, as two risk meetings within four weeks of the CIRS feedback meeting - unseen before - may appear as ‘the start of a new chapter in patient safety at the department’, this also has to be put into perspective. These meetings were still a resemblance of the ‘rather chaotic’ or ad-hoc ways of how non-clinical activities unfold at the department and which had been observed throughout the observation period (the head of department for example, although his secretary had scheduled the meeting for him, had ‘forgotten’ about the meeting; the deputy head of department joined the meeting ad-hoc, so did the new head nurse who just happened to be around when the meeting was about to start and was spontaneously invited by the head of department to join).

The funding possibilities for any of the ideas mentioned in these meetings, including the continuation (i.e. active support) of the OEGGG CIRS project at the department were also unclear and the head of department wanted to address this with the hospital directorate at a suitable opportunity.

It was therefore assumed that no immediate major changes were about to take place at the department and that hence data collection could be considered as

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35 The researcher had communicated per email with the risk manager. In order to keep the main contact person, the deputy head of department respondent d2, in the loop respondent d2 was copied into an email to inform the risk manager about the researcher’s study at the department and that contained the blank questionnaire which researcher had used earlier at the department. Respondent d2, apparently without checking the content of the attachment, assumed that the researcher had forwarded the findings of the questionnaire, which were agreed to be kept confidential. Respondent d2 saw that as a breach of agreement and violation of the so important exclusivity of the project, not involving anyone from the hospital directorate or WKAV. Although the misunderstanding was quickly resolved it left a ‘bad taste’ and showed how important it was for respondent d2 as the initiator of the project to keep it exclusive.
saturated, resulting in the researcher leaving the field and moving to final data analysis and writing up the thesis. Contact with the hospital was maintained for verification of data.

7.8. Discussion

This chapter presented findings from the fieldwork observation of CIRS in use at the department. The chapter set out with information about the reporting frequency, stating that CIRSmedical had barely been used at the department. This was not just a start-up problem as underreporting was evident over the 18 months since the CIRSmedical training session and until the start of fieldwork observation. Going into the field gave the opportunity to gain insight into why staff were not using CIRS, if and how they found alternative ways of communicating incidents, and how they were making sense of patient safety more generally. Ethnographic studies usually result in a lot of data and this also applied to the fieldwork observation that stretched over five months at the department. Data collected had to be transposed into meaningful sequences that could communicate ‘what was going on’ to a wider audience and this resulted in 134 descriptive codes, 71 contextual codes, 14 categories, and four themes. These codes, categories, and themes also provided the main structural framework for the presentation of this chapter.

CIRSmedical appears to be a platform that provides free access to users. Hospitals deciding to use CIRSmedical should however consider what action they want following the submission of reports. Analysing reports is costly, at the same time it is this analysis of reports that leads to meaningful insight that can guide improvements. In that light reports are of great value to an organisation and health care organisations need to consider how much control they want to have about their own reports and how dependent they want to be from the
operator of the reporting system. As the head of department rightly concluded at the first CIRSmedical feedback session using CIRSmedical is for free, but the important part, the analysis and feedback are not. This should be considered at the very beginning of a project. Otherwise reporting organisations might end up having to ‘buy back’ (analysis of) their own reports. To run a CIRS merely for personal reflective purposes of the reporter [which was one of the original intentions of the group around CIRSmedical at the University Clinic in Basel (Kaufmann et al., 2002) but has lacked international support from the international patient safety community] seems little meaningful. In addition, although ten minutes for reporting might seem little, in comparison with the average less than two minutes doctors spend with patients this is a lot of time and probably asking too much for too little feedback in exchange.

Although CIRS was provided to the department at no cost, except for support costs, it appeared that the hospital’s collegial leadership and the hospital’s risk management department did not really understand where or how the OEGGG project should fit within their own priorities and plans, including the development of their own risk management programme. The ‘chaotic’ hospital and department environment seemed to foster, allow, and in some way even to require prioritising ad-hoc activities and the serving of immediate needs over other (more strategic) goals with the potential of making a more efficient and long(er) term contribution to safety. It also appeared that the relationship between the department’s medical lead, the new head nurse (which was not placed at the department directly anymore but overlooking a number of departments), and the hospital’s risk manager was such that each wished to develop their own ideas and hence following different paths in quality management and patient safety. At the conclusion of the research it was not clear if and how any funding would be secured from the trust to support the OEGGG CIRSmedical project and in case funding could be secured if this would be channelled towards Expert 1 or elsewhere. Towards the end of the
fieldwork it appeared that the relationship between Expert 1 and the hospital may have been complicated by the lack of progress and (financial) investment in additional training sessions. Expert 1 had made attempts to promote his services commercially and had run several private sessions for paying customers at other hospitals.

It was not a primary goal of this study to do an assessment of the reporting system CIRSmedical itself. However a few things can be said about CIRSmedical. The information provided by Expert 1 that CIRSmedical fulfilled the basic requirements of a CIRS in terms of anonymity, confidentiality and extramural data management and that the reporting form was designed with appreciation of current patient safety knowledge was mostly verified. From a practical perspective though, considering the little knowledge and training staff at the department had, it may be noted that the CIRSmedical reporting form contains two free text passages. This requires from the potential reporter an ability to structure the event in a meaningful way, which requires trained staff, and this did not happen. The free text passage also seems to complicate the anonymisation and analysis process and hence increases the resources needed for running the system and providing feedback. It may therefore be worth considering if low budget projects such as the OEGGG CIRS should include such a free text passage or not. It is probable that a simpler and faster to fill in reporting form would be used more frequently and be more meaningful in creating rough statistics on incident occurrence. These statistics may liken payout of additional funds that could be used for sophisticating CIRS - creating a better reporting environment and using a more complex reporting form.

Finally, a few last comments on the OEGGG. The OEGGG could not provide accurate information on how many Women Hospitals exist in Austria (the email respond read “about 100 departments”, this imprecision may be caused by definitional issues where it is not entirely clear if an institution counts as a
Women Clinic or just part of another department) and how many of them had replied to the OEGGG round letter that had motivated hospitals to use CIRSmedical. This might have to do with the fact that hospitals were asked to direct any queries directly to Expert 1, thus also leaving all responsibility with him. Regarding the relatively low response rate, somewhere between 10 to 15 hospitals out of approximately 100, the OEGGG could have probably followed this up further, sending another reminder or an additional invitation, which to the knowledge of the researcher has not happened. It might be pure coincidence but the round letter was sent out around Christmas, a quiet time, and this might have affected the low response rate. Hence, the overall role of the OEGGG in this project has to be seen in relation to its limited funds and more as a kind of moral support, taking a stance for this project, and notifying and encouraging Women Hospitals in Austria to use CIRSmedical. The unfolding of events in the present study suggests that the OEGGG is a representative body and not in a position to financially or otherwise directly support individual hospitals in their use of CIRSmedical.

In summary findings from the fieldwork observation found little empirical evidence of supportive measures to CIRS and other non-clinical issues with relevance to safety of staff and patients. While CIRS, in line with other safety relevant activities, may have been perceived by the majority of staff as a sensible or ‘good’ thing to do they did not find a meaningful way to incorporate CIRS into their daily agenda. The OEGGG CIRS project has thus initiated some discussion on patient safety, especially towards the end of the observation some 22 months into the project, but has so far not turned out any tangible results that would have improved safety.

The next and final chapter will draw conclusions to this research.
CHAPTER 8: CONCLUSION

8.1. Introduction

This final chapter discusses the findings emanating from this research and conclusions drawn. Section 8.2 provides a critical perspective on management responsibilities in patient safety in Austria. In eight subsections it discusses conclusions to patient safety literature in Austria (8.2.1), error rates in health care (8.2.2), error rates in Austria (8.2.3), Heinrich’s ratio (8.2.4), the value of critical ethnography in health care related research (8.2.5), CIRS in Austria (8.2.6), the clinical / non - clinical continuum (8.2.7), and finally the question if it was ethically and morally right to implement CIRS (8.2.8). Section 8.3 presents a summary of the contributions to knowledge and considers the potential of the research from the perspectives of three main interest groups; managers, policy makers and researchers. Section 8.4 discusses the limitations of this study before section 8.5 points out areas for future research. This chapter closes with some reflections in section 8.6.

8.2. A critical perspective on management responsibilities in patient safety in Austria

8.2.1 Patient safety literature in Austria

 Whereas finding out about the “written rules” of a health system and its endeavours in patient safety can be a rather straight forward task in some countries, for example in the UK through one of the many DOH, NHS, NPSA and NRLS reports, or in the United States through government white papers, AHRQ, NPSF, IOM, IHI, this turned out quite a different and challenging task for
Austria (but also for EU and WHO data in general, which are a lot less extensive than those national and independent reports from the US and the UK). This is mostly due to a lack of in-depth government reports and/or a general lack of independent and academic publications about patient safety and incident reporting in the Austrian health system.

A good general independent source of reference in Austria is usually the Supreme Audit Institution of Austria (German: Rechnungshof), an independent government institution of the National Council (German: Nationalrat), which performs financial and/or legal audits on the executive branch of power. However, their last report on the Viennese health system (WKAV) dates back to the year 1998, which was a first evaluation of the then newly (1992) founded WKAV. Back then the Supreme Audit Institution of Austria (Rechnungshof, 1998) mentioned the inception of a pilot project in 1994 for the development of an executive support unit for quality management within WKAV. It criticized the lack of a standardized or unitary approach to quality management, with a lack of differentiation between quality assurance and quality management, and lack of reference towards an entire hospital or specific areas of medical expertise in the hospital. The report especially criticized a lack of documentary evidence and reports accompanying any such efforts. The quality endeavours were therefore not possible to be traced down. As a consequence WKAV hospitals did/do not fulfil the requirements of the Viennese hospital act of creating the conditions for comparative analysis and assessment of quality assurance between hospitals (Rechnungshof, 1998). Since then and until publication of this thesis there has been no further assessment report of the WKAV by the Supreme Audit Institution of Austria or another independent body.

In this light it might not come as a big surprise not to find much information on the health system in Austria in general and the documentation of quality endeavours and the safety of patients in particular. Austria does have its share
of preventable adverse events leading to death. The problem with these few events of medical malpractice and iatrogenic injury in hospitals in Austria that come to light is that they are only publicised through the media. Any other investigations, if any have been undertaken, are literally impossible to get access to. This manifests a cover up mentality where errors in the Austrian health care system are not properly investigated, root causes not identified, and hence no systematic changes are initiated (Langbein, 2009; Pateisky, 2008).

This stands in contrast to developments in the US and the UK where errors are increasingly discussed more openly. One significant example from the UK is the ‘Kennedy Report’, officially The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol’ (Kennedy, 2001), which was a major step forward in understanding events that allow major disasters in health care to happen and how they may be prevented. The Kennedy report presented the results of a thorough investigation on 540 pages. In comparison for example a big murder scandal in the 1980’s in a public hospital in Vienna that caused hundreds of deaths. In fairness it has to be said that the Austrian cases involved negligence and criminal acts. However, it is likely that a number of contributing factors, for example regarding the culture of the organisation, work procedures, protocols and the like, played an important role in this. Unlike in the UK there is no public report about the causes and circumstances of those events in Austria. This sheds a bad light on transparency in patient safety endeavours in Austria. Incidents in the Austrian health system, whether or not they led to harm, are often covered up rather than investigated (Pateisky, 2008). At the conclusion of this thesis a series of deaths at the University children’s clinic in Innsbruck, Austria makes news, where probably seven children have died due to allegeable medical errors (www.oe24.at). Although it is desirable, it is questionable that there will be an ‘Austrian Kennedy report’ anytime soon.
8.2.2. Error rates in health care

From an international perspective patient safety has become a much more prominent topic with increasing attention given to error. The past decade has seen numerous patient safety initiatives, accompanied by an avalanche of publications. Despite this patient safety is still a relatively immature agenda and little is known whether initiatives have worked or not and if health care has become any safer. Moreover, a lack of systematic measurement and evaluation in health care was (and is) hindering understanding the extent of error in health care. It is believed that this is hindering improvement in health care safety across the world.

Throughout the period of study and in an attempt to find out more about the error rate in Austria the issue of ‘the scope of the problem’ continuously reappeared in patient safety publications, almost exclusively citing the IOM numbers or derivatives of it. The first contribution of this thesis stems from a critical assessment of this literature on the error occurrence and provides a possible explanation to why progress in patient safety is so seemingly slow, and difficult to measure. The author found a number of controversies and inconsistencies in current estimations regarding screening and sampling methods, limitation of retrospective reviews, causal relationships, preventability of adverse events, immediate and short term survival of patients experiencing adverse events, the reproducibility of number of patient deaths, terminology, and general accuracy issues of studies. While building this argument consisted mostly of drawing together the handful of critical studies (McDonald et al, 2000; Brennan, 2000; Sox and Woloshin, 2000; Hayward and Hofer, 2001; Gray, 2003) that were published shortly following the IOM report into one coherent account this thesis points to additional areas that appear inconclusive either in the report itself, the scientific work underlying it, or in published work rejecting criticism and aiming to add to the IOM report’s credibility.
Despite early calls for reliable and representative studies on the occurrence of preventable adverse events (for example Vincent et al., 2001) such studies have never come forward, commissioned, nor can they be expected to come forth any time soon (Vincent, 2010 and 2011 personal email conversation). On the contrary, those IOM numbers, or extrapolations based on IOM methods and numbers, have spread throughout the international patient safety literature and found their way into major government, WHO, and EU reports and recommendations on patient safety. These reports seem to be caught in a “triangulation of error” with one report referring to another about the supposedly high number of preventable deaths. Accordingly extrapolations must be considered incorrect. As yet there is no reliable and representative data available on the extent of errors which result in patient harm and how many of those might be preventable. Until today it cannot be said with any certainty how many adverse events occur in hospitals, and what effect they may have on patients and staff.

It is somewhat uncomforting to know that unsubstantiated data occur in what became a prestigious report, and that the report as a whole, data from the report, and methods for adverse event estimations has been cited and or been used uncritically, and been used in major reports of the DOH, the European Union, and the World Health Organization, rather than those institutions investing in and conducting original research themselves in order to fulfil their proclaimed goal of building a strong foundation for patient safety. These numbers are not plainly incorrect but may have a number of untoward implications. First of all those numbers may contribute to fear amongst patients and staff, opening the doors to litigation claims, and creating a culture of blame, the very thing they subscribe themselves to fight against. Secondly, governments and institutions may be motivated to engage in or recommend particular patient safety initiatives based on wrong grounds. Organisations may ‘rush’ into projects unprepared, not understanding the severity of the problem,
unaware of the intricacies of existing data and how to interpret it in a given (national) context. Thirdly, it shades the need for new and reliable data on error occurrence and the enormous amount of resources that is required to making a worthwhile contribution to safety that is similar to high reliability industries and which would require involvement of a high number of stakeholders, including hurt patients and their relatives, health care personnel, lawyers, insurers, experts from other high risk non medical industries, funders, and politicians.

It has been argued that the currency of patient safety can only be measured in terms of prevented harm and saved lives (WHO, 2005a). If the numbers against which progress should be measured are incorrect this will thwart results. If for example the actual adverse event rate is much higher than currently estimated then later and more reliable assessments will not show the expected success. It need also be considered that patient safety organisations are up against a very disciplined, hard working, and most of all critical bunch of front line staff, the clinical experts on which running any such initiative is dependent on. Some of these might be eager to discovering and feeding into a ‘credibility gap’ (Handy, 1999), pointing to unreliable and hence easily rejectable statements and generalisations, which may well contaminate future attempts of ‘external involvement’ in this matter and overthrowing an entire patient safety concept. This gap presents an opportunity for any country with an interest in patient safety to become the first nation with reliable and representative data on error occurrence. On a more operational level organisations and decision makers concerned with health care need to develop a more critical and reflective attitude - as the study shows - even when data comes from apparently reliable sources, and assess if supposed shortcomings in safety and possible solutions that come with it would also apply to their specific context.
8.2.3. Error rates in Austria

How often adverse events occur in general in Austria cannot be said with any certainty due to a lack of systematic data collection and interpretation. Those publications that refer to an adverse event rate cite numbers suggested by the IOM (2000), may it be reports in the local media, statements from politicians, or books on patient safety (for example Langbein, 2009; Pateisky, 2005). Langbein (2009), a journalist in Austria, even made extrapolations for the adverse event rate in Austria. Based on the German APS study (2007) that 4 percent of hospital inpatients suffer from preventable adverse events, 1 percent from medical malpractice, and that 0.1 percent of all cases result in preventable deaths he calculates that in 2.5 million hospital inpatients in Austria 100,000 patients suffer from preventable adverse events, 25,000 from medical malpractice, and that every year 2,500 hospital inpatients die in Austria as a result. However, the formula for his calculation itself presents a chain of error as it is derived from the IOM report, trough to the UK DOH report, through to EC and WHO publications, and the German APS study, before it ended up in the local media in Austria, which persists that preventable adverse events in health care leading to death occur frequently.

As yet there is no clear epidemiological and statistical data in Austria to either very or reject this claim. The fact that comparatively little data exists about errors in health care must allow the conclusion that either health care in Austria is exceptionally good or that many cases go unnoticed (Paula et al., 2011) and that the problem of preventable adverse events leading to death in the health system in Austria might indeed be as severe as referrals to IOM data suggests. While the extent of adverse event rates in Austrian hospitals is unknown international literature clearly indicates that they present a serious problem in health systems in developed countries. Considering that with regard to the number of in-patient stays Austria ranks first in Europe, with 27.9 inpatient-stays
per 100 inhabitants (average length of stay 5.7 days) registered in 2007 compared to an EU-average of 17.2 inpatient-stays (average length of stay 6.1 days) (BMG, 2010), and leaving out other factors, the risk of experiencing an adverse event might indeed be high for Austrians.

8.2.4. Heinrich’s ratio

In addition to the controversies surrounding the scope of the problem of preventable errors in health care it became apparent that another often used source (various IOM, DOH, NPSA reports) might be not as credible as it first appears, and this concerns one of the key arguments for using CIRS more generally - the Heinrich ratio or iceberg model (see section 4.3.1 and figure 4.1). Similar to the IOM numbers the iceberg model continuously reappeared during the study. It is often referred to in papers and presentations on patient safety, however, often without using any citation. The iceberg model is based on Heinrich’s ratio, which is from the year 1941, and asserts a relatively fixed ratio between the incidence of no-harm incidents, minor incidents and major incidents (Gallivan et al., 2008). The author could not get hold of the original work of Heinrich and referred to the ratio as described in the patient safety literature and giving reference to it by using the model as presented in a DOH NPSA (NPSA, 2005c) presentation, nevertheless being puzzled if a study from 1941 would still apply in today’s modern context of health care delivery and if there was any up to date work. The only such piece of research could be found in Gallivan et al (2008:637), who claim to have invalidated Heinrich’s ratio, revealing a “hitherto unrecognised systematic pattern of change that contradicts the principle of the Heinrich ratio”. Their study suggests that introducing measures to reduce the occurrence of minor incidents will not inevitably reduce the incidence of major incidents pro rata and they conclude that any safety policies based on the Heinrich ratio needs to be rethought (Gallivan et al., 2008). This presents an interesting comment on a relatively dated study that had little
criticism or verification over the years. Future research could investigate further if indeed Heinrich’s findings still apply to today’s organisational settings or not. Any programs based on Heinrich’s ratio, such as the wide scale enrolment of CIRS in health care, need to be reconsidered in the light of these new findings.

8.2.5. The value of critical ethnography in health care related research

In relation to the scarce information on CIRS and patient safety in Austria the philosophical and methodological approaches of this study shed a new light on patient safety. This section briefly discusses the value of critical ethnography in patient safety research.

Ethnographic accounts about the managerial aspects of a CIRS during the implementation phase and use are extremely rare, both in Austria and internationally. This approach to studying the phenomenon is not seen as superior compared to other approaches but as adding value and “meaning” to those studies conducted in more “traditional” and positivistic ways. The European Union Network for Patient Safety (EUNetPas, 2011), the newly installed Federal Institute for Quality in the Health Care System (BIQG; see BMG, 2010, 2011a and b), and the Austrian association of resident doctors (OAK) seem to all rely on self-evaluation sheets in assessing CIRS in Austria. The EUNetPas (2011) for example, based on a three page self-evaluation questionnaire sent to hospital (association) directors, states that Austria has two CIRS already in place. One of which was described as the WKAV CIRS system “Working with CIRS”, a governmental run voluntary and confidential near miss reporting system, launched in 2006, on a regional level for hospitals of the Vienna City Hospital Association (WKAV), for all health care workers, with no public disclosure of individual reports (EUNetPas, 2011), which actually is the WKAV pilot CIRS that was run as a pilot project in only a few departments of the entire hospital network and saw little acceptance (BMG, 2011a).
Recent attempts by the newly installed Federal Institute for Quality in the Health Care System (BIQG; see BMG, 2010, 2011a and b) so far suggest that they too rely on self-evaluation data. The Austrian association of resident doctors (OAK) too mainly “evaluates” quality and safety through a one page self-evaluation sheet that is sent out to doctors every couple of years (and reminds the author of the immigration form passengers have to fill in when flying into America, asking passengers if they were a terrorist). Basically it is impossible to fail this self-evaluation safety test. Accordingly information obtained through these means of self-evaluation might not always result in very reliable and in-depth information about CIRS and might lead to misinterpretation of data. The study site hospital for example appears in those statistics as a forerunner in safety and forward thinking hospital as it “uses” two CIRS, the one studied in this thesis and the WKAV pilot CIRS. That both systems are barely used and that they (currently) do not lead to any meaningful action improving safety is not mentioned. It may therefore create a false impression that CIRS are already operational in Austrian hospitals, which findings in this study suggest otherwise, and probably a feeling of safety and security in patients who decide to consult this hospital for health services.

The critical approach adopted in this study has helped to pause on those occasions where the study hit controversies, regardless if they were considered at the outset of the study or not, and allowed to uncover and identify flaws in the patient safety discourse. The most apparent outcome of this is chapter 2 in this thesis which rejects the popular notion of the IOM report and subsequent publications, including those in Austria. However, one must ask "how is it possible for this to remain undiscovered and/or not acknowledged for so long?" The suggested answer is that first and foremost the "organisation of health care organisations" is to be blamed as it currently does not allow staff to take a critical stance towards their work. This may include various clinical things but most certainly includes a critical, and probably as much an informed, stance
towards various patient safety initiatives. This study shows how overwhelmed clinicians are in dealing with these things. A conclusion from this study is that 'somebody' in the health care organisation and on department level should have as its job 'being critical'.

The amount of "organisational threats" identified in this research (section 7.5), together with the absolute lack of management knowledge in the implementation of CIRS (compared for example to writers such as Handy, 1999) call for 'a manager' in the department who can take a critical stance. However, looking at theory and practice in other organisations immediately stifles hopes of such a manager and rather poses a question to the general organisation and management discourse. If concepts such as "systems thinking" and the "learning organisation" solve problems then why don't organisations as a rule have "systems' managers", "directors of learning", or "director of internal communication"? Instead common practice is to shift this on staff as "it is the task of everyone" -which, surprisingly, is also a common notion in patient safety. Even if the author tends to agree with this statement the findings in this study suggest that involvement of everybody in patient safety will still need 'a someone' to instigate and lead through change. Although ultimately responsible it is unlikely that the CEO or department leader has time for it.

8.2.6. CIRS in Austria

CIRS was an initiative by enthusiasts within the gynaecology and obstetric departments in Austria. It was ignited by Expert 1 and the OEGGGG and was picked up by the medical department leaders in the study site department. The origins and development of CIRSmedical at the department suggest that the initiative was the product of enthusiastic professionals with an interest and belief in current patient safety initiatives and a desire to promote change from within the health care profession and from within front line practitioners. They appeared as maverick leaders who resisted a lack of action from the hospital's collegial
leadership and the Vienna City Hospital Association (WKAV), knowing that their action could be restricting on their relationships with the hospital’s collegial leadership. The project developed and progressed independently from the hospital leadership and was the only operational CIRS in the hospital. Despite the efforts and enthusiasm of Expert 1 and the department leaders to introduce CIRS at the department this study finds that the project contains significant conceptual weaknesses. While Expert 1 used his expert knowledge to provide rich theoretical and empirical foundations to the initiative during the one CIRS training session the detail and volume of information may be too great to be effectively delivered within a single event. Expert 1’s involvement was largely restricted due to financial constraints of the department.

The projects stated objectives were to foster a risk conscious culture through providing staff with a new way to anonymously report critical incidents. Given the lack of financial aids for the project, additional training and information sessions (lack of understanding what a critical incident is; lack of understanding how incidents contribute to adverse outcomes; lack off “emotional” support from hospital leadership thus the danger to “get into trouble”; lack of policy bringing clarity about legal protection for reporters; lack of feedback), coupled with the constraints put on the system through current working conditions at the department (such as the small number of computers available to staff for their core duties, a problem that affects potential reporters as they do not have a free computer to write a report; lack of privacy for reporting; no internal CIRS trustee; lack of time to report), the fact that staff rarely used CIRSmedical, and the lack of agreement between hospital’s collegial leadership, risk management, department’s medical leadership and the new head nurse on the nature of risk and error and the efficacy of measures intended to improve safety it seems unlikely that the department’s current efforts will make great progress in fostering a culture of safety within the department. It is probable that the CIRSmedical initiative becomes one in a list of projects that are “a great idea,
but lack of support and hence practical value”. More importantly, it seems unlikely that the department and/or hospital learn from this project as to why it was not as successful as its initiators first anticipated. Another enthusiast, another project will come, and can fail in the same way, further lowering the morale of staff to participate in “non-core” projects and wasting scarce resources that are much needed to improve work for staff and safety for patients.

The CIRS initiative at the study site showed that existing recommendations on the implementation and use of CIRS had not been acknowledged at the study hospital, apparently because those involved in the implementation process were not aware of those recommendations. Medical and nursing staff probably underestimated the complexity of and were overwhelmed by the task of implementing and meaningfully using CIRS, despite their good intentions. However, the review in chapter four has shown that establishing a comprehensive voluntary CIRS requires an enormous investment of time and resources. Serious involvement in patient safety will require strong leadership and accountability and cannot be expected to emerge out of good will of individual practitioners who are both ill-resourced to do so and predestined to be rejected by their peers (i.e. doctors versus nurses; department external risk manager versus department physicians). It should not be the task of busy health care professionals to manage a CIRS.

If success of a CIRS may be measured by the frequency of reports, staff’s knowledge and awareness of CIRS, and actions as a result of reports that improve safety then the OEGGG initiative at this department was not a success. Nevertheless, feedback from the department indicates how it might work better and suggests that a CIRS project may consist of three phases: (1) implementation, (2) use, and (3) analysis and feedback; and that each of these three phases should have a manager accountable for progress. The first
‘implementation phase’ should for example explain operation, purpose and expected outcome of CIRS to all staff and from all levels, provide initial training and take-away information, or identify department specific barriers and incentives (such as the possibility of integrating existing documentation and staff into CIRS, see sections 7.6.1. and 7.6.2) to reporting (at a later stage this implementation phase is repeated with implementing action from the analysis of reports). The second ‘use phase’ should present an overhead that staff can turn to with questions and concerns, identify possible additional local barriers to reporting, keep CIRS operational and running, and introduce tangible measures to development and progress. The third ‘analysis and feedback’ phase should analyse reports, provide regular feedback to reporters (even if only little reports have been coming forth), and instigate action following the feedback. These three phases are not sequential and run in parallel, with the managers for each phase corresponding with each other and guiding the overall project. This concept loosely corresponds with developments in aviation where the Commercial Aviation Safety Team (CAST, 2011), a public-private-partnership that has been credited with reducing the commercial aviation fatality rate in the US by 83 percent over the past decade, is made up of three core teams (CAST, 2011): a joint safety analysis teams (perform data analyses), joint safety implementation teams develop safety enhancements), and a joint implementation measurement team (develops a master safety plan, measures effectiveness and identifies future areas of study). The strength of CAST lies in its extensive membership, its proactive commitment to safety, and its ability to design and broadly implement strong system changes (Pronovost et al., 2008). The cost of implementing the safety enhancements was projected to be USD 500 million, spread out over 10 years, with the safety enhancements put in place by the CAST Safety Plan predicted to save the industry more than USD 600 million each year (CAST, 2011). If patient safety wants be serious it will need serious funding.
If CIRS is implemented and run in a way such as in the study site hospital there is an inherent danger that while it is “officially implemented and used” it actually does not work, is not used, and takes time off the few people who do spend time with it. If however a severe error would occur at that hospital the organisation could still ‘use’ CIRS in order to defend themselves by stating that “we did everything we could, we even have a CIRS”. With hindsight of the findings the OEGGG recommendation for hospitals to ‘participate in CIRSmedical as hospitals would otherwise run danger having superimposed on them other reporting systems and procedures, which would inhibit the meaningful handling of incidents’ (OEGGG, 2005) has to be seen more critically. The findings suggest that the OEGGG CIRSmedical project, under current conditions and with the current lack of resources, is in itself not a meaningful way of managing error. This calls again the governing body into responsibility to take honest, credible and resourced actions in patient safety that include regulations and assessments that no one can ‘escape’.

In order to undertake systemic changes in the health care system in Austria it is necessary to identify what kinds of local incident reporting systems are in use across the nine states of Austria, what experience organizations have with it, and how those experiences can be shared. This might also involve investigating how advanced non-health care organisations in Austria are in their use of incident reporting systems. Experiences could be bundled and shared amongst umbrella organisations and professional societies in order to set up a concept for nationwide incident reporting systems in Austrian health care institutions. Existing resources can be used to promote collaborative patient safety programs that involve (as) many stakeholders (as possible), from agency constituents, the health professionals community, academia and the public, and this should be done from a more critical and in-depth perspective than the current self-evaluation procedures. This would also incorporate addressing other shortcomings, for example the need for standardisation of terms and
definitions. Staff need to know the correct terminology in order to know what to report, and where to report it to. Without clear definitions findings will be difficult to compare, for example if adverse events are defined differently in different reporting systems and those reports are then merged in a shared database this would distort results (it would eventually result in similar ‘findings’ to the IOM report, see the discussion throughout Chapter 2). This is an important and challenging task as was discussed in section 4.3.3 the WHO World Alliance for Patient Safety (WAPS) and the European Union Network for Patient Safety (EUNetPas) do not have German amongst their output languages. It is not clear how Austria and other German speaking countries will overcome this problem. None of the above discussed issues is explicitly addressed in any of the recent government publications on patient safety developments in Austria, such as BMG (2010) and BMG (2011a and 2011b).

8.2.7. The clinical / non-clinical patient safety continuum

Probably stating the obvious this study stresses that the implementation of a CIRS is a non-clinical task and suggests a principal separation of clinical and non-clinical tasks at the department. Proper patient safety is a complex task that requires experts. While medics and nurses should be involved in the process it seems unrealistic to expect them to manage a CIRS “just along the way” and on top of their clinical duties. Similar to the non-clinical task of implementing and running a CIRS this study identified latent managerial factors that complicate the performance of health care professionals and can potentially contribute to adverse outcomes / events. During the observation a number of situations came up that revealed managerial demands on the clinical team that can potentially compromise patient safety. These were often quite simple non-clinical problems that occurred in the daily operations at a hospital in and outpatient department. While medical error is an important issue, as the literature frequently points out, this study suggests that in order to apply the systems concept of organisational
error in health care efforts have to go beyond an exclusivity of clinical incidents and seriously consider the role that non-clinical issues play in the organisation and delivery of health care services. According to the systems theory in error science any one failure in the system may contribute or trigger an adverse event.

This study provided evidence that situations can arise where managerial demands are recognised but left unattended as attention is given to core clinical tasks (see ‘organisational threats’ throughout section 7.5, as well as section 7.6.3). Those managerial tasks are left unattended and therefore pose latent threats in the system that have the potential to contribute to adverse outcomes and potentially impact patient safety. In addition these latent conditions are suspected to have a negative impact on staff motivation, staff communication, and efficient use of hospital resources. Moreover this study points out a system that not only makes it easy for individuals to err, but also for the health care organisation, due to its (lack of) allocation of management responsibilities, to leave known errors and system deficiencies unattended. It makes it easy for them to engage in patient safety initiatives without adequate knowledge and resources for handling them, and even allows the organisation to apparently ‘get away’ with an unsuccessful implementation and appear as a forward thinking and leading organisation in patient safety. It is believed that the critical ethnography approach in this study in particular allowed sufficient investigation and subsequently uncovering of these issues.

The themes and categories identified in this study (see section 5.6.5 and figure 5.4) may be related to one or another patient safety event taxonomy. However, as has been discussed earlier (in section 1.3 and in section 4.3.3) the international efforts to establishing a standard taxonomy for patient safety events, even if one of them should become a standard, do not apply to German speaking countries for semantic reasons. Moreover, Tamuz et al’s (2004)
comments on defining and classifying incident reports need to be kept in mind (Tamuz et al., 2004:19): ‘How does the definition of events channel managers’ attention? How does the classification of events into one category or another trigger organizational routines for gathering and analyzing information? How do definitions channel the attention of providers and managers? How does event classification influence data gathering and analysis? Patient safety events may be categorised and classified in many ways, if they do not trigger action because an event might not fall into one of these categories this becomes meaningless. That this is a real danger has not just become evident in the present study, but there are indications that this might be a real threat in other, more sophisticated CIRS such as the NHS NRLS (see section 7.6.3). Consequently it seems as if current risk procedures, in both the Austrian and the UK hospital, are set up in a way to fit existing thinking of the medical/hospital system and do not sufficiently reflect the error models that explain organisational error.

It may therefore be concluded that (1) a principal and first level distinction should be made between clinical on one hand and non-clinical tasks and quality problems on the other hand. This concept is oriented towards the facilities management discourse (see section 5.2.4) and Barrett’s (1995) core / non-core business continuum in facilities management. This is exemplified in figure 8.1.
In figure 8.1 an arbitrary interface between clinical and non-clinical activities is used. The key is that this interface is not shown as a vertical divide but that it accommodates the notion that an activity in the hospital can be (a) wholly clinical, (d) wholly non-clinical, or (b and c) part clinical, part non-clinical. Wholly clinical activities can be seen as the raison d’etre functions of a health care organisation. The function shown at point (a) in figure 8.1 could be any of the clinical issues identified in section 7.3.1. Incidents, such as the communication issues identified in section 7.3.2 would be placed on point (b) or (c) in figure 8.1 as they are closely associated with clinical work but contain non-clinical elements (i.e. the ‘system’ that provides unsafe means of communication and lacks standard procedures for safe communication). The organisational threats identified in section 7.5 would be placed on point (d) in the continuum in figure 8.1. The amount of non-clinical events that were observed affecting the daily operations at the department call for dedicated accountability of those management issues. It is suggested that the principal separation between
clinical and non-clinical incidents could be placed in front of existing organisational error models, such as Van der Schaaf’s incident causation model (Schaaf, 1992), as technical, human, or organisational error can occur in either purely clinical as well as non-clinical activities. The system approach to patient safety, when put into practice, appears to currently cover only parts of a range and scope of issues (the clinical activities). These issues seem to reflect the fact that compared to other domains and industries ‘systems thinking’ in patient safety is a relatively new approach with a degree of confusion and ambiguity amongst its constructs, concepts and methods (Waterson, 2009).

In relation to CIRS it appears that this split between clinical and non-clinical events is an issue that reporting systems in non-health care organisations do not have to face. They can run a “universal” CIRS. A future study could investigate the consequences of this and find out how applicable findings about CIRS in organisations outside health care really are, and how much discipline specific issues will play a role. By allowing to report non-medical reports, analysing them, and providing feedback and taking appropriate actions it could be investigated if this correlates, i.e. boosts reporting of medical incidents (i.e. staff get used to the reporting procedure; if one is observed by peers when using a CIRS, which in this study was inevitable, this does not automatically mean that one is reporting a medical incident as CIRS would not be exclusively for medical incidents; staff learn to trust the system; staff see the purpose of reporting and find it meaningful to use the system - like they used the technical support team function). A system inclusive of all incidents (this of course shall include analysis of and response to all incidents) may serve not only to reduce error but also to foster a systems culture that, by moving away the focus from medical events only, encourages reporting relevant to whole system improvements.
Concerning the complexity of tightly coupled healthcare organisations, where practically everything can have an impact on patient safety, starting from the temperature of tap water to logistics of meals, from floor tiles to education and training, health professionals can feel overwhelmed by the sheer magnitude of the problem (Leistikow et al., 2011). Staff might think it useless to improve one aspect of care when the problem can just strike elsewhere. In addition staff can end up in heated discussions about which safety problem is the most urgent, often with both sides being right (Leistikow et al., 2011). A working universal CIRS could fulfil an important purpose in documenting these various quality and safety problems, concerns and suggestions for improvement. In this way it could aid in prioritising safety problems and channelling efforts to where they are most needed, at the same time giving the “runner-up” a perspective of when he can expect constructive comments and support regarding the safety problems he feels are important. This of course requires an environment where it is safe, easy, and worthwhile to report.

Secondly it should be the declared goal of the organisation that those non-clinical tasks and quality problems are equally managed and attended to as are clinical matters. However, it is suggested that this is not done by doctors and nurses but by a professional manager. The methods and findings of this study cannot point to any specific requirements of this manager but, as general management thinking seemed to be absent from the department and in the OEGGG CIRS implementation, a general management approach could make a promising start. A future investigation could focus on the requirements of such a role. The findings in this particular hospital suggest though that this individual should not be from within the hospital directorate, such as the hospital’s risk manager, but either a new post in the department or someone independent from the hospital directorate, i.e. not a superior to the staff he aims to help (the above raised point that this individual should be a manager rather than a health
professional inherits that he doesn’t come from either doctors or nurses, as this is likely to cause resentment from either one of the two groups).

Patient safety seems to consist of several components, medical, nursing, technical, and managerial components. Currently there seems to be an imbalance amongst those and tasks being committed to medical and nursing personnel only. The findings in this study suggest that patient safety is probably best described as a problem of management AND medicine, and ways have to be found how organisation and management experts can work together with clinical “core” personnel in order to provide safe and efficient services to patients and staff.

8.2.8. Was it ethically and morally right to implement CIRS?

The discourse on organisational change distinguishes between change and innovation and holds the popular notion that while all innovation is considered change, not all change is innovation (for example Hernandez and Kaluzny, 1997). Although the OEGGG project resulted in some discussions on patient safety at the department it would be too early to call this an innovative change. Before CIRS implementation the department could not know with certainty if this change will result in an innovation or not. However, given the limited resources of any hospital, considering that with any project comes at least the costs of staff involvement and possible staff (de)sensitisation to a subject, as well as the numerous ethical considerations around conducting the study, this thesis wants to address one last question: Was the decision to implement CIRS under the given conditions ethically and morally right? The findings of this study suggest that a principal differentiation should be made in all hospital operations between clinical and non-clinical operations. Accordingly two perspectives, a clinical and a non-clinical, will be consulted to answer this question.
First, people involved in the decision to implement CIRS were mostly physicians. To some extent these physicians may, or at least should have been influenced in their decision by the Hippocratic principle “first do no harm”, as this serves as one of the principal precepts of medical ethics. Accordingly physicians are aware that in some situations it may be better to do nothing rather than risking to cause more harm than good. This is a fine line that physicians have to cross and refers to what Davidoff (2011) calls the ‘snail’ or the ‘evangelist’ perspective. One can either become a celebrated pioneer of medical innovation or loose his reputation and job. More often than not was and is the medical elite divided over this question. The history of medicine, and innovations in medicine, provides examples where doctors did cross this line successfully. For example the pioneering work of Blalock, Thomas and Taussig (Thomas, 1998) broke the taboo in medicine of operating on the heart. When they decided to cross the line, against resistance from their medical peers, they made possible the first successful open heart surgery in 1944. What was unthinkable during their time has now become acceptable medical practice, standard, and best practice in medicine. As of 2004, in the United States alone, more than 1.75 million heart operations are performed every year. Progress in medicine is thus likely to be dependent to some extent on trial and error.

However, it is not known to what extent physicians involved in the decision to implement CIRS perceived it to be a “medical decision”, hence a decision that would underlie the rules of medical ethics. The physicians’ involvement in the decision making process indicates that, to some extent, they perceived it as one of their responsibilities, notwithstanding that they are trained medics and not trained managers. Therefore it may be argued that they perceived the CIRS implementation as something “medical”; or otherwise, perceive management tasks, such as the decision to implement CIRS, as something they are largely responsible for, and at the same time feel adequately equipped to do so. This
goes in line with the tradition in the medical profession which, over history, has strongly objected any involvement of a third party (Coburn and Willis, 2000).

Secondly, from a management perspective, a manager with knowledge of the complexity of patient safety interventions and with responsibility for the outcome of such an intervention would probably have consulted the literature on CIRS implementation and other patient safety interventions. This would have provided insight into the complexity of the matter as well as possible and probably more urgent alternatives. Before implementing CIRS he could have assessed the safety culture at the department, find out about the environment in which CIRS is expected to grow, and allocate resources to prepare the department for an implementation. In this way a decision for or against CIRS implementation could have been based on insightful data from the very department.

Accordingly from a medical perspective the decision to implement CIRS was ethically justifiable. On one hand because clinical staff did not know better, on the other hand, with the benefit of doubt and from an ‘evangelist perspective’, because clinical decision makers at the department may learn their lesson and do it better next time. As there was no manager to offer a critical perspective the implementation was, under current conditions, right. From a management perspective, or a patient safety perspective, considering the (lack of) an evidence base and the situation at the department a more ethical decision would have probably been to postpone implementation and to do more preparatory work that would facilitate a successful use of CIRS. The question is therefore rephrased if current conditions at the department are ethical and moral. This may be addressed in future research and by using phronetic research, asking four value-rational questions: Where are we going? Who gains and who looses, and by which mechanisms of power? Is this development desirable? and what, if anything, should we do about it? This is strikingly similar to Drucker's (2003, oriented on Hammer's work, 1990) questions about the
profession of management and ways to 'work smarter'. These questions were "What is the task?", "What are we trying to accomplish?", "Why do it at all?" resulting in eliminating those things that do not need to be done.

This is a valid question in patient safety because hospitals operate on limited budgets. It may be argued that implementing CIRS in the way observed at the hospital is threatening safety itself because it unnecessarily occupies staff who could otherwise use their time more usefully. Contrary to CIRS in health care there is evidence, in particular from the 'lean discourse' that eliminating unnecessary processes in hospitals increases safety. Hospitals should take a more critical approach to what they are and what they are not doing, in clinical as much as in non-clinical agendas.

8.3. Summary of contribution to knowledge

This section shortly summarises the six main contributions to knowledge emanating from this present study. It will conclude with a consideration of the potential of these contributions from the perspectives of three main interest groups managers, policy makers and researchers.

1. Clinical / non-clinical patient safety continuum model: The first contribution relates to a principal classification of hospital activities. Findings suggest that the current organisation of public hospitals (in Vienna) is ill resourced to implementing new patient safety strategies and effectively identifying and addressing critical incidents. The 'systems approach' to error in health care currently focuses too much on core medical tasks. The study identified latent managerial factors that complicate the performance of health care professionals and potentially contribute to adverse outcomes. As a consequence this study suggests a principal and first level separation of
clinical and non clinical aspects of service provision. This has resulted in a clinical / non-clinical continuum model that accommodates the notion that an activity in a hospital can be wholly clinical, partly clinical / non-clinical, or wholly non-clinical. The amount of non-clinical events that were observed affecting the daily operations at the department call for dedicated accountability of those managerial issues. This is illustrated in figure 8.2 below, which is an amended form of the clinical / non-clinical patient safety continuum model as presented in figure 8.1. It shows the current focus of WHO, DOH, and AHRQ on clinical aspects of patient safety and gives examples of other (partly) non-clinical activities in the continuum.

Figure 8.2: Amended clinical / non-clinical patient safety continuum model

![Figure 8.2: Amended clinical / non-clinical patient safety continuum model](image)
2. Patient safety framework: The second contribution emanating from this study is the patient safety framework as presented in figure 5.4. The 14 categories and four themes (possible reports, barriers, organisational threats, and practical implications) identified in this study present a framework that subsequent researchers in patient safety may want to consider using to structure their inquiries. It may in particular present a framework for larger scale and more positivistic studies. The fragmentation into categories and themes may be helpful in conceptualising (also other more qualitative) studies at an early stage when they have to pass detailed ethical approval processes.

Figure 8.3: CIRS Patient safety framework

3. Phases of CIRS: The third contribution relates to the use of CIRS at a hospital department. This study suggests that there are three stages for a meaningful operation of CIRS: implementation, use, and analysis and feedback. The findings in this study call for a clear accountability and investment in each of these three stages. Without adequate monitoring and support a CIRS may be a barrier to improvement and may present in itself a threat to safety. This study provides insight into real world as well as conceptual problems pertaining to CIRS and an efficient and safe health care service.
4. Method: The fourth contribution of this thesis is to be seen in the methodological approach chosen for this study. The study shows that this type of research can contribute to the growth of knowledge on managerial aspects of patient safety. Observational studies can serve to identify latent managerial system vulnerabilities and leverage points that can aid the identification, development and implementation of system improvements. These studies can also generate empirically grounded hypotheses, “discoveries” (Roth et al., 2004), that can be tested using more traditional, controlled experimental methods. Moreover, as the currently predominant self-evaluation assessments of patient safety in Austria may lead to misinterpretations of the performance and workability of CIRS in Austria, the critical ethnography in-depth approach adds meaning to these statistics. It is suggested that critical ethnography is sufficiently capable of conceptualising the many different elements pertaining to the complex entity patient safety.

5. Research ethics: The fifth contribution relates to research ethics in health care related research. This study found substantial differences in ethical requirements to management studies in the Austrian and the UK national health systems. These differing requirements and the effect it has on design and execution of studies need to be considered when interpreting studies from different health systems. Outcomes of ethnographic studies in Austria and the UK (and possibly any other health system) may differ due to being subjected to (more or less) substantial manipulation of different ethical bodies.

6. Incorrect error rate estimations: The sixth contribution of this thesis stems from a critical assessment of the literature on error occurrence. Current estimations about the occurrence of preventable adverse events leading to death are incorrect. Despite this they are still widely used in the patient safety literature and from reputable institutions like the WHO, EU, or the
DOH. Currently there is no reliable data of a representative scale on the actual occurrence of preventable error in health care contributing to death. This is critical as it does not allow channelling limited resources to where they are most needed and might rush health care organisations into patient safety projects which they are ill-resourced to execute. A correct estimate of the occurrence of adverse events in health care is needed as it presents a prerequisite for measuring progress in patient safety.

The findings from this research have implications for various stakeholders in patient safety. This section will now conclude with a brief consideration of those implications from the perspectives of three main interest groups: managers, policy makers, and researchers.

Management perspective: From a management perspective it seems important to take a more critical stance towards the various available patient safety initiatives and not to hook on any trend that may come along. Effective patient safety requires an understanding of organisational settlements, a theoretical understanding of improvement initiatives, and a spirit of reflexivity and learning to enable and facilitate change in a particular national and organisational context. Those responsible for patient safety should first develop an understanding of their own core processes and then look at various approaches for identifying and tackling risks. Any approach to improving safety needs to be adequately costed and budgeted. Running into a “ready made solution CIRS” can be perceived meaningless by employees when they are first encouraged to reporting incidents but not all reports do trigger managerial action because limited funds do not allow for adequate analysis and action following those reports. “Half baked solutions” may have a long term negative impact on the relationship between clinical staff and management. Discouraged staff may cease support for future projects. In this respect it seems important for
managers to create some kind of evidence base at the outset of a project against which progress can be measured and communicated to the rest of the organisation.

If the decision is made for a CIRS management should consider the three stages for its meaningful operation: implementation, use, and analysis and feedback. In each of these stages it is important that all staff are adequately informed about CIRS and its implications. Important barriers for the use of CIRS have to be, as much as possible, obtained beforehand from the literature. These barriers need to be adequately considered and additional barriers in the project need to be identified and addressed. The findings in this thesis suggest that staff prefer to use CIRS as a holistic system that includes organisational and non-clinical threats. This preference may relate to litigation issues and staff wanting to get used to CIRS with less sensitive issues. However, it also points to the relevance of non-clinical and apparently simple threats, which have so far been largely unaddressed in the patient safety discourse. In a system approach to safety these reports must not be ignored.

Local applications of CIRS may create different practical implications for its successful use. Findings in this thesis especially point to stronger integration of various staff and synergy effects with already existing documentation. It is the task of a manager to identify those opportunities and to integrate CIRS into the rest of the organisational processes. The various managerial demands for CIRS, any other patient safety initiative, and the high number of organisational and non-clinical threats call for dedicated accountability by a non-clinical manager to facilitate and support core clinical processes. The three phases of CIRS, the clinical / non-clinical patient safety continuum model, and the patient safety framework developed in this thesis can be used for conceptualising a safety framework for organisation.
Policy makers: The most immediate implication for policy makers comes from the critique of the patient safety literature and the incorrect error rate estimations. Like managers in health care organisations policy makers need to take a more critical stance towards error rate estimations, check their reliability, and consider if and how they apply to a national context. This should also include under which ethical regulations studies have been conducted and how this may have influenced research outcomes. As yet there is no reliable data of a representative scale on the actual occurrence of preventable error in health care. The critique in this thesis comes as a call to policy makers worldwide, who can take a forerunning role if they are to provide accurate and representative data on preventable error occurrence. On one hand this would allow channelling limited resources to where they are most needed. On the other hand this would present a prerequisite for measuring progress in patient safety; a measure that has been absent for the past decade of patient safety endeavours and which has left everyone in the dark how efficient these endeavours have been and if and how much progress has been made.

As a consequence of the various shortcomings presented in this thesis it is suggested that a share of patient safety funds should go into the design of health care processes and the organisation and management of non-core and supportive agendas. In a systems concept these non-clinical issues are as viable a part as other, probably more complex and clinical agendas. This calls for dedicated non-clinical managers at the frontline. It should be the task of these managers, not clinicians, to assess, implement and facilitate patient safety initiatives. In this respect policy makers should also reconsider the entry requirements for academic researchers into the field and re-assess their ethical approval strategies; many of which seem to favour positivistic approaches over qualitative ones, and discourage or render ethnographic and more action orientated research approaches impossible. Furthermore assessment
procedures in patient safety need to move on from self-assessment exercises to more independent, thorough and reliable assessments, and should develop key indicators of safety than can be used for national and international comparison. Here special attention should be given to the development of a German patient safety taxonomy similar to the developing English taxonomy used by the WHO and JCAHO.

Researchers: The critique of the patient safety literature and in particular of the incorrect error rate estimations should on one hand alert researchers when using and interpreting those studies. On the other hand the identified shortcomings open new areas for research, most apparently in adequately determining how big a problem preventable error in health care really is. Identifying the correct scope of the problem will present patient safety organisations with a rigorous and systematic evidence base against which progress can be measured.

The high occurrence of non-clinical reports presents the opportunity for further investigation and if allowing staff to report non-clinical events could be used to desensitising staff toward CIRS. Although the literature at current does not provide accounts of cross professional executives who would give organisational threats the attention they deserve future researchers may be able to identify such individuals. A study could look into what kind of organisation behaviour and culture fosters the implementation of such hybrid managers. On the other hand it may be possible for researchers, to a certain extent, to take on this role themselves, to identify its role and responsibilities, to investigate its acceptance, and to study the impact it may have on safety.

As this thesis studied CIRS under budgetary pressures future researchers may want to study CIRS in a higher budget research environment. This could test the hypothesis if more funding will also result in more reports, and investigate wider system pressures on organisation behaviour and its impact on patient
safety. Furthermore researchers need to consider the ethical requirements under which studies were conducted and how this may have had an impact on the research outcomes. It seems that more careful attention needs to be given in the formulation of research hypotheses and problems when using studies from different backgrounds. This study also makes apparent that the patient safety discourse in general, and the discourse in German speaking countries in particular, lack of a patient safety taxonomy. Future researchers will need to address this issue.

In regard to the methods used the author can only encourage fellow researchers to using qualitative methods and ethnography to study organisation development and patient safety in health care organisations. The overwhelming impression was that, after a first phase of scepticism towards the researcher and his intentions, staff were generally very interested in and supportive of his work. Probably because they themselves see the need for change and are ‘stuck’ in a gridlock system that doesn’t allow very much time for doing things differently. The experiences from this research, together with the models that evolved from the study, present future researchers with a framework they may want to consider when structuring their own enquiries.

8.4. Limitations

The limitations of this study relate predominantly to the research method employed and the scope of data collection and analysis.

This thesis used one hospital as a study site. It adopted a critical realist stance, which presupposes that the social world is made up of open systems in which individuals respond differently in similar situations and on different occasions. Hence, generalising the results of this study to other groups of buildings should
be done with caution because conditions and relationships might differ. A larger study examining more than one site would allow for the theories and explanations generated in this research to be tested more widely. It might have been interesting to compare the study site hospital with another hospital in Vienna that participated in the OEGGG CIRS project. However, the decision was made against it in order to provide a rare in-depth account of CIRS.

Another limitation relates to the comparability of findings from this study to other health care systems. Different health care systems in different countries provide different conditions, which may present other barriers or opportunities than those identified in this study. This also applies, although to a lesser extend, to hospitals from different regions in Austria. Although Austria is a small country, the health system reflects the bureaucratisation of the state and is divided into nine states, each of which is responsible for the public hospitals within that state. This study acknowledged this issue through including the top layer ‘filters’ in the conceptual framework (figure 1.1). As has been discussed earlier different ethical requirements will also need to be considered when comparing this study with others.

Another limitation relates to the research context. The study was very much dependent on the state of patient safety in Austria, the investigated organisation, and the (lack of) action of the department. It may be argued that observing the implementation of a resourced CIRS such as the UK NRLS might have produced results that could be more easily related to the international patient safety literature. Nevertheless it was important to document the current state of patient safety and CIRS at hospitals in Vienna, regardless of whether or not those hospitals make progress in patient safety.

Last but not least it is important to reiterate the systemic nature of error in health care and hence the need for a systems approach to patient safety. This research has focused on non-clinical elements in patient safety. While this study
stresses the impact of organisational issues on patient safety in a systems approach and points to the current under-representation of those in the patient safety literature, organisational issues present only one element of patient safety and need to be seen in co-existence rather than competition to more traditional and clinical approaches to patient safety.

8.5. Future Research

In addition to testing the findings presented in this research and the practical implications as presented throughout section 7.6 of this thesis the following areas for future research are suggested:

Reliable data on error occurrence: All nations face the same essential challenge of how to improve quality, foster innovation, and ensure value for money spent on health care. This study has shown that current estimations on the extent of error in health care are incorrect. Identifying the correct scope of the problem will present patient safety organisations with a rigorous and systematic evidence base against which progress in patient safety can be measured. Furthermore, and considering finite resources, identifying the most serious threats would allow principle causes to be explored, specific risk reduction strategies to be identified and costed, and would allow channelling of limited resources to where they are most needed.

German patient safety taxonomy: Another important barrier related to progress in patient safety and CIRS is terminology. The English patient safety literature provides the opportunity for health care and patient safety organisations to using a (proposed) standard patient safety event taxonomy, either from the JCAHO or the WHO. However, neither the JCAHO nor the WHO have German as an output language. It is not clear at the moment what effect this will have on
patient safety developments in German speaking countries, such as Germany, Austria, or Switzerland, and how operators of incident reporting systems that are run in German will address this problem of a lack of a standard terminology. The JCAHO classification implies that classifying of events is a highly structured process and therefore will need a strategic overhead. At current it is not foreseeable which body in any of the German speaking countries might take on this substantial task. Future research might investigate the feasibility of translating the English taxonomy into German.

More funding - more reports: This study found wider systems factors influencing the implementation of CIRS. For example budgetary pressures restricted access to patient safety training, dedicated (i.e. paid work-) time to meaningfully use CIRS, or more equipment (for example more computers for reporting and better special arrangements to allow privacy for reporting). Future research may investigate the impact wider system pressures have on behaviours in hospitals in regard to CIRS and find out if more funding will also result in more reports.

Inclusion of non-clinical reports to boost reporting of clinical incidents: Considering that underreporting is a common occurrence in many CIRS and that many of the reports submitted to CIRS were identified by the system administrator as not CIRS-classifiable (see section 7.6.3) it might be interesting to investigate if staff could be desensitised towards CIRS by allowing them to report non-clinical incidents on CIRS. It is conceivable that, through using CIRS also for non-clinical issues, staff may become familiar with the system and reporting procedure and may find it meaningful, as feedback is provided, and trust the system so that they may also be increasingly willing to report clinical incidents.

Role and responsibilities of a non-clinical manager: The amount of non-clinical events that were observed affecting daily operations at the department call for
dedicated accountability of those managerial issues. This is in line with, for example, Kaluzny and Shortell's (1997) notion of a 'physician executive'. They (ibid, 1997) predicted a redefinition of the role of physicians, based on changing demographics and epidemiology, new technologies and their emphasis on assessment and outcomes, as well as fundamental changes in the configuration of health services. They argued that this would include greater involvement of physicians in managerial activities, coupled with a requirement for physicians to become increasingly knowledgeable about the organisational and managerial environment in which they work in (Kaluzny and Shortell, 1997). Kaluzny and Shortell (1997) call those professionals who are trained in both administration and medicine 'physician executives'.

However a role such as the physician executive as predicted by Kaluzny and Shortell (1997) who would possess the skills and resources to manage CIRS was not evident in the department. They role as such may exist in theory, as the department leaders (respondents d1 and d2) were both responsible for managerial tasks but at the same time occupied with clinical core responsibilities. It happened more often than once that the head of department was required in his role as department leader but was unavailable because he was operating in the operating theatre. If they had been less occupied with clinical work they could have probably spent more time on CIRS. However, it is questionable if it would indeed be desirable to have medics performing more non-medical tasks. A management executive, who would possess managerial skills and resources to run a CIRS, and at the same time have sufficient insight into the clinical environment, was similarly not evident.

Currently the literature does not provide accounts of any such cross-professional executives. At the same time it is difficult to imagine that none such persons exist, only that not much is known about their work. This provides an
opportunity for future investigation, to identify positions in an organisation where managerial work and clinical work overlap and are successfully managed.

Another investigation could install and explore the role of a non-clinical manager who would oversee the organisational threats as identified in this study. The investigation could address acceptance of such an individual at the department and, most importantly, the impact he has on safety at the department. Until such a role is introduced at hospitals independent researchers could make a useful contribution through, for example, action research or soft systems methodology. This is discussed further in the following section.

More actionable research: Contrary to the many warnings the researcher received prior to entering the field the research experience was such as that the ‘researcher as an outsider’ was warmly welcomed (with a few exceptions) and that staff would have been thankful for more direction and information about CIRS and other non-clinical issues. A conclusion from the fieldwork is that clinicians, while they wish to preserve their autonomy in clinical matters, long for and indeed are in need of support in managerial and non-clinical matters. Who is and who isn’t an outsider is up to interpretation. For a nurse a student of organisation and management may be as much an outsider as a physician. A doctor may regard anyone who does not possess the exact domain specific medical knowledge as an outsider. This could include anyone, even the head of department who, for example, isn’t an expert in endocrinology. Nurses and doctors may regard anyone an outsider who does not belong to their particular department, even if he belongs to the same hospital and is in some way “responsible” for them. This was the case for example with the hospital’s risk manager who was not from the department and many staff were apparently reluctant to share information with him (see footnote 35 in section 7.7.2).

On the other hand the researcher was often approached by staff asking for more information and advice both on CIRS (for example regarding reporting
issues, expected feedback, progress of other hospitals using CIRS) and on general patient safety questions. It is suggested that support of this kind can be offered but it needs to comply with the philosophical and methodological underpinnings of the study. This was not the case in this study where the aim was to be an independent observer with as little as possible direct influence on the activities at the department. Given that budgetary constraints of health care organisations are not likely to change dramatically any time soon and that a non-clinical manager be introduced at the department this might present interesting opportunities for more actionable research that would benefit from high staff interest and input, for example by using soft systems methodology, action research, ethnography and phronesis.

Comparing the effect of different ethical requirements on ethnographic studies in different health systems: An initial aim at the outset of this study was to compare CIRS in Austrian and NHS hospitals. The preliminary work that had been done, and which eventually led to the decision not to pursue the comparative approach, points to considerable differences in ethical requirements pertaining to research in health care organisations in Austria and in the UK. Non clinical studies in Austria currently do not require ethical clearance from an overseeing special ethics body and are granted locally, as has been the case in this study (see Appendix B). In contrast any study in the NHS requires ethical clearance from the NHS NPSA National Research Ethics Service36 (formerly through the NHS Research Ethics Committee), which can be a lengthy and possibly constraining process. The procedures in place for granting ethical approval in the UK seem to generally operate on a more medical model of research. Completing the NHS ethics form it becomes

35 some of this is based on the author’s own experience and some on reflections the University of Sheffield (unknown) document “Reflective Summary: Application for NHS ethical approval” which can be found here:
apparent that it is not designed for someone planning to undertake ethnographic research as it often asks the applicant to state in advance and in detail the number of participants, the length of time to be spent with each, and the specific date for completing the fieldwork.

Future research may address if and how this quite rigid approach to research design has repercussions in the field where the ethnographer is often driven by spontaneity and flexibility, and where responsiveness to what occurs in a particular context and setting, which includes unexpected and unplanned twists and turns, marks an elementary characteristic of his ethnographic endeavour.

If what and how something can or cannot be studied is dependent on a particular ethical body then this needs to be taken stronger into consideration in the international patient safety literature, which constantly draws together and compares contributions from all different kinds of health care systems, hence studies that have been subjected to different ethical regulations. To what extent this will be feasible is questionable. If at all it is suggested these differences might be documented in a direct comparative approach where the researcher (possibly the same individual or at least member of a group that closely communicates) investigates a setting that is most similar but for the ethical requirements (due to different national regulations). Changes, differences, and inhibiting factors that are caused by different ethical regulations should be documented as they appear before it is considered what implications this has on the research.

From the researcher’s point of view it may be added that ethical considerations are important but they need to be put into perspective. It is questionable if a student of organisation and management should have to go through a lengthy national ethical approval process on top of the ethical approval from both study site and the University. More flexibility in this respect would make health care organisations much more attractive to researchers of organisation and
management. To close with a note on the UK context it might be said that ethnography originally evolved during the colonial period of the British Empire (although some elements may date back to antiquity) and largely thanks due to anthropological studies the British undertook in order to gain understanding of unfamiliar cultures (Fielding, 2008). As outriders in ethnography on foreign grounds the British could pay tribute to their very own tradition and adapt ethical requirements for organisation and management studies in the NHS. Doing so ethnographic studies would have the potential to add (more) meaning to the hundreds of thousands of reports currently collected in the NHS NRLS (National Reporting and Learning System).

8.6. Reflections

There are certainly many important aspects related to patient safety that do not yet get addressed and that were beyond the scope of this study. Key controversies, methodological, political, financial, and ethical issues in patient safety research became manifest in the case study. This adds to Bates’ (2008) thought whether patient safety is sufficiently distinctive to represent its own discipline. More work on these issues is important to further understanding of patient safety and to map its topography. Critical ethnography potentially offers a perspective that is sufficiently capable of conceptualising patient safety in all its facets.

Nothing in the theoretical framework underpinning this thesis should be taken to suggest that effective patient safety is not a realistic expectation. Rather, it is arguing that effective patient safety requires (on top of substantial funds) an understanding of existing organisational settlements at a local level (for example a department or hospital), a theoretical understanding of current procedures for improvement in health care and non health care organisation, as
well as a 'spirit of reflexivity and learning' (Peck, 2005) to inform the ways in which changes may be brought about in a particular national and cultural context. A reporting system that not only allows but also analyses organisational and non-clinical incidents may provide a valuable information channel across multiple stakeholders. Even if non-clinical issues are not reported other strategies have to be found to identify and manage them. Otherwise they continue to present latent threats in the health system, threats that presumably would often be rather straightforward and inexpensive to overcome.

Carrying out this study has underlined some of the practical problems in conducting research on patient safety more generally and ethnographic research in this subject area in particular, such as access to good quality data, as well as different ethical considerations in different health systems. Work in the clinical professions can be both physically and psychologically demanding, and so is undertaking research in this area. For it to be carried out the researcher has to have patience, perseverance, be flexible, and probably most important of all, have an honest interest in serving those who are in need. Finally, the author hopes that the findings and conclusions emanating from this study will provide the foundation for further research in the subject area and contribute to helping those many courageous individuals at the sharp end of patient care in their effort to providing safe, efficient, and affordable services.
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Word count (excluding references and appendices) = 87.866

Word count (excluding appendices) = 94.839

Total word count = 106.498
APPENDICES
Appendix A: Ethical approval Sheffield Hallam University
Faculty of Organisation and Management Research Ethics Checklist

This form is designed to help students and staff complete an ethical scrutiny of their proposed research. It also enables the University and Faculty to keep a record of research conducted that has been subjected to ethical scrutiny.

While it is not possible to provide definitive guidelines, by answering the questions below will help decide whether your research proposal requires ethical review by the Faculty Research Ethics Committee (FREC). In cases of uncertainty members of the FREC can be approached for advice, alternatively students and staff can refer to the O&M Research Ethics Policy. The large majority of research proposals will not need further scrutiny after completion of this form.

This form should be completed by the principal investigator for staff research. For student projects it may be completed by the student or the supervisor. In all cases it should be counter signed by the supervisor and kept as a record that ethical scrutiny has occurred and a full review by the FREC is unnecessary. Please note it may still be necessary to conduct a risk assessment for the proposal - for information contact the Faculty Safety Coordinator.

Name of student or principal investigator
Konstantin Weicht

Name of supervisor (if applicable)

Title of research proposal
Incident Report on Critical Incident Reporting for Gynaecology and Obstetrics in Austria - Exploratory Study

Outline of methodology*
The exploratory study will define the participant hospitals and the research will be conducted under their respective ethical requirements.

*If the research may have a number of phases where the full methodology or research subjects are not clear at the outset, a separate ethical approval is needed for each phase. In this case, the research title must make clear if approval is only being sought for an initial phase of work - e.g. "XYZ Study - Phase 1 - Initial exploration"
Appendix A

Question

1. Does the research involve human participants? ____________________ YES
   If NO please go to question No. 6.
   If YES, then please answer the following questions No. 2 - 5:

2. Will any of the participants be vulnerable? NO
   (E.g. Young people under 18, people with learning disabilities, people who may be limited by age or sickness or disability from understanding the research, etc.)

3. Is there any reasonable and foreseeable risk of physical or emotional harm to any of the participants? (E.g. Distressing interview questions, experiments involving participants, asking participants to consume samples etc.)______________________________

4. Will anyone be taking part without giving their informed consent? NO
   (E.g. Research involving covert study, coercion of subjects, where subjects have not properly understood the research etc.)______________________________

5. Will the research output allow identification of any individual who has not given express consent to be identified? NO
   If the answer to any of the questions 2 - 5 is YES then the research proposal must be submitted to the FREC for approval unless it falls into a category/programme of research that has already received category approval.

6. Does the research involve the use of live animals? NO
   If the answer to questions 6 is YES then the research proposal must be submitted to the FREC for approval unless it falls into a category/programme of research that has already received category approval.

7. Does the research require approval from any external ethics committee, e.g. the NHS? YES
   For NHS research, this includes any work using NHS Patients (incl tissues, organs, or data), NHS staff, volunteers, carers, NHS premises or facilities.______________________________
   If the answer to question 7 is YES then the research proposal must be submitted to the relevant external body. For NHS Research Ethics Committees please refer to http://www.corec.org.uk

If the research proposal does not require submission to either the FREC or an NHS or other external REC then standard approval applies.

If the research proposal requires submission to the FREC please refer to the Faculty Research Ethics Policy, or contact a member of the committee for more information. Approval awaited applies until the proposal has been considered by the FREC.
ETHICAL APPROVAL (please tick):

□ (Standard approval) This project does not require specific ethical approval.

□ (Category approval) In my opinion this work falls within the category of .............................................. projects which has been previously approved by the FREC and it does not therefore need individual approval.

□ (Approval awaited) This project must be referred to the FREC for individual consideration - the work must not proceed unless and until the FREC gives approval.

I can confirm that I have read the Sheffield Hallam University Research Ethics Policy and Procedures document and agree to abide by its principles (please tick). □

Signed ............................................. Name .................................. Date............................

Student / Researcher/Principal Investigator (as applicable)

Signed ............................................. Name .................................. Date............................

Supervisor or other person giving ethical sign-off (as defined by O&M Research Ethics Procedures)

Note: University Research Ethics policy available from the following web link:

http://www.shu.ac.uk/research/researchhallam.html

Students - If standard approval applies, please return this form at the same time you submit your research project proposal form to your supervisor.

Staff - If standard approval applies, please keep this form for your own records.
Appendix B: Ethical approval Study Site Hospital in Austria
Accompanying Social Science Research Study on the Implementation of CIRSmedical

Sozialwissenschaftliche Studie zur Implementierung von CIRSmedical

am:

Student:
Konstantin Weicht, MRes
Sheffield Hallam University,
Fakultät für Organisation und Management,
City Campus, Sheffield S1 1WB, UK
English Version:

The implementation of CIRSmedical at the Department for Gynecology and Obstetrics, will be accompanied by Konstantin Weicht in form of a doctorate in social sciences. The implementation of CIRSmedical is part of the project “Doctors learn from pilots”, initiated by the Austrian Federation for Gynecology and Obstetrics (OEGGG). The student will be introduced to staff in the department as a social science researcher.

The aim of the study is the documentation of the implementation of CIRSmedical and the analysis of its impact on the organizational culture of the department. The research findings will be fed back into the project and should support a successful implementation of CIRSmedical.

The research methods include:

- Attendance at CIRSmedical introduction sessions
- Staff mapping with job descriptions
- Access to existing quality assurance guidelines and regulations
- Questionnaire on situation analysis and acceptance of CIRSmedical
- Observation of human factors in staff interpersonal communication
- Interviews with management and clinical staff
- Access to the user report rates of CIRSmedical but not to the confidential content of the reports
- Feedback event

For this study, no patient files will be accessed, nor will any patient data be researched. The student will be informed about the number of messages reported in CIRSmedical, but has no access to the confidential content of the reports.

This social science research will be conducted observing all rules of medical confidentiality and with the agreement of both the hospital director and the head of department. The study fulfills all ethical requirements of the hospital.
Die Einführung von CIRSmedical wird in Form einer Doktorarbeit von Konstantin Weicht wissenschaftlich begleitet.


Die Forschungsmethoden umfassen:

- Erfassung der Mitarbeiter und ihrer Funktionen
- Interviews mit Management und klinischem Personal
- Beobachtung
- Fragebogen
- Einsicht in Leit- und Richtlinien für Qualitätssicherung
- Teilnahme an der CIRSmedical Einschulungsveranstaltung
- Einsicht in die Anzahl der Meldungen in CIRSmedical
- Feedback Veranstaltung


Konstantin Weicht, MRes
Sheffield Hallam University    Datum:    Unterschrift:

Trustee CIRSmedical    Datum:    Unterschrift:

Head of the Department for Gynaecology and Obstetrics    Datum:    Unterschrift:

Medical Director    Datum:    Unterschrift:
Appendix C: Interview guiding sheet
# Leadership Interview Guiding Sheet

<table>
<thead>
<tr>
<th>No.</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Does your hospital have a dedicated department for Quality Management? (C.1)</td>
</tr>
<tr>
<td>2</td>
<td>Does your department have a quality manager? (C.2)</td>
</tr>
<tr>
<td>3</td>
<td>When did you fist hear about CIRSmedical? (C.21)</td>
</tr>
<tr>
<td>4</td>
<td>Which other CIRS in health care do you know of?</td>
</tr>
<tr>
<td>5</td>
<td>Why have you decided to introduce CIRS at your department?</td>
</tr>
<tr>
<td>6</td>
<td>Who in the department is the initiator of the CIRS project?</td>
</tr>
<tr>
<td>7</td>
<td>Why has the product CIRSmedical been chosen? (0.25)</td>
</tr>
<tr>
<td>8</td>
<td>Will CIRS be implemented in your department only or also at other departments in this hospital?</td>
</tr>
<tr>
<td>9</td>
<td>Do staff in your department have experience with CIRS or have had any training on error management? (C.16)</td>
</tr>
</tbody>
</table>
| 10  | Please give your opinion on the safety culture in your department. (C.10) Critical Incidents are:  
|     | □ Mentioned and cause is identified  
|     | □ Mentioned but cause not identified  
|     | □ Often not mentioned  
|     | □ Not recognised |
| 11  | Would you describe your department as change friendly or rather change avers? (C.12) |
| 12  | Have you ever caused or witnessed a critical incident? (C.17) |
| 13  | Please describe how the situation was dealt with at the time (for example was one individual punished or was there a wider investigation into |

Numbers in brackets refer to the occurrence of this same question in the staff questionnaire.
(C.18) underlying causes that might have contributed to the event).

14 Do you think that reporting this particular event with an anonymous reporting system would have been of advantage / disadvantage?

15 Have you ever logged on to CIRSmedical or looked at the demo version?

16 Was the decision to implement CIRS a top-down approach or was this more of a democratic process involving front line staff?

17 What do you expect in general from the anonymous reporting system in your department?

18 Experience with other IR systems shows that there are disincentives to reporting. CIRSmedical is designed with consideration given to known factors (for example it is anonymous, data is managed externally). However, what do you think could still prevent staff in your department from reporting?

19 Who in the department will be responsible for CIRS?

20 What activities are/were planned to prepare and train staff before the CIRS implementation?

21 What activities are planned to motivate staff to use CIRS following the implementation?

22 Do you think that these activities are/will be sufficient?

23 Against what criteria do you consider to measure this project? When is it a success?

24 How long will CIRS be tested at your department?

25 Please estimate how many reports will be submitted to CIRSmedical from your department each week.

26 Please estimate the costs that occur due to medical errors made at your department.

27 What is the budget for this project?

28 How do you see the role of OEGGG as the project initiator? Do you expect any more support from them?

29 Do you expect support for the implementation of CIRS at your department from any external body (for example WKAV), as it was the
What do you personally consider most important in regards to Quality Management. Are there other projects you would like to see prioritised over CIRS and that might be 'simpler' (for example improving hand washing)?
Appendix D: Questionnaire
Please consider that the original questionnaire was in German and that hence formatting of the original questionnaire is different to this translated version.

1. Does your hospital have a dedicated department for Quality Management?
   □ Yes    □ No    □ Don’t know

2. Do you know whom to approach within your department regarding quality issues?
   □ Yes    □ No

3. Do you feel that your suggestions in regard to Quality Management are heard and considered from management?
   □ Yes    □ No    □ Not applicable

4. Do you feel that your suggestions in regard to Quality Management are heard and considered within your work area?
   □ Yes    □ No    □ Not applicable

5. Do you use the Quality Management guidelines and standards folder that are available in your department?
   □ Yes    □ No    □ Not applicable

6. How would you estimate the information provided in these folders?
   □ Good    □ Could be better    □ Bad    □ Don’t know    □ Not applicable

7. How would you estimate the general information on quality and safety in your department?
   □ Very good    □ Too much and not to the point
   □ Sufficient    □ Not sufficient    □ Not existent
   □ Not applicable

8. How would you describe the work climate in your department?
   □ Good    □ Could be better    □ Bad

9. How would you describe the work climate in your working area?
   □ Good    □ Could be better    □ Bad

10. Please give your opinion on the safety culture in your department.
    Critical Incidents are:
    □ Mentioned and cause is identified
    □ Mentioned but cause not identified
11. Please give your opinion on the safety culture in your working area. Critical Incidents are:
   □ Mentioned and cause is identified
   □ Mentioned but cause not identified
   □ Often not mentioned
   □ Not recognised

12. Would you describe your department as change friendly or rather change avers?
   □ change friendly □ change avers

13. Do you feel that your work environment encourages you to apply your theoretical Quality Management knowledge into practice?
   □ Yes
   □ No, because
     □ Hierarchical problem □ Lack of resources
     □ Not relevant
   □ Other

14. Do you think that Quality Management in this department should be the predominant task of
   □ Every individual working here
   □ Head of department
   □ Internal department for Quality Management
   □ External manager

15. What do you personally consider most important in regards to Quality Management. Are there other projects you would like to see prioritised over CIRS and that might be ‘simpler’ (for example improving hand washing)?
16. Do you have experience with...
   □ Local incident reporting systems
   □ Error management
   □ Human factors training
   □ No answer appropriate

17. Have you ever caused or observed a critical incident?
   □ Caused  □ Observed  □ Caused and observed
   □ No  □ Don’t want to answer

18. Please describe how the situation was dealt with at the time (for example was one individual punished or was there a wider investigation into underlying causes that might have contributed to the event).

19. Do you think that reporting this particular event with an anonymous reporting system would have been of advantage / disadvantage?
   □ More advantages  □ More disadvantages
   □ No advantages or disadvantages

20. Please give your opinion why the anonymous incident reporting system will be implemented in your department.

21. When did you first hear about CIRSmedical?
   □ CIRSmedical Introduction session
   □ I haven’t heard about it yet
   □ Other

22. Do you have access to a computer in order to use CIRSmedical?
   □ At work  □ Private  □ No

23. Have you ever logged on to CIRSmedical or looked at the demo version?
   □ CIRSmedical  □ No
24. Did you contribute to the decision if and which reporting system will be implemented?  
☐ I had the opportunity and did contribute  
☐ I had the opportunity but didn’t contribute  
☐ Management inhibited a contribution from my side  
☐ I didn’t know about the upcoming implementation  

25. Why do you think has management chosen the product CIRSmedical?  

26. In general, do you welcome and support the CIRSmedical project in your department?  
☐ Yes  ☐ No  ☐ No answer  

27. Do you have enough information and trust in CIRSmedical to report incidents?  
☐ Yes  ☐ No  

28. Do you wish to have ongoing support for using CIRSmedical?  
☐ Yes  ☐ No  

29. Do you trust the CIRSmedical trustee in our department?  
☐ Yes  ☐ No  ☐ Not applicable  

30. Do you have concerns to give Quality Management data, even anonymous, to someone external?  
☐ Data should be kept internal  
☐ I don’t have any concerns as long as the data is anonymous  

31. What do you expect in general from the anonymous reporting system in your department?  

32. What feedback do you expect when submitting a report in CIRSmedical?
33. Against what criteria do you consider to measure this project? When is it a success?

34. Please estimate how many reports will be submitted to CIRSmedical from your department each week.

35. Experience with other IR systems shows that there are disincentives to reporting. CIRSmedical is designed with consideration given to known factors (for example it is anonymous, data is managed externally). However, what do you think could still prevent staff in your department from reporting?

36. Do you have experience in using a computer? □ Yes □ No

37. Do you have experience with data safety on the internet (for example using online banking or “e-bay”)? □ Yes □ No

38. How do you see the role of OEGGG as the project initiator? Do you expect any more support from them?

39. Do you expect support for the implementation of CIRS at your department from any external body (for example WKAV), as it was the case for example during the digitalisation of patient data? □ Yes, in form of ____________________________ □ No

40. Please estimate the costs that occur due to medical errors made at your department:
Appendix E: The OEGG CIRS project
In order to provide some background information on the study this section introduces the OEGGG (Austrian Society for Gynaecology and Obstetrics) CIRS project, introducing the reporting system CIRSmedical that has been used at the study site, the gatekeepers to the project, how the project was initiated by the OEGGG, as well as how the researcher familiarised with the project in order to develop an interview guiding sheet and a staff self administered questionnaire (6.3.4).

**CIRSmedical**: This section introduces the CIRS that has been used in the study site hospital, namely CIRSmedical. CIRSmedical is a worldwide voluntary anonymous online critical incident reporting system for all areas in medicine and all members of the health care system. A critical incident is described by CIRSmedical as (2006): “An event which had the potential to lead to an undesirable outcome if left to progress.” Or otherwise, a critical incident is “…an event* which could have/has resulted (without/ despite intervention) in an undesirable outcome for a patient, i.e. a physical or psychological damage (*event as a result of patient treatment and not as a result of patient condition per se)” (CIRSmedical, 2006a). In the critical incident technique information is collected on incidents that have or could have a crucial role, positive or negative, in the behaviour of a system. Critical thus does not imply that the incident itself was an emergency or a matter of life and death (CIRSmedical, 2006b).

CIRSmedical was originally developed in 1996 from the “Perioperative Patient Safety Group” at the department of Anaesthesia at the University of Basel in Switzerland (CIRSmedical, 2006c) in collaboration with psychologists from NASA and is largely based on the Australian Incident Monitoring Study
This makes it one of the first incident reporting systems in health care (CIRSmedical, 2006a, b, c). CIRSmedical describes itself as an international forum where critical incidents that happen daily in health care are collected and distributed. Reporting is voluntary and anonymous and works with username and password protection.

The online reporting form consists of a minimum data set that takes users through four categories reporter, patient, incident, and evaluation. This minimum data set should ensure a basic analysis as well as, to some extent, comparison of data between different reporting systems. A standardised data set also facilitates anonymity in reports. The first category (reporter) inquires the professional category of the reporter and his relation to the incident. The category patient asks about patient age and the mode of treatment. Category three identifies the type of incident, workload, time, educational status of responsible person, location and the like through the use of drop down menus or tick boxes. In addition this category offers the reporter to describe the incident in his own words in a free text form, as well as the management and consequences of the situation, which is followed by the outcome of the event (if already known) and whether or not the incident was preventable. Category four evaluates the incident, again through the use of tick boxes, in regard to personal factors, team factors, and system factors in order to identify the cause of and a possible recovery from the incident. A template reporting form is attached in Appendix H. The form however is ‘live’, i.e. if a certain box is ticked other options might become unavailable or new boxes may come up.

As a fully online system it does not require any installation or additional hard- and software. As soon as staff are issued with a password they can start
reporting, either from a computer in their hospital or from any other computer with an Internet connection. CIRSmedical offers four different applications:

- A local application for a single department;
- A network application to use in the hospital intranet;
- A closed user group application within a particular medical area;
- An “open application” with a secure connection over the Internet with a password.

Those hospitals taking part in the OEGGG initiative all use the open application. Hospitals in an open application anonymously share their experiences. It is not possible to identify whether a particular event happened in a hospital in Basel, in Vienna, Munich, Berlin or in any other city with a participating hospital. The following figure E.1 demonstrates what happens after the submission of a critical incident.

- **H1**: An employee in hospital 1 submits a report.
- **T1**: The elected CIRSmedical trustee ensures that the report does not contain any data that could identify the reporting person, a patient, or the institution where the event occurred.
- **Data Pool**: After the report has been anonymised it comes together with all other submitted reports in Austria. In a further step, this data is shared with the German and Swiss colleagues.
Figure E.1: Reporting of an Incident with CIRSmedical (own source)

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<th>H2</th>
<th>H3</th>
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Data-Pool Austria

Data-Pool Austria, Switzerland, Germany

Because CIRSmedical is an anonymous reporting system users do not receive personal feedback. Feedback in CIRSmedical is provided through means of comments on the website, which can come from experts or other users. CIRSmedical (2006) also invites users to share possible additional sources, for example links to websites, journal papers and the like, if they are relevant to a report. The CIRSmedical website also provides statistics on incoming reports, for example which profession or in which setting it was reported. This data is generated from the minimum data set on the online reporting form. The report collecting institution can also issue alerts, for example on the website or through
email alerts to participating hospitals. The system therefore lives from active contribution of users, in form of reading and writing comments, as well as visiting the website to check for alerts or any other information.

**Gatekeepers:** In this study there were two key people, or gatekeepers, for the researcher. Expert 1, who provided background information and initiated contact with organisations and respondent d2, the deputy head of the department where the study was conducted. Expert 1 is a gynaecologist and obstetrician, University Professor at a large public teaching hospital in Austria, and former president for the Austrian Society for Gynaecology and Obstetrics (OEGGG), the representing body for gynaecologists and obstetricians in Austria, which oversees the about 100 departments in public hospitals. He is the leader of one of the hospital’s (not the study site) department for quality management and a renowned critic, author and speaker on patient safety in Austria. Like most hospital doctors in Austria Expert 1 works mornings in the hospital and afternoons in his private practice. This has become a common practice amongst hospital doctors and many of them argue they couldn’t “survive” with just one of the two jobs. In addition to these two jobs Expert 1 is an associate of a private patient safety consultancy which he founded, “not to get rich” (Expert 1), but out of a frustration in his various roles in the public health service over the years about the constraints put on him by “the system” and the subsequent ‘lack of progress in patient safety’ (Expert 1). Engaging in patient safety through a private consultancy gives him the freedom to apply his expert (patient safety) knowledge and making a practical contribution to patient safety in Austria, thus standing up and fulfilling ethical and moral standards in medicine. He is not just a receiver of commands, he wants to make an active contribution to safety and sees this as an inherent responsibility of a medical doctor. Expert 1 is the initiator of the OEGGG CIRSmedical project that provides all Women Hospitals
in Austria with access to an operative CIRS and holds the CIRSmedical introduction sessions at participating hospitals.

The researcher first met Expert 1 at a presentation on error in health care where Expert 1 was the keynote speaker. In an informal conversation after the presentation between Expert 1 and the researcher the benefits and feasibility for an academic study on critical incident reporting systems at gynaecology and obstetric departments in Austria were discussed and Expert 1 agreed to act as a gatekeeper. In this role he provided information about the project as well as access to hospitals who participated in the OEGGG project.

Respondent d2 is the deputy head of department where CIRS had been investigated for this present thesis and is the second important gatekeeper. Respondent d2 has a long standing professional relationship with Expert 1 and is the key initiator of CIRS at the department and the researcher was introduced to respondent d2 by Expert 1 as an independent researcher. Respondent d2 served as the main point of contact at the study site, helped with the formalities and in establishing access to respondents.

**Initiation of Project:** As described above Austria did (and does) not have a national CIRS. Not only was it that Expert 1 was frustrated with the situation, according to him this was a general perception amongst his colleagues, an impression that was verified in a number of informal talks with professionals in Women Hospitals. Considering that a CIRS, CIRSmedical, had already been developed at the University Clinic in Basel there was an attitude that the Vienna City Hospital Association (WKAV) didn’t need to ‘reinvent the wheel and waste more time’. Conversations with several other clinical staff brought up the concern that from a government side nothing will happen anytime in the near future (a period of five years was mentioned). In addition a CIRS run by the
Vienna City Hospital Association seems problematic as staff would have to, anonymously or not, report directly to superiors which according to the literature is one of the main barriers to reporting. Respondents were quite emotional when they talked about the lack of action and rumours of the governing body. As a physician in one of the participating hospitals said:

“Oh, they [the Vienna City Hospital Association] are just bullshitting! Nobody really wants to do anything for staff. This is all just a political decision.” (respondent d45)

At about that time the Vienna City Hospital Association (WKAV) held a conference on quality management in health care, which the researcher attempted to attend. This however was turned down by WKAV (over the telephone) with a short comment that ‘outsiders are unwanted and no detailed information can be shared on this sensitive subject. As leadership of all hospital departments had been invited the researcher took the opportunity, when he - in order to familiarise with the project - visited CIRSmedical information sessions that Expert 1 held at some of the Women Hospitals, and asked department leaders about content and nature of the WKAV event. Their unanimous response was that it was ‘more like a social event’ with ‘no hope for any concrete actions or real information’ or as respondent 1 said “this is just a blah-blah, and it is always like this, this is why we start with CIRSmedical”.40

On the other hand Expert 1 had been promoting CIRS for Women Hospitals at various national and international profession specific conferences and it was at one of those conferences in 2005 that many of the department leaders first heard about CIRS. As a consequence of the inaction of the governing body

40This was further verified in a more general sense in Informal talks with other senior medical staff who were not connected to the OEGGG initiative in any way (respondents 4, 5 and 6) and generally felt that much more could and should be done regarding safety and that there was no overall strategy for quality and safety in public hospitals in Austria.
Expert 1 together with the Austrian Society for Gynaecology and Obstetrics (OEGGG) initiated the incident reporting project. In his role as the then acting president of the OEGGG Expert 1 arranged with the presidents of the German and Swiss Societies for Gynaecology and Obstetrics to all use one and the same CIRS, namely CIRSmedical, and to share anonymised data amongst each other. With the joint CIRSmedical application CIRSmedical becomes a reporting system for an entire German-speaking region stretching across Central Europe. As the data pool grows so does the opportunity for learning from incidents and near misses. In addition this joint application contributes to the anonymity as reports can come from organisations in any of the three countries.

The OEGGG promoted the project in a letter to all Women Hospitals in Austria encouraging them to join CIRSmedical. In this three-pages round letter, attached with an article about CIRSmedical, the president of the Austrian Society for Gynaecology and Obstetrics (at that time not Expert 1) explained the need for and benefits of using a CIRS. In line with their year long efforts of promoting quality and avoiding errors the OEGGG offers Austrian Women Hospitals access to CIRSmedical and encourages their timely participation in order to establish a large profession specific database in German. This is necessary as Women Hospitals otherwise run danger of having an externally run CIRS (i.e. by the Vienna City Hospital Association or another governing body in other states respectively) superimposed on them ‘which could hinder a meaningful engagement’ with CIRS (OEGGG, 2005). The conditions for participation in the OEGGG project were as follows (OEGGG, 2005):

- obtain permission from the hospital’s collegial leadership for participation in CIRSmedical (contract templates regarding confidentiality and anonymity of data being provided by OEGGG)

- requesting CIRS password from OEGGG via email
Appendix

- data contract with OEGGG and a private patient safety consultancy (Expert 1)
- annual administration fee of 350 Euro to OEGGG
- acquiring CIRS password from the data managing company in Switzerland
- training session held by private patient safety consultancy (Expert 1)

The OEGGG provided a further incentive in offering the first ten hospitals to join a waver of the fees, which are Euro 1100 (exclusive of taxes) per training session and exempt travel expenses (OEGGG, 2005).

Unfortunately no accurate data was available on how many hospitals had been addressed by the OEGGG and how many had responded. As responses were addressed directly at Expert 1 information was obtained from him and according to Expert 1 somewhere about 10 to 15 hospitals expressed their interest and the training sessions were scheduled.

**Further familiarisation:** To further familiarise with the project and with the environment in which the study was about to take place the researcher joined some of these ‘training sessions’ (4 in total and exempt of the actual study site), which were half-hour presentations by Expert 1, followed by a question and answer session. The visited sites were all gynaecology and obstetric departments in public hospitals in Austria. Typically those departments consist of the five inpatient areas: labour room/ward; operation theatre; gynaecology (and possibly an oncology) ward; obstetric ward; nursery, as well as an outpatient department for gynaecology, pregnancy, and hormone treatment. Departments usually employ around 100 staff. The departments are lead by the head of department and his deputy (two medics) and a head nurse and her deputy (two nurses). The role of obstetric nurses in the hierarchy of the
departments is not entirely clear as from 2001 onwards they are a dedicated profession of their own and do not belong to the nursing profession anymore. The leadership team reports to the hospital leadership team called “Kollegiale Fuhrung” (German for “collegial leadership”) which typically consists of four people: medical director; nursing director; technical director; administrative director. The medical department leaders report to the medical director and the head nurse reports to the nursing director respectively.

In each of the five departments Expert 1 and the medical leaders already knew each other from various other profession specific seminars and meetings. Following a number of emails and telephone calls Expert 1 was then formally invited to give a presentation about CIRS to all staff. In all cases Expert 1 was invited by the medical leaders of the department, i.e. it was a medical (medics who also hold a managerial position) rather than a nursing initiative. The training sessions took place at departments and during the daily morning meetings. Some departments hold their morning meetings together with nurses, some do separate meetings. Accordingly attendance at meetings was either around 30 people (nurses and doctors together) or about half of it (only doctors). In those cases where only doctors were present there was no separate event for nurses, but information from the session communicated through the head nurse (who, as part of the department’s leadership team, attends the doctors’ meeting).

Visiting training sessions and having informal conversations with staff added to information gathered in the literature and aided in the development of a guiding sheet for semi-structured interviews with leadership and the development of a questionnaire. The interview guiding sheet and the questionnaire, as well as interview techniques (recording) were tested with volunteers at these departments. The final questionnaire to be distributed at the training session at the study site consisted of 40 questions. The final guiding sheet for semi-
structured interviews with department leaders at the study site consisted of 30 questions. With this the engagement with other hospitals ended and the study was continued as a single site in depth investigation, although the text will continue to occasionally make references to these other hospitals (for example in the next section on the training session, which was observed to have followed a common scheme all five observed hospitals). The next section describes the training session at the study site.
Appendix F: CIRSmedical demo reporting form
Please use this form to add a critical incident, that means an event* which could have/has resulted (without/despite intervention) in an undesirable outcome for a patient, i.e. a physical or psychological damage (*event as a result of patient treatment and not as a result of patient condition per se).
incident
lack of personnel
out of organization reasons

out of problem

out of problem

exp
Appendix G: Questionnaire findings
This section presents findings from the questionnaire providing more details.

**Safety attitude:** Questions 1 to 15 were aimed at getting an understanding of the general safety attitude in the department, finding out how much staff were currently reaching out or being reached by existing patient safety measures. Questions concerned issues like accountability (1 and 2), how staff were already involved and/or encouraged to participate in patient safety (3, 4, 14, 15), how this might relate to their work environment (8, 9, 12, 13), if the were using existing patient safety material at the department (5, 6, 7), and how they perceived the current handling of critical incidents at the department (10 and 11).

Question C.1 “Does your hospital have a dedicated department for Quality Management?” wanted to find out if staff knew about the quality/risk manager in the hospital and hence if they were being reached or could reach out to him. 60 percent (23 respondents) answered “yes”, while 24 percent (9 respondents) didn’t know if there was a quality management department, 13 percent (5 respondents) explicitly stated that there was no quality management department, and 3 percent (1 respondent) gave no answer. This means that 37 percent (14 respondents) either didn’t know or were convinced that there was no quality manager at the hospital. The data does not allow interpretation if the 60 percent (23 respondents) who answered “yes” all referred to the same department or person. Question 2 “Do you know whom to approach within your department regarding quality issues?” was targeted at the situation directly at the department. 60 percent (23) of respondents stated that they did not know who to approach regarding quality issues in the department. This makes it likely that many questions staff may have regarding CIRS will remain unheard. In a very optimistic light one may also assume that CIRS would present a channel for these voices to be heard. However, as an anonymous CIRS does not allow department specific feedback (nobody knows from which department reports
are coming) any significant contribution from a CIRS in this matter seems unlikely.

That so many staff did not know who to approach regarding quality in the department may be related to their perception that quality management should be the predominant task of every individual working at the department (66 percent, question 14). What specifically these quality endeavours were and how CIRS was to be seen in relation to them was asked of respondents in the open question 015. Possible improvement efforts other than CIRS that were mentioned include ‘more personnel’ and ‘more time with the patient’, as well as preparing for and obtaining first, or at least second, hand information about patients (questionnaire 5, 6, 10, 13, 14, 22, 23, 34, 27), increasing standardisation of processes and compliance with those standards (questionnaire 5, 15, 18, 19, 22, 34), and better hygiene through increasing use of gloves and better hand-washing (questionnaire 3, 7, 17, 25, 35). However, many of these potential areas for improvement may not be acted upon as staff do not communicate their concerns to management (42 percent, question 3), in their work area (32 percent, question 4), or because suggestions are “not heard and considered” by management (16 percent, question 3) or in the work area (8 percent, question 4). On the other hand 37 percent (question 3) and 52 percent (question 4) respectively stated that their suggestions regarding quality management were heard and considered. This may be interpreted, also considering answers to question 2, that staff feel more comfortable discussing issues in a small group and with people they regularly work with, i.e. in their work group. In regard to CIRS these answers suggest that CIRS is seen as one of many equally important improvement efforts and that staff do not specifically perceive CIRS as something that may lead to or foster implementation of other improvements (question 0.15).
50 percent of staff (question 13) felt that their work environment was supportive in applying staffs’ knowledge regarding quality management, with resource issues (13 percent), hierarchical issues (8 percent), and ‘other issues’ (11 percent) being the main inhibitors of applying knowledge into practice. This largely corresponded with staffs’ perception of the work climate in the department (50 percent ‘good’, question 8) and the work group (63 percent ‘good’, question 9). Respectively 42 percent (question 8) felt that the work environment in the department ‘could be better’ or was ‘not good’, and 34 percent (question 9) said the same about the work group. 72 percent attested the department to be ‘change friendly’, while 26 percent described it as ‘change averse’.

In terms of general information provided on quality and safety at the department (question 7) 44 percent thought that information was ‘sufficient’. While 26 percent attested it to be ‘very good’ 15 percent thought it was ‘not sufficient’, with 7 percent even stating that it was not existent. 66 percent of respondents stated that they were using quality guidelines and standards folder (question 5) and that the information contained was good (74 percent, question 6). 16 percent did not know about and 13 percent stated they were not using those folders (question 5).

Questions 10 and 11 asked respondents about their opinion on the safety culture in regards to critical incidents at the department and in the work group respectively. Possible answers were that critical incidents are ‘mentioned and causes identified’, ‘mentioned but causes not identified’, ‘often not mentioned’, and ‘not recognised’ and multiple answers were possible. The majority of staff thought that critical incidents were already being mentioned and causes identified (71 percent at department, 66 percent in work group). 18 percent thought that critical incidents were mentioned but not identified (for both areas), not mentioned (18 percent in department, 11 percent in work group), and not
recognised (5 percent work department, 3 percent work group). When added up this means that staff think that in 41 percent the cause for a critical incident is not identified at department level and in 32 percent at work group level.

**CIRS perception:** While the above section concerned general safety attitude questions the second part of the questionnaire (questions 16 to 40) aimed to identify issues directly related to the implementation and peoples’ individual perception of CIRS at the department. Topics covered include experience staff may have with CIRS or other patient safety related topics (16), their experience with critical incidents and how CIRS may help approach these issues in the future (17, 18, 19), their involvement in and perception of the implementation of CIRS (20, 21, 23, 24, 25, 26), trust, confidentiality and anonymity (27, 29, 30, 37), expectations and feedback (31, 32, 33, 34, 40), support (22, 28, 38,39), as well as possible barriers to reporting (35). Many of these CIRS questions can be used to compare or verify information from the leadership interviews (16, 18, 20-22, 24, 28, 31, 33-35).

This second section sets out with question 16 if staff had any experience with a CIRS, error management, or human factors training. While two respondents did not answer and one respondent stated he had had human factors training all remaining respondents (92 percent) stated they had no experience with a CIRS, error management, or human factors training. Question 17 asked respondents if they had ever caused or witnessed a critical incident. 50 percent stated that they had either caused or witnessed a critical incident, while 32 percent stated explicitly that they had not caused or witnessed a critical incident, with remaining respondents choosing not to answer. 13 percent stated that they had caused and witnessed a critical incident, and 5 percent stated that they had only caused a critical incident but not witnessed one. The open question 18 then asked of respondents how the incident had been dealt with. The majority of the
16 answers provided stated that the incident had been talked about and that nobody in particular had been blamed. Four respondents mentioned negative feedback, a 'mischievous reaction of some colleagues' (questionnaire 9), that other colleagues didn't feel they had also contributed to an error, causing 'frustration and capitulation' in the individual who had committed the active error (questionnaire 13), that errors were being perceived as 'personal failure' (questionnaire 28), and in one case that the employee had been sacked (questionnaire 18). Only two respondents (questionnaire 17 and 31) stated that the cause of the incident had been removed following its discovery. Other responses stated that while the incident was communicated, sometimes just in the work group and 'due to lack of time not discussed in the staff meeting' (questionnaire 8), 'nothing had really changed' (questionnaire 10), the cause hadn't always been removed (questionnaire 14), or that only informal recommendations had been issued (questionnaire 7, 8, 10, 27). Two respondents explicitly stated that the incident had been documented (questionnaire 10, 14) and one respondent (questionnaire 27) stated that the incident was followed by a series of talks with the patient concerned, the superior, and the interdisciplinary team (questionnaire 27).

The next questions concerned issues around the implementation of CIRS. 24 percent of staff had first heard about CIRSmedical at the training session (see section 6.3.5), 50 percent had heard about it at another occasion (which could have been before or after the training session), and 10 percent had never heard about CIRSmedical (question 21). While 63 percent didn't know about the upcoming implementation 26 percent stated that they had contributed to the decision making process leading to the implementation (question 24). One respondent stated that his involvement was inhibited by management. 24 respondents answered the open question 20 why a CIRS was being implemented at the department. Answers provided were positive throughout and stated that 'it would make a long term contribution in avoiding errors and
‘critical incidents’ (questionnaire 1, 5, 19, 28, 34, 35), to ‘improve or assure quality’ (questionnaire 1, 2, 6, 20, 27, 30, 31), ‘because it makes sense’ (15 and 17), ‘because it is in fashion and due to public pressure’ (questionnaire 7), ‘to analyse root causes and think about the entire hospital system’ (questionnaire 4), ‘because it provides the opportunity to make changes’ (questionnaire 28), ‘so that everyone can be honest’ (questionnaire 23), because everyone suffers from error but the fear of image loss keeps people silent (questionnaire 8), and because people would use it’ (questionnaire 25).

According to these answers staff did not fear that the implementation was some sort of control organ superimposed- on them. While there was a ‘canon of improvement’ in answers to questions 20 the 21 answers given to the open question 25 why in particular the system CIRSmedical was being implemented were more diverse. 4 respondents could not say why (questionnaire 23, 25, 28, 35), four respondents knew of no alternative system (questionnaire 5, 6, 8, 9), two stated that CIRSmedical was used because it was really anonymous (questionnaire 4 and 7) and one stated that the Vienna City Hospital Association (WKAV) did not offer a CIRS (questionnaire 18). One respondent stated ‘because of personal contacts’ (questionnaire 1) and that ‘the offer was probably good, but is it useful?’ (questionnaire 22). The open answers also suggested that at least two respondents (questionnaire 19 and 34) seemed to had confused this OEGGG initiative as a Vienna City Hospital Association (WKAV) project. Overall 89 percent of respondents welcomed the implementation of CIRSmedical at the department (question 26). The remaining 11 percent were ‘no answers’. No one stated explicitly that he wouldn’t welcome the implementation.

The next set of questions (27, 29, 30, 37) regarded trust, confidentiality and anonymity. 55 percent of respondents stated that they had not enough trust in the system to report incidents, while 37 percent stated that they had (question
Question 29 asked respondents if they trusted the CIRStttee. 42 percent answered no, 24 percent stated that the CIRStttee had not yet been elected, and 13 percent stated they trusted the CIRStttee. These answers suggest that some of those who responded ‘no’ may have done so out of a principal aversion against the role of a CIRStttee (similar to the discussion in the training session where some marked out the position of a CIRStttee as the weak spot of the system, see section 6.2.5) and that those who answered ‘not yet elected’, which was an answer ‘option’ added by respondents themselves, may have in principal agreed with the necessity of a CIRStttee but made it a person related matter, i.e. if they were to trust one particular person in the role as CIRStttee. 68 percent had no problem sharing data with a third party if the data was anonymous, while 21 percent did not want to share data even if it was anonymous (question 30). Question 37 was added to find a possible correlation between trust in CIRS and previous experience with other online services that require trust, such as online banking or use of eBay. 50 percent of respondents had and 50 percent had no experience with online security (question 37).

Questions 31, 32, 33, 34 and 40 were concerned with expectations and feedback and were all open questions. Question 31 asked staff about their general expectation of a CIRS at the department. Many of the 25 respondents explicitly stated that they expected a reduction of error occurrence at the department (questionnaire 1, 6, 9, 10, 13, 14, 18, 19, 23, 25, 32, 34, 35, 37). Others expected more discussion and analysis of critical incidents (2, 4, 7, 8, 15, 28, 34, 35) and that improvement efforts would be based on real data (10, 15), ‘not just criticising and talking about it, but that changes would actually be forthcoming’ (questionnaire 23). The general expectation was that with increased information would come increased analysis, followed by action based on evidence, reducing both risk and actual occurrence of critical incidents at the department. One respondent stressed that his only expectation was that it was really kept anonymous’ (questionnaire 21) and another (questionnaire 24)
stated he would probably only study reports but not submit reports himself. The respondent in questionnaire 5 saw CIRS as a way around the fact that usually only harmful events give rise to analysis, action and improvement and that lessons could be learned from no harm events and without the need for tragedies.

22 respondents answered the open question 32 “What feedback do you expect when submitting a report?”. Nine respondents (questionnaire 1, 5, 15, 17, 18, 21, 23, 28, 36) stated they did not expect any specific feedback or did not know what kind of feedback to expect. While some respondents may have not expected any feedback at all others (for example questionnaire 18) may have wished feedback but did not expect it stating that ‘as long as no institution processes data there will be no feedback’. Other respondents expected some action, 11 (questionnaire 4, 6, 7, 8, 9, 10, 13, 14, 22, 27, 37) in regard to safety and in form of recommendations, analyses and implementations, or in regard to ‘reporting’ in form of a feedback that the report had actually been accepted, been put on the system without alterations, and quickly processed (questionnaire 1, 25, 37). One respondent (questionnaire 5), although not expecting any immediate feedback, hoped that ‘colleagues would read reports and, based on those reports, develop a strategy how they could deal with similar events’. There was one respondent (questionnaire 32) who expected ‘negative feedback’.

26 replies were made to the open question 33 against what criteria CIRS could be measured and when the CIRS medical project would mean a success to them. ‘Reduction of error’ was the most prominent answer (questionnaire 1, 7, 10, 26, 37) although one respondent (questionnaire 21) wondered if a reduction of error would be measurable. Another respondent (questionnaire 1) wondered if an improvement could be at all related to CIRS due to its anonymity. Others pointed out improved communication as a success factor, as in more
‘discussion’, ‘the possibility of unbiased discussions about error and quality deficiencies’, or ‘positive feedback from patients and staff’ (questionnaire 2, 7, 8.). Many respondents suggested that for CIRS to be a success it needed to produce some ‘visible’ results, for example ‘more information about what kind of errors also happen at other departments’ (questionnaire 35), ‘changes in the system’ (questionnaire 4), ‘better error management’ (questionnaire 6), ‘reduction of infection rate’ (questionnaire 7), provision of statistics showing the frequency of errors, leading to solutions, and publicised (questionnaire 15, 17, 18, 19), cost savings (questionnaire 26) and that reports needed to be processed (questionnaire 34). One respondent stressed that CIRS should not mean additional work load for staff (questionnaire 27) and the respondent in questionnaire 28 stated that reporting itself would mean a success to him if it was ‘reflective’. Three respondents answered that they wouldn’t know how to measure success of the project (questionnaire 13, 14, 36).

Expectations or estimations regarding the reporting frequency at the department were addressed in the open question 34. This seemed to proof difficult to answer as 24 respondents did not give an answer. The remaining respondents though that either no report (questionnaire 2), one report per week (questionnaire 6, 7, 22, 35), two reports per week (questionnaire 5, 9, 10, 27, 36), or four to five reports (questionnaire 9, 11, 25, 28) would be submitted each week. Similarly respondents found it difficult to answer question 40 about the costs that occur at the department due to medical error. This question wanted to test if staff made any relation between medical error and additional costs to the department. From the 30 replies 25 respondents stated that an estimation was just not possible; one (questionnaire 25) thought that costs were around 3.000 Euro, another one (questionnaire 6) that costs were around 40.000 Euro, and two respondents (questionnaire 36 and 37) thought that costs were around 1.000.000 Euro.
Questions 22, 28, 38 and 39 regarded support, either technical support through provision of enough computers for reporting, ongoing general support and training, or support from the OEGGG as initiating organisation or any other related organisation. 76 percent of staff stated that they had access to a computer at work, 32 percent stated that they had access to a computer at home, and 21 percent stated that they had no access to a computer for reporting whatsoever (question 22). 74 percent of staff explicitly stated that they wanted ongoing support in the project and 13 percent did not want any ongoing support (question 28). Staff did not expect any particular support from the OEGGG or another related organisation but wished to have ‘more information whether or not the project was budgeted’ (questions 38 and 39).

In the open question 035 staff were asked what they perceived as possible barriers to reporting. From the 30 replies 15 respondents (questionnaire 1, 2, 3, 4, 5, 6, 7, 8, 21, 22, 24, 25, 34, 35, 37) named concerns about the anonymity as a barrier to reporting, sometimes relating it to concerns in use of a computer, the internet, or the internal CIRS trustee. Respondents made frequent use of the word fear (questionnaire 1, 5, 8, 15, 21, 22, 24) and mistrust (questionnaire 2, 4, 7). Time (questionnaire 18, 19, 26, 34) and problems with formulation/too complicated input (questionnaire 7, 18, 19, 22, 34) were other popular answers. Other possible barriers were named once: false shame (questionnaire 17), a lack of experience with the system (questionnaire 25), a perception that the incident was not ‘important’ (questionnaire 27), fear of technique and media (questionnaire 15), and laziness (questionnaire 9). One respondent (questionnaire 3) thought that the external data management might be a barrier. Three respondents thought that there wouldn’t be any barriers to reporting (questionnaire 10, 13, 14).

Similar to interviews with the leadership it also became apparent that respondents had not used CIRSmedical before. 97 percent of respondents had
never logged on to CIRSmedical (or the online demo version that didn’t require a password) and only one respondent stated he had already logged on (question 23). Nevertheless 26 percent stated that they had contributed to the decision making process leading to the implementation (question 24).