Diploma Thesis

Implementation of a System for Patient Safety and Quality Management in a Peripheral Hospital in South India

Submitted by

Karla Walburga Thomas

For Attaining the Degree of

Doctor medicinae universae
(Dr. med. univ.)

at the

Medical University of Graz

Performed at the

Department of Anesthesiology and Intensive Care Medicine

Under the Supervision of

Dr. med. univ. Andreas Schöpfer

ao. univ.- Prof. Dr. med. univ. Gottfried Fuchs

Graz, August 12, 2018

Statutory Declaration

Declaration I hereby declare that this thesis is my own original work and that I have fully acknowledged by name all of those individuals and organizations that have contributed to the research for this thesis. Due acknowledgement has been made in the text to all other material used. Throughout this thesis and in all related publications I followed the “Standards of Good Scientific Practice and Ombuds Committee at the Medical University of Graz“.

Graz, August 12, 2018 Karla Thomas eh

Acknowledgment

A very special gratitude goes to the entire staff at the SFS Healthcare Center in Kakkaveri with special emphasis on Dr. Sr. Francina, the director of the Doctor Typhagne Memorial Charitable Trust. I am honored to get the opportunity to be part of this cooperation and to get an insight into your inspiring work.

I am also grateful for my motivated Austrian team of the Global Health and Development, which made this project possible: Isabella Dicker, Anneliese Pfeifer, Sylvia Sammer, Angelika Schirnhofer, Andreas Schöpfer and Angela Schöpfer. At this point I would like to express special gratitude to Andreas Schöpfer, my supervisor, who guided my work with constructive and patient encouragement.

A special thanks and appreciation goes to Sven Bartsch, who did not lose patience reading the different versions of my thesis and kept encouraging me to improve my work on and on.

I also want to thank my friends Isabella Dicker, Ariane Mansuri Maschhadi and Elisabeth Schreiner for their continuous support and motivational companionship.

Furthermore, I would like to express my deep gratitude for my immediate family, Andreas, Angelika, Leni and Andi Thomas, who unconditionally supported me in choosing my way and enthusiastically observed the whole journey. I also want to thank my grandmother Marianne Stampka, who taught me the importance of being an authentic person. Last but not least a special thank goes to my grandparents Wolfgang and Jutta Thomas, who showed me how important it is to look beyond my own horizon and to overcome national and cultural boundaries.

Zusammenfassung

Hintergrund: Weltweit gibt es zahlreiche Projekte zur Verbesserung der PatientInnensicherheit, die das Ziel haben, Qualitätsstandards zu definieren und zu verbreiten. Warum einige Projekte nachhaltiger wirken als andere ist noch nicht vollständig geklärt und die effiziente Nutzung von Ressourcen daher gefährdet. Um die Projekte vergleichen zu können, ist es essenziell, den Ablauf von der Zielsetzung bis zur Umsetzung zu dokumentieren und so der Öffentlichkeit zugänglich zu machen. Das erste Ziel dieser Arbeit besteht daher darin, ein Projekt in Südindien vorzustellen und das erstellte Konzept zu Basismaßnahmen bezüglich PatientInnensicherheit und Qualitätsmanagement weiterzugeben. Das zweite Ziel dieser Arbeit ist es, Faktoren zu ermitteln, die den Erfolg des Projekts beeinflusst haben.

Methoden: Die Beschreibung des Projekts wurde in Form einer Plan-Do-Check-Act-Studie durchgeführt und Daten wurden mittels Beobachtung und Interviews erhoben. Für den analytischen Teil wurden 12 KrankenhausmitarbeiterInnen aus verschiedenen Hierarchieebenen zum Thema „Faktoren, die Veränderungen im Weg stehen“ interviewt. Die Korrelation zwischen dem Auftreten bestimmter Faktoren und dem Erfolg der Vorschläge wurde mit der Spearman Korrelation analysiert.

Ergebnisse: Dieses Projekt basiert auf einer Kooperation zwischen Global Health and Development, dem Department für Entwicklungshilfe der Medizinischen Universität Graz, und einem peripheren Krankenhaus, Teil des Doctor Typhagne Memorial Charitable Trusts in Südindien. Die Beobachtung wurde mithilfe einer selbst erstellten Checkliste und bestehender internationaler Leitlinien für Entlassung, PatientInnenübergabe, Handhygiene, einer chirurgischen Sicherheitscheckliste und einer Checkliste für Handwaschplätze durchgeführt. Die Priorisierung der Vorschläge erfolgte mithilfe einer adaptierten Risikomatrix. Das gesamte Projekt zeigte eine Erfolgsquote von fast 92%. Eine statistisch-hoch signifikante, negative Korrelation mit „starker“ Effektgröße wurde zwischen dem Erfolg eines Vorschlags und der Ablehnung durch die PatientInnen gefunden. Die höchste Erfolgsrate bezüglich der sofortigen Umsetzung hatten Empfehlungen, die

zuvor aufgrund eines fehlenden Auslösers nicht umgesetzt worden waren. Dieser Faktor zeigte eine signifikante positive Korrelation und eine "mittlere" Effektgröße.

Schlussfolgerung: Der stärkste positive Faktor für den Erfolg von Vorschlägen war die Miteinbeziehung von bereits vorhandenen Ideen des indischen Teams innerhalb der Planungsphase. Den negativsten Einfluss auf die Akzeptanz von Vorschlägen hatte die mutmaßliche Ablehnung durch die PatientInnen, die daher in Zukunft durch eine direkte Erhebung überprüft werden sollte, um Misserfolge aufgrund von Missverständnissen zu vermeiden.

Abstract

Rationale, aims, and objectives: There are numerous patient safety projects around the world that have the goal of defining and disseminating quality standards. Why some projects are more sustainable than others is not yet fully understood and the efficient use of resources is therefore at risk. The documentation of the course of action is essential for a comparison. Therefore, the first goal of this thesis is to present a project in South India and to share the created concept for implementation of basic measures regarding patient safety and quality management. The second goal is to determine factors that influence the success of the project.

Methods: The descriptive part was conducted as a Plan-Do-Check-Act study and data were collected via observation and interviews. The analytic part was performed by carrying out 12 interviews with the hospital employees to pinpoint factors towards improvement. The correlation between the appearance of certain factors and the success of the suggestions was analyzed using the Spearman Correlation.

Results: This project is based on the group collaboration between Global Health and Development, an Austrian development aid organization, and a peripheral hospital in South India which is part of the Doctor Typhagne Memorial Charitable Trust. The observation was performed using a self-created checklist and existing international guidelines for discharge, handover, hand hygiene, a surgical safety checklist and a washing facility checklist. The prioritization of implementations was made using an adapted hazard scoring matrix. The entire project showed a success rate of almost 92%. A highly statistically significant, negative correlation with "large" effect size was found between the success of a suggestion and resistance of the patient. The highest success rate regarding immediate implementation showed recommendations that had previously not been implemented due to a lack of a trigger. This factor showed a significant positive correlation and a "medium" effect size.

Conclusion: The strongest positive factor for the success of measures was the inclusion of existing ideas of the Indian team during the planning phase. The most negative impact on the acceptance of suggestions was the patient's suspected rejection, which should therefore be reviewed by assessment of the patients' opinion to eliminate failure due to misconception.

Table of Contents

Statutory Declaration i

Acknowledgment ii

Zusammenfassung iii

Abstract v

Abbreviations and Definitions viii

Registration of Illustrations ix

Registration of Tables x

1. Introduction 1

2. Background 3

2.1. Quality Management 3

2.2. Patient Safety 8

2.3. General Situation in India 11

2.3.1. Lack of Resources 11

2.3.2. Burden of Disease 12

2.3.3. Lack of Awareness 13

2.3.4. Error Management 14

2.3.5. Safety Culture 15

2.3.6. Accessibility 16

2.4. SFS Health Centre in Kakkaveri 18

3. Material and Methods 20

3.1. Descriptive Part 20

3.2. Analytic Part 22

4. Results I: Descriptive Part 23

4.1. Project design 23

Step 1: Defining the Objective 24

Step 2: Overall Project Run-off 27

Step 3: Creating Measurement Tools 27

Step 4: Perform the Measurement 29
Step 5: Finding Solutions 30
Step 6: Prioritization and Procedural Planning 30
Step 7: The Final Decision About Implementation 31
Step 8: Long-Term Feedback 31
4.2. General Project Conduction 32
4.2.1. Overall Project Run-off 32
4.2.2. Initial Situation 33
4.2.3. Step by Step Proceed: Plan-Do-Check-Act 40
5. Results II: Analytic Part 50
5.1. Success and Failures 50
5.2. Interviews “Factors Towards Improvement” 50
5.3. Correlation Between the Seven Collected Factors and the Success of Implementations 51
6. Discussion 54
6.1. General Project Running 54
6.2. Low Opinion About the Necessity 56
6.3. The Resistance of Staff vs. Resistance of the Patient 57
6.4. Disagreement Between Hierarchies 57
6.5. The Missing Equipment 58
6.6. Lack of Knowledge 58
6.7. Missing Trigger 59
6.8. Special Findings in Context to India 60
6.9. Limitations 62
7. Conclusion 63
Bibliography xi
Appendix xxii
Appendix I: Checklist for Observation and Interview xxii
Appendix II: Factors Stated Within The Decision-Making Process xxviii
Appendix III: Percentage of Suggestions Attached to the Respective Factor xxxi

Abbreviations and Definitions

ADR	Adverse Drug Reaction
DTMC	Doctor Typhagne Memorial Charitable
ECG	Electrocardiogram
FMEA	Failure Modes and Effects Analysis
GDP	Gross Domestic Product
HCW	Healthcare Worker
HFMEA	Health Failure Modes and Effects Analysis
IOM	Institute of Medicine
ISO	International Organization for Standardization
NGO	Non-Governmental Organization
N.U.	Name Unknown
PDCA	Plan- Do- Check- Act
SFS	Saint Francis de Sales
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Registration of Illustrations

Figure 1 SFS Health Centre: main entrance (Doctor Typhagne Memorial Charitable Trust, 2018) 18

Figure 2 Kakkaveri, Tamil Nadu. (OpenStreetMap Foundation, 2018)..... 18

Figure 3 SFS Health Centre: X-ray. (Doctor Typhagne Memorial Charitable Trust, 2018) 19

Figure 4 SFS Health Centre: Laboratory. (Doctor Typhagne Memorial Charitable Trust, 2018) 19

Figure 5 Plan-Do-Check-Act (PDCA): Data adapted by (Hughes, 2008) 21

Figure 6 Suggestions concerning general hygiene 44

Figure 7 Suggestions concerning patient safety..... 46

Figure 8 Suggestions concerning staff safety 48

Figure 9 Suggestions concerning surgical safety 49

Figure 10 Percentages of factors stated within the decision-making process sorted by outcome 1= missing equipment, 2= staff resistance, 3= patient resistance, 4= low opinion about necessity, 5= disagreement between hierarchical levels, 6= missing trigger, 7= lack of knowledge..... 51

Figure 11 Results of Spearman Correlation 53

Registration of Tables

Table 1 The seven quality management principles. Data adapted from (International Organization for Standardization, 2015) 4

Table 2 WHO risk fields concerning patient safety. Data adapted from (World Health Organization, 2015a) 9

Table 3 Implementation process 23

Table 4 Hazard scoring matrix. Data adapted from (VA National Center for Patient Safety, 2014) 31

Table 5 Schedule of the stay 32

Table 6 Availability of washing facilities in percentage 35

Table 7 Results of Spearman Correlation, statistically significant values = * 52

Table 8 Factors stated within the decision-making process xxxi

Table 9 Percentage of suggestions attached to the respective factor xxxi

1. Introduction

There is a huge gap between guidelines and the reality of developing countries. To cite just one example: 50% of the injections given are graded as unsafe while the indication for injections is also often made too frequently, leading to additional injections. The result is 1.3 million deaths each year (World Health Organization, 2015a). If health care ends in harm instead of healing, immediate change is urgent. But although there are many passionate people trying to improve the system, experts claim that the progress is going on too slowly (Madhok et al., 2012). We have to take a closer look at the reasons why.

One apparent cause for the gap is the lack of resources, which prematurely limits the ability to follow the guidelines. But in many cases, this lack is not only a problem of not having the resources. According to the WHO, 20-40% of all health expenses are lost because of the bad quality of healthcare, e.g. patient safety issues like hospital-acquired infections and consequences of poor treatment like additional hospitalization. Resources are spent by fixing failures and also due to an increasing amount of litigations (Madhok et al., 2012, World Health Organization, 2017a).

Additionally, in developing countries is often a lack of knowledge concerning the effective use of capital on the one hand (Diamond, 2005) and delivering effective and save care on the other hand (Pakenham-Walsh and Bukachi, 2009). This default could be caused by the low amount of evidence-based information available. Three factors contribute to the fact that developing countries are struggling with the systematic reviews existent:

1. few studies hit the relevant issues and priorities of developing countries
2. many recommendations which are effective cannot be implemented because of shortage of resources
3. the amount of research conducted in low-income-countries is less than in developed countries (McMichael et al., 2005).

All of this results in a problem of evidence-based decision making and therefore a poor process performance (International Organization for Standardization, 2015).

The last problem to mention is the resistance against change - not only in developing countries, but everywhere in the world - which is often a result of communication

problems between the employees and leadership (Van Dam et al., 2008, Ford et al., 2008, Coch and French Jr, 1948). Before an innovation can be implemented, it has to be ensured that the employees also gain benefit by supporting the reform (Zwick, 2002).

“There is no change without a trigger,” said Dr. Sr. Francina, the director of the Doctor Typhagne Memorial Charitable Trust (DTMC) and cooperation partner of the project, which is the core element of this thesis. As simple as this factor may sound, without simplified and practically-orientated guides it is very difficult to provide or to be such a trigger. The cooperation which is the subject of this paper tried, nevertheless, to fulfill this position. The partnership between Global Health and Development (GHD), a department of the Medical University of Graz, and the DTMC Trust was initiated in 1986. The aspiration was to increase patient safety and implement sustainable change through a systematic evaluation of problems and to find realistic solutions. The minimum target of this project was to increase the awareness of patient safety.

This thesis is building a framework around the project trying to answer the question how it is possible to do a basic check-up on patient safety and quality management in developing countries, and what kind of factors have an influence on the success. For that, firstly a description of the current situation and the implementation process was done and the gained information was compared to today’s literature. Secondly, the success-rate of implementations was analyzed by factors, which were collected via interviews with the staff. The goal was to investigate the correlation between these factors and the outcome of decision making of the representatives on-site to use this knowledge for similar projects.

2. Background

This first chapter shall provide a deeper insight into the core items of this thesis. Therefore, common definitions and their connected subitems are presented. Afterward, the general situation in India is described and the SFS Health Centre in Kakkaveri, where the project took place, is going to be introduced.

2.1. Quality Management

Saraph et al. identified eight key factors of quality management which have an immediate effect on the outcome (Saraph et al., 1989). These are:

1. The role of top management leadership (Garvin, 1983)
2. The role of the quality department (Juran, 1981)
3. Training (Ishikawa, 1976)
4. Product/service design (Crosby, 1979)
5. Supplier quality management (Deming, 2000)
6. Process management (Leonard, 1982)
7. Quality data and reporting (Garvin, 1983)
8. Employee relations (Juran, 1981)

These key factors also contribute to the quality management in medicine. To identify the importance of the factors above, correct measurement methods are important. Brook et al. propose three domains which should be covered within an evaluation of quality in medicine: Structure, process and outcome (Brook et al., 1996).

During the described Indian project, a check-up of processes was performed, but that does not mean there was no focus on the outcome at all. The processes mentioned above are only relevant for quality if they actually have an effect on the outcome (Brook et al., 1996, Chassin and Galvin, 1998).

To evaluate the current status of the processes, it is necessary to do a check-up on the different components of the system. The ISO 9001 2015 (International Organization for Standardization) suggests seven items, which have to be balanced:

The Seven Quality Management Principles
Customer Focus
Leadership
Engagement of People
Process Approach
Improvement
Evidence-Based Decision Making
Relationship Management

Table 1 The seven quality management principles. Data adapted from (International Organization for Standardization, 2015)

The priority of the different principles differs from organization to organization and can change over time (International Organization for Standardization, 2015). In medical context these seven points were defined as followed:

1. Customer focus (table 1) in the context of healthcare means putting effort on the needs of the patient. It contains providing the right care, recognizing the requirements of the patient and his/her relatives and to establish a relationship of trust (Epstein et al., 2010).

   Studies conducted by Oates et al. (2000) and Little et al. (2001) indicate that customer focus increases not only the patients' satisfaction but furthermore leads to an improved outcome and reduced costs. Stewart (2001) found that patients attach special importance to the following points: A proper exploration of the medical history, respect and understanding, mutual goal setting and treatment, enhancing of prevention and of the continuity of the doctor-patient relationship.
2. Leadership (table 1) is about determining the future direction and the main purpose of the organization. If long- and short-term goals are well defined the company gains a better internal coordination, improved communication, effectivity and efficiency and in the end an improvement of the company (International Organization for Standardization, 2015).

   In a review of Butler, development programs for leadership showed a positive effect on quality management due to an increased workforce, enhancing development, reducing costs and better strategic prioritization (Butler, 2008).

3. Engagement of people (table 1) is a factor which has a very strong relation to the performance of healthcare and therefore with the outcome and quality management. An employee survey with 10,000 participants showed the following points as related factors to high employee engagement: Patient centeredness, focus on patient safety and a positive assessment of the own health care service and retention. (Lowe, 2012)
4. The factor process approach (table 1) addresses the importance of understanding the interrelations between the different processes. The goal is to receive predictable and constant results. This step includes the need of defining every element of the company consisting of responsibilities and accountability, the objectives and needed processes, process independencies, interrelation, which affect efficiency and effectivity, the extent of necessary information, monitoring and analysis and risks that affect the outcome (International Organization for Standardization, 2015).
5. The principle of improvement (table 1) means to have a continuous aspiration to increase the quality level and to react to internal and external conditions. The goal is to decrease the amount of waste, rework and complexity. But despite these specific efforts, the main goal of this point is to create a positive and non-punishing atmosphere which encourages learning and enhances communication (Berwick, 1989). Implemented correctly, it will lead to a better process performance and an increase of patient satisfaction (International Organization for Standardization, 2015). Otherwise, if the pressure leads to fearful workers, improvement will stop and failures will be kept secret losing the chance to learn (Berwick, 1989).
6. Evidence-based decision making (table 1) leads to a higher probability of reaching the desired outcome (International Organization for Standardization, 2015). This step involves some challenges because the decision-making process in medicine contains multiple types of parameters, which can be interpreted differently (Black, 2001). Furthermore, there are two different job fields with differing points of views, which factors should be considered: the medical and the management side. There is a gap between the research base and the decision making process of a clinician on the one hand and an economic on the other hand. This results in a need of a translation of knowledge between

both sides (Walshe and Rundall, 2001). Furthermore, it is important to balance population-based knowledge and the needs of the single-patient. The implementation of global study findings has to be adapted to the local and national environment, the patients' expectations and the respective structural conditions and tools (Clancy and Cronin, 2005).

7. Relationship management (table 1) deals with the bond between the patient and the hospital. If all of the interests are well-balanced and optimized, it leads to better performance. Therefore, it is necessary to know about the parties involved, to share information and provide feedback (International Organization for Standardization, 2015).

Although the priorities of the seven principles provide detailed information about processes, it is not the best one concerning concision. This is the domain of another guiding of the IOM in 2001: It is called the "six aims of improvement" (Institute of Medicine Committee on Quality of Health Care in America, 2001). It has not the effort to provide a step by step guideline, but to put in a nutshell what the most important requirements for quality management are (Corrigan et al., 2004).

Health care should be:

1. Safe
2. Effective
3. Patient-centered
4. Timely
5. Efficient
6. Equitable

(Institute of Medicine Committee on Quality of Health Care in America, 2001)

This list names "safety" as one of the main features of quality management, which will be the topic of the next chapter 2.2..

The second term "effective" means the over and underuse of care should be avoided. It is a common approach to weigh the effectiveness against the cost to decide e.g. if screening programs are reasonable or not (Frazier et al., 2000).

“Patient-centeredness” is a factor which is also part of the seven principles. It addresses the individual needs of a patient in the sociocultural context (Saha et al., 2008).

The term “timeliness” brings up the importance of avoiding delays and waiting times which could be harmful. Prentice and Pizer conducted a study to investigate the correlation between waiting times and mortality and found out that the mortality rate within the cohort with a delay of 31 days or longer was significantly increased (Prentice and Pizer, 2007).

The fifth item “efficiency” phrases the effort to reach the desired goal with the minimum of effort and costs. Efficient healthcare needs to be built on research, but experts need to evaluate if it is reasonable to implement the innovations in the present context. This is a balancing act: For example on the one hand, Ford et al. estimated that the mortality rate of cancer could be decreased by 10% if the treatment would be actually performed to the current state-of the art (Ford et al., 1990). On the other hand, Reaume et al. found out that the premature application of new treatment can lead to inefficiency and could actually harm the patient (Reaume et al., 2005 cited in Graham and Tetroe, 2007).

“Equity” means to provide the same quality for every patient irrespective of e.g. race or ethnic origin (Berwick, 2002). There are different definitions in the literature about the existing types of equity in health care (Mooney, 1983, Culyer, 2001). Oliver and Mossialos named three important domains of equity in health care: Equal access, utilization and outcome (Oliver and Mossialos, 2004).

Quality of medicine is a complex term and different definitions were made. The last definition presented was made by the Institute of Medicine (IOM) and sums it up well: Quality of care is the “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Institute of Medicince, 1990 cited in Lohr and Schroeder 1990, p. 21).

2.2. Patient Safety

“First do no harm” is a popular quote although the origin is unknown. It is often used as a definition of patient safety shortened on the effort to prevent from injury in the first place and it became the safety goal of the first World Alliance of Patient Safety in 2004 (World Health Organization, 2018). This saying is often believed to be part of the Hippocratic Oath because it reflects some parts of the content very accurate: "Practise two things in your dealings with disease: either help or do not harm the patient" (Lloyd et al., 1983) But despite the question if Hippocrates was the author or not – patient safety has one important difference to this well-known vow: patient safety cannot be an issue for one single person.

Leape and Lucian assumed that most of the medical errors are caused by systematic errors of processes and not – how it is often believed – of individuals (Leape, 2000). The Committee on Quality of Health Care in American presumed that failures of the information flow are aggravating the unsafe conditions and are a barrier towards improvement. One reason mentioned is the fact that healthcare delivery systems usually have a decentralized and, because of the huge number of persons and specialties involved, fragmented structure (Kohn et al., 2000). This set up requires a careful weight up between data safety and data access. Rules which restrict an open access to medical files will lead to an increase of data safety. At the same time there might be circumstances as for example an emergency situation, where it may be necessary to disclosure essential data without the patient’s permission (Meingast et al., 2006). In Australia, 11% of the preventable failures are caused by communication problems and therefore a lack of information flow (Zinn, 1995). This results in a need for balancing the different requirements in changing situations and obtain standards. The continuity of information flow was one of the basics to explore within the presented project.

But patient safety includes more than this and therefore it is necessary to define the term itself. In the standard work “To Err is Human,” safety is defined as “freedom from accidental injury” (Kohn et al., 2000, p. 21). This definition tries to hold on to what is most important from the patients’ view (Kohn et al., 2000). Unfortunately, the term “injury” is very wide-ranging. The Evidence-Based Practice Center (EPC) of the University of California at San Francisco (UCSF)-Stanford University defines

patient safety practice as “a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of disease and procedures (Evidence-based Practice Center, 1999 cited in Shojania et al., 2001, p. 1).”

This second definition focuses on preventing adverse events, which is often used as an objective of patient safety (e.g. World Health Organization, 2005, Baker et al., 2004, Rothschild et al., 2005, Vincent et al., 2001).

Localio et al. defined medical adverse events as injuries which are more likely to be caused by the medical intervention than by the patient’s previous health status, and lead either to a prolongation of the hospitalization, disability or death (Localio et al., 1996).

Referring to guidelines of the WHO (World Health Organization, 2015a) the risk fields, in which adverse events occur, can be categorized as follows:

Area	Example
Clinical Practices	Lack of Hand Hygiene, Unsafe Injections, Medication, Blood Products
Processes	Interpersonal Communication Like Handover, Wrong Diagnosis, Misdiagnosis and Follow up
Organisational Culture	Blaming Culture, High Pressure, Poor Training and Education, Bad Error Management (no Learning From Adverse Events)

Table 2 WHO risk fields concerning patient safety. Data adapted from (World Health Organization, 2015a)

Even in developed countries, those adverse events are estimated to be found in 10% of hospitalized patients and 4-17% of hospital admissions. Up to 21% of these errors are leading to death, though half of them are believed to be preventable (World Health Organization, 2015a).

This WHO statistic opens up a new subcategory. Adverse events are classified as “preventable” and “not preventable”. A preventable adverse event occurs if an error happens due to faulty management not being able to supply the current level of expected performance for the average practitioner or system (Bates et al., 1995b, p. 452-462). According to Reason, there are two types of failures in medicine which can result in adverse events: Error of execution and error of planning. An error of

execution occurs when an intervention or action is not performed although it was needed. In contrast, an error of planning is happening when it was already the wrong intervention set for this situation (Reason, 1990, p. 8). So, the adverse event is a well usable and common objective for patient safety and can be caused by either failure within the planning or the execution.

But it is important that there is one more type of event left, which additionally has a high potential in the prevention of harm. It is the so-called “near miss”. This type of failure was defined by Barach et al. as an incident which could have caused negative consequences but did not, and this factor is as well the only distinguishable criteria from an adverse event (Barach et al., 1991 cited in Barach and Small, 2000). This term has its origin in the air-traffic control (Nashef, 2003). In medical context it is defined as an act or omission which had the potential to harm the patient but did not, because of chance (e.g. wrong medication, but no negative effect occurred), prevention (e.g. doctor prescribes the wrong dosage, but the pharmacist identifies the mistake) or mitigation (a drug overdose was corrected with the antidote) (Erickson et al., 2003). Heinrich called the theory that near-miss events have a similar root cause as adverse events, “common cause hypothesis” (Heinrich, 1931 cited in Wright, 2002, p. 3), an opinion, which is also shared by Lamp and Nagpal (Lamb and Nagpal, 2009). This mechanism is the reason why near-misses should not be underestimated in their value for harm prevention. One of the basic targets of the current Indian project was to increase the awareness of medical errors so that some of the near-miss events are recognized in the first place. This policy is based the seven stages of Phimister et al., which includes the dissemination of information to increase awareness as important part of near-miss identification and risk reduction (Phimister et al., 2003). The near-miss events or “potential” adverse events were measured to account for almost the half of all incidents (Bates et al., 1995a). This huge number is an advantage when it comes to building up databases for analyses to learn about failures and their effect. Furthermore, because there is less risk of being punished, the willingness of the staff may also be more positive when it comes to reporting events (Sheikhtaheri, 2014, World Health Organization, 2005). To monitor the near-misses and to compare the amount before and after implementing change was seen to be a powerful tool to check on the effectiveness and correctness in various industrial sectors (Callum et al., 2001).

2.3. General Situation in India

India has various issues to struggle with. On the one hand there are problems of conditions like a lack of resources and a high burden of diseases and on the other hand, there are problems regarding the health care system itself, like low investment and missing error management. The main issues are going to be described in the following chapter.

2.3.1. Lack of Resources

Although India was on the 3rd place of the Gross Domestic product ranking worldwide in 2011, in relation to the number of inhabitants (gross domestic product per capita) India slips to number 127 (World Bank, 2014). While the GDP has grown immensely within the last decades, the health expenditures showed only a moderate increase. In 2013/2014 the total government health expenditure was estimated to be 1.15% of the GDP, which is not enough compared to the total health care expenditure of 4.02% of the GDP. So, where does the missing money come from, if it is not government-funded? About 69% of the current health expenditure is covered by out-of-pocket expenditures (National Health Systems Resource Centre, 2016). This burden on the private households is reflected by the fact that Krishna found healthcare expenses as one of the most frequently mentioned causes of poverty in India (Krishna, 2004).

The next problem is the irregular grade of qualification in India. About one-third of the doctors do not fulfill the international requirements of graduation, completing only an educational level up to the secondary school (World Health Organization, 2000). This problem is exacerbated by the trend that highly trained employees are more likely to emigrate from India (World Health Organization, 2016), a problem called “brain drain” (Oommen, 1989, p. 411).

This trend leads to the second important resource, which is missing in India: The workforce. There are 0.60 doctors, 0.80 nurses and 0.47 midwives per 1000 inhabitants living in India, which makes a 1.87 ratio of workers per 1000 (World Health Organization, 2006a). The critical minimum ratio of the WHO is 2.28 per 1000 inhabitants, a proportion which is necessary to receive a stable coverage of essential services like skilled birth attendance and child immunization (World Health Organization, 2008). Additionally, referring to a study about work absence time, up

to 40% of the personnel in primary health care is not on their scheduled workplace during their shift, a problem which is found to be more often in low-income countries (Chaudhury et al., 2004).

2.3.2. Burden of Disease

India and Sub-saharan Africa are affected by the greatest portion of the worldwide burden of diseases (Murray and Lopez, 1997). About 41 % of the patients in the urban regions of North India are dying because of an infectious disease like pneumonia, diarrhea or inflammatory brain infection (Singh et al., 2005). India is also the country with the highest incidence of tuberculosis with 2.79 million cases in 2016 (World Health Organization, 2017b). Thirty-seven million Indians suffer from hepatitis B, which corresponds to 15.4% of the global cases (Puri, 2014). Furthermore, the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that 2.1 million Indians are living with HIV, of whom only 77% know about their disease (UNAIDS, 2016).

One big challenge for developing countries is to provide clean water. The majority of drinking water (78%) in rural areas of India is contaminated with fecal coliforms (Suthar et al., 2009) and even in the 21st century, 18% of deaths among Indian children aged 5-14 years are caused by diarrhea (Morris et al., 2011).

Other country-specific transmission paths of diseases are the mosquitos which are the vector for malaria and dengue fever. These hazards are sometimes likely to be underestimated due to a lack of documentation regarding death causes (Hay et al., 2010). Estimations by Park, who is trying to adjust for this gap, found Dengue fever to be the third most frequent reason for hospitalization and mortality among children in India (Park, 1979 cited in Raheel et al., 2010). Although protective measurements of the private and public sector were taken, the trend shows a further increase in 2009 with 11476 affected patients (Park, 1979).

All of these risks lead to an urge to increase patient and, equally important, staff safety. Both topics go hand in hand. The safety of patients depends on the adequate number of qualified staff (Oulton, 2006). As already mentioned in the chapter 2.3.1., there is already a shortage of staff in India. Beckmann et al. showed that a shortage of personnel increases the number of incidents (Beckmann et al., 1998). Oulton argued furthermore that there is a connection between an increase of patient

mortality and the risk for the nurses. To stop the global nursing shortage she recommends to ensure staff safety to interrupt this negative downward spiral (Oulton, 2006).

Pai et al. showed that 50% of the healthcare workers (HCW) in rural India showed a positive tuberculin skin test or interferon γ (IFN-γ) assay as a sign for latent tuberculosis (Pai et al., 2005). Jindal et al. found out that 4% of the HCWs is hepatitis C positive, which is twice as much as the rate found in the general population (Jindal et al., 2006). The risk factors which contribute to transmission are various. HCWs, who were employed for at least one year, had an increased risk of 16.8% to have had a needle stick injury during their career (Sharma et al., 2010). This tendency could be the logical effect of risk addition through repeated exposure. But there are contradictory studies which indicate that the underlying processes are not yet fully understood: For example, Jindal et al. (2006) conducted a study about seroprevalence of hepatitis C in HCWs in New Delhi and found no correlation between the employment period and the risk of infection. This apparent “compensation” of the cumulative risk mentioned above could be explained by the fact that long-term staff is found to be more likely to take protective measurements (Kermode et al., 2005b). Further questions about the incidence of needle stick injuries during the last month showed that senior residents, laboratory technicians and nursing students had the highest rate of events (Sharma et al., 2010). The reasons for this attribution may follow different pathways.

There is more research needed and this problem could be very much dependent on the particular hospital and its processes. Therefore, it is essential to have an in-place troubleshooting, to trace the particular error in the individual case.

2.3.3. Lack of Awareness

Risky moments occur very frequently within Indian staff. About 63% of the HCWs say they had a needle injury within the last year (Kermode et al., 2005a). It is suspected that lack of awareness is an important factor for this issue. The reason for this presumption is that there are problems in taking pre-protective steps during the performance of risky procedures. For instance, Pati et al. found that only 55,4% of the HCW were reportedly vaccinated against hepatitis B (Pati et al., 2008), while the rate in the U.S. comes to 75% (Simard et al., 2007) although the risk of exposure

in the U.S. is lower. There are immunization programs in both countries, but during the Indian implementation, problems like the lack of knowledge about the necessity of three dose immunization occur. This lack of knowledge and the fear of wasting material by opening unnecessary multidose vials lead to an under and misapplication (Lahariya et al., 2013).

Despite the missing prevention, another problem in India is the high frequency of exposition with infectious material: 68% of the HCW do not use indicated eye protection when it is necessary and 40% are recapping needles occasionally (Kermode et al., 2005b). But is it a problem of missing resources or are the existing tools underused? Pathak et al. found that the most common reason for HCW not taking a hepatitis B vaccine is a lack of knowledge about the number of doses (45%), followed by negligence (41.6%) (Pathak et al., 2013a). So, it seems to be a mix of both issues and therefore, there are more and more campaigns for raising awareness in developing countries in addition to fundraising projects (World Health Organization, 2015b, Madhok et al., 2014).

2.3.4. Error Management

If mistakes are not noticed, they are more likely to occur again, because the leading cause can not be removed. As already described in the chapter 2.2. it is very important to report and understand near misses to check on the effectiveness and correctness of implementations (Callum et al., 2001). One very important step is to have a working environment without a blaming culture (Kohn et al., 2000). But especially this problem seems to occur in India. During a questionnaire among HCWs about barriers towards patient safety, the punitive approach to errors was mentioned to be one of the top five issues (Landefeld et al., 2015). This factor may be connected to the Indian tendency to strict hierarchies which is reflected by the high “Power Distance Index” analyzed by Hofstede et al. (2010).

For a proper error management, it is essential to have an easy reporting system for failures (Reason, 2016). Elhence et al. claim that there is no official reporting system in India for, e.g. errors concerning blood transfusion, as in other countries. (Elhence et al., 2012). Other reporting systems as the ADRs (adverse drug reactions) do exist but are fairly unknown to HCWs. The reason may be a lack of knowledge, awareness or time (Nadeem et al., 2018).

2.3.5. Safety Culture

This topic addresses the safety culture of the general population. There is still an immense lack of knowledge about essential hygienic behavior, especially in rural areas. A questionnaire conducted with mothers of little children in India showed that although the general relation of hand washing and communicable disease is known, 61.12% did not know, that handwashing can prevent diarrhea and 77.82% think it is sufficient to wash the hands without soap (Datta et al., 2011). Although handwashing without soap also reduces the number of microorganisms, especially concerning Enterococcus species, water alone leaves 15% of the bacteria on the skin, while water and soap let only 3% of the bacteria survive (Burton et al., 2011).

Rajaraman et al. (2014) interviewed people of seven villages about their opinion on a project that promotes soap usage. Although it was conducted by a non-governmental organization (NGO) in cooperation with local hospitals, some people suspected it might be sponsored by soap companies or politically influenced. So, despite the missing knowledge, there is also a certain amount of skepticism towards change.

A contributing factor to the infrequent use of soap may be the problem of accessibility. Banda et al. (2007) conducted a survey about water handling and sanitation in South India and found that the majority of people in rural areas defecate in open areas (74.2%). The greater proportion of them has no toilet available at home. But besides this problem of accessibility, the fact that there is also a number of people with access to toilets, who still prefer to use open areas, indicates that it may not only be an issue of access. One reason for this preference is the respondents' belief that defecating in open areas is more hygienic, even though the performance of hand hygiene is more difficult in this setting. Banda et al. found furthermore only 4% of the interviewed population considered dirty water as a potential cause of diarrhea occurred again (Banda et al., 2007). This survey confirms the results of the questionnaire among mothers by Datta et al. (see above) showing a lack of knowledge concerning the connection between hygiene and illness.

Landefeld et al. found that the demand within the population for receiving medications in form of an injection is one of the most frequently mentioned barriers

towards patient safety in Kerala, South India (Landefeld et al., 2015). On the one hand, this popularity could be caused by a fascination towards the action of performing an injection described by Reeler (2000), whereby the associated pain is seen as a sign of its effectivity. On the other hand Drucker et al. summarized that the “popular faith in the power” (Drucker et al., 2001, p. 1991) or “wonder of the injection” (Wyatt, 1984, p. 913) might be a result of antibiotic therapies in the 1950s (Drucker et al., 2001) and the almost immediate and visible effect of injections on yaw and kala-azar lesions (Wyatt, 1984). Additional factors may be the rapid accessibility on the one hand because an injection can be performed very fast, and economic considerations on the other hand, because some of the providers charge less for this service (Reeler, 1990). But every injection is an injury and, combined with the fact that almost 77% of the injections in India are considered to be unsafe, an actual threat.

Unsafe practices include reuse after boiling pan sterilization and needle recapping, performances which can harm the recipient or the provider (Pandit and Choudhary, 2008). This deficiency leads to injection-associated infections found as follows (median fraction of infected people attributed to injections):

- 46% of the hepatitis B cases
- 38% of the hepatitis C patients
- 12% of the people living with HIV

(Reid, 2012)

2.3.6. Accessibility

There are three different types of access problems regarding healthcare. The first one is caused by infrastructure and geographical distance. On the one hand, there is inequality between the budgets of the different states in India, on the other hand, there is a gap between the rural and urban areas in general (Singh et al., 2003). The ratio of qualified allopathic physicians per head is more than nine times lower in rural than in urban areas (Rao et al., 2012). The reason may be the relatively low state expenditure on healthcare in rural areas compared to urban districts (Deogaonkar, 2004). One of many effects is the lower coverage of vaccinations in rural districts (Balarajan et al., 2011) and a bad diagnostic success rate, with 46.6% wrong diagnoses and 41.7% unnecessary or even harmful treatments (Das et al., 2012).

Das et al. (2012) also found that doctors of rural regions have a lower level of qualification, a fact which could contribute to this high rate of mistreatment. But although urban regions show a higher level of qualification, the adherence to medical checklists is not higher, but similarly bad in urban and in rural regions. This non-use of checklists, which could be used independent of the level of qualification, shows there may be a problem of awareness. Without standardized treatment, access to the same level of quality care cannot be ensured.

Other factors contributing to limited access may be the socioeconomic status. Children with mothers, who have little education, have a risk of dying before their first birthday which is twice as high compared to mothers with at least 10 years of school education (International Institute for Population Sciences, 2007). The poverty rate in rural areas is higher than in urban areas (Fan et al., 2005) which matches with an almost three times higher infant mortality rate in these regions (weighted number of cases) (International Institute for Population Sciences, 2007).

Almost 14% of the rural households are spending more than 10% of their expenditure on healthcare, which is a 2% higher proportion of households than in urban areas. These payments have, in context of the already weaker financial position of rural regions, a severe effect on the affected households. Selvaraj and Karan (2009) claim that costs in case of e.g. chronic diseases health care can often reach extends of so-called “catastrophic payments”. As a result, approximately 39 million people in 2004/2005 slipped into poverty because of health care expenditures.

Thus Ahmed et al. (2006) found the cost of healthcare services to be a serious barrier for Indian citizens with lower socioeconomic status and therefore emphasize the importance of NGOs to ensure accessibility for all .

2.4. SFS Health Centre in Kakkaveri

Figure 1 SFS Health Centre: main entrance (Doctor Typhagne Memorial Charitable Trust, 2018)

The Saint Francis de Sales Health Centre is part of the Doctor Typhagne Memorial Charitable (DTMC) Trust and was built in 2008 in Kakkaveri, Tamil Nadu. The DTMC Trust itself, a non-governmental organization, was established in January 1999 under the Salesian Missionaries of Mary Immaculate Convent and the head-office is located in Salem, about 40 km away from the hospital.

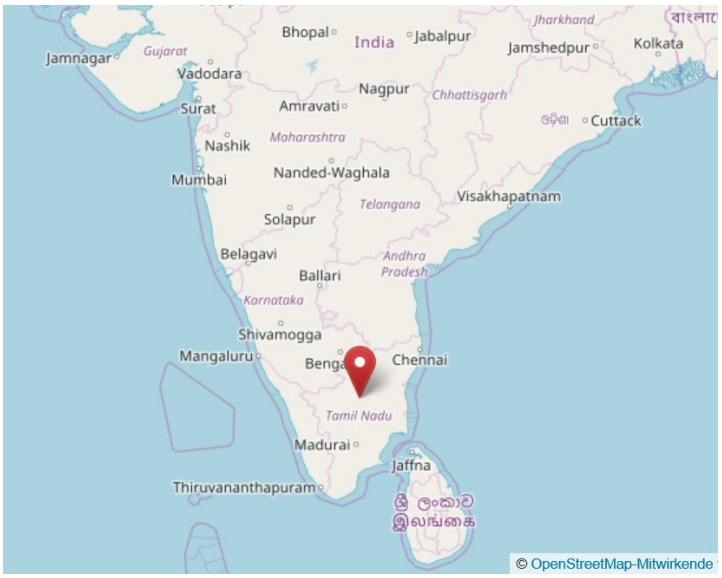

Figure 2 Kakkaveri, Tamil Nadu. (OpenStreetMap Foundation, 2018)

Kakkaveri is a rural area in the South of India and the SFS Health Centre, with a capacity around 60 beds, is an important cornerstone for the basic medical care of this district.

The hospital offers, on the one hand general services as general medicine, general surgery, maternity and childcare and, on the other hand, specialized fields like diagnosis and care for patients with tuberculosis, leprosy and sexually transmitted diseases, as well as a separate care unit for people living with HIV. It is equipped with an X-ray, ECG, ultrasound and owns and operates a laboratory and a pharmacy.

Figure 3 SFS Health Centre: X-ray. (Doctor Typhagne Memorial Charitable Trust, 2018)

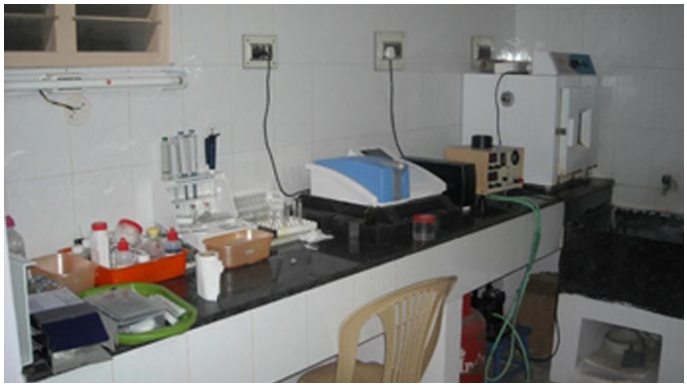

Figure 4 SFS Health Centre: Laboratory. (Doctor Typhagne Memorial Charitable Trust, 2018)

The annual number of patients amount to an average of 2,170 in the inpatient sector and 12,576 in the outpatient sector (Doctor Typhagne Memorial Charitable, 2017).

Due to the specialization in infectious diseases, it is important to follow strict safety rules. This will be discussed further on in this thesis. Secondly, because the hospital belongs to the private sector and is funded by donations, it is important to get the most out of the limited budget and make efficient investments. Otherwise, it may be not feasible to provide free healthcare for HIV patients in long term.

3. Material and Methods

3.1. Descriptive Part

How is it possible to conduct a project for quality management and patient safety in South India?

The descriptive part of this thesis is based on research about the general situation in India and on documentation of the current project. The goal of this fraction is to build a framework around this venture and put the process in context to other projects and typical struggles of developing countries.

A tool for planning and documenting the project was searched and comparisons between common study designs were made involving Six Sigma, Lean Product System/ Toyota Production System, Failure modes and effects analysis (FMEA), Health failure modes and effects analysis (HFMEA), the Root Cause Analysis and the Plan-Do-Check-Act (PDCA). Six Sigma was designed for business strategy and involves elements of the PDCA, expanded to more steps involving either statistical calculations of defects per million or estimations of process variations. The focus is laid on cost saving and because of the number of samples needed and bureaucracy, it is mostly used in larger companies and therefore not suitable for the size, effort, and length of this project (Antony et al., 2005). The Lean Product System has intersections with Six Sigma but places its focus on removing activities, which are not valuable (Hughes, 2008). This goal is only one small part of the current project and therefore this design was also declined. The FMEA is an evaluation and analyzation technique used for proactive interventions. Similar to the HFMEA, it is a practical tool for decision making, but not for planning the project. The Root Cause Analysis is a retrospective intervention used for identifying the source of an event that has already happened. Because it is indispensable to have data about errors which occurred it was not possible to perform this kind of project, although it may be a useful tool for the future. The last study design, PDCA, was the most suitable kind for this project. It is a common tool for healthcare improvement, because of its cyclical nature. (Hughes, 2008) Especially in countries with limited resources, it is not possible to change everything at once. Every change has to be weighed and it is more effective to run little, frequent implementations (Berwick, 2003). This

proceeding is one strength of the PDCA because it is suitable for driving change step by step.

Problematic issues which needed immediate change were implemented right during the project. The change could be observed during the stay and the gained knowledge could be used for adapting the implementations towards viability.

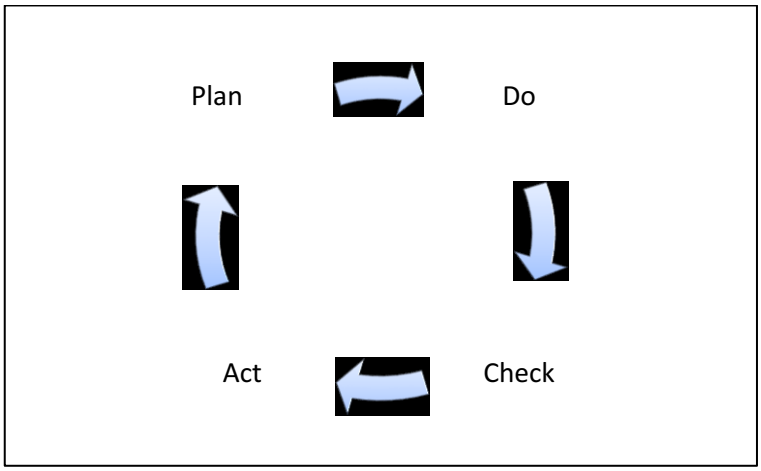

Figure 5 Plan-Do-Check-Act (PDCA): Data adapted by (Hughes, 2008)

For the planning process, Pubmed and Google Scholar were used for research using inter alia the keywords: patient safety, quality management, implementation, India, developing countries, error, near miss, adverse event, six sigma, seven quality management principles, checklist, healthcare, healthcare-associated infections, equity, efficiency, efficacy, patient-centered, timely, cost-benefit, evidence-based decision making, awareness, hand hygiene, resources and burden of disease. This knowledge was compared with interviews and observation on-site. Checklists were used to measure the actual state of patient safety and quality management (chapter 4.3.).

The step “do” means (figure 5), in this case, the first part of implementations which could be implemented immediately on the site of action. “Check” (figure 5) was performed by a final discussion with feedback at the end of the stay to optimize the end suggestions. “Act” (figure 5) is the last step and means the implementation of the complete catalog of recommendations.

3.2. Analytic Part

What kind of positive and negative factors can influence the outcome of cooperation in developing countries?

The success of the implementation process was documented by feedback of the head of the hospital in form of “suggestion accepted” or “suggestion declined”. Additionally, semi-structured interviews with members of the different job fields were performed within the 12 days of the stay: three student nurses, two nurses, two pharmacists, one X-ray technician, one laboratory technician, one doctor, the head of SFS Health Centre and the Head of the DTMC-Trust. In total, 12 interviews were performed. The key question of the interview was: What kind of barriers towards improvement did you recognize? After the feedback of the success was given, the factors were set in context to the success rate.

The analysis of the correlation was conducted referring the method of Spearman Correlation. This method was chosen because it has no requirements regarding normal distribution and sample number. The condition of having variables which are ordinally scaled is fulfilled. The goal is to find out if factors have a positive or negative correlation or if they do not affect the outcome. For this test a ranking of success (x) was conducted as follows: Suggestion “accepted, immediate implementation” and “future implementation” were rated as positive outcome = 1 and “suggestion declined” as negative outcome = 0. Using the program SPSS, the outcome was defined as variable one and the attachment to the particular factor was defined as variable two.

The gained correlation was valued using the effect size of Cohen, who ranked a correlation coefficient = 0.10 as “small”, 0.30 as “medium” and 0.50 as “large” (Cohen, 1988).

4. Results I: Descriptive Part

4.1. Project design

This chapter will describe the eight steps which were essential for the planning of this project.

Step 1	**Defining the Objective**	Increasing Patient Safety and Quality Management as Main Goals Objective: Continuity of Information Flow, Awareness of the Staff About His/Her Respective Responsibility, Identifying Risks for Patient Safety and Implementation of Standards (With Special Attention on Hygiene)
Step 2	**Overall Project Run- off**	General Estimation of Project Extent and Limitation 6 Months Planning Period (Group Discussions and Email Correspondence) Design and Preparation of Needed Tools for Step 3-7 Based on Research and Experts (Hygiene and Management). Schedule for the Stay (Chapter 4.2.1.)
Step 3	**Creating Measurement Tools**	Method: Observation and Interview Questions and Checklists Based on Research
Step 4	**Perform the Measurement**	Observation Using a Created Checklist (Appendix I). Semi-structured Interviews With Members of the Different Job Fields
Step 5	**Finding Solutions**	Research and Group Discussion
Step 6	**Prioritization and Procedural Planning**	Prioritize the Improvements Based on the Discussions and Main Barriers and Add the Steps Together to Receive a Short-Term and Long-Term Strategy
Step 7	**Final Decision About Implementation**	Presentation of the Recommendations by the Austrian Team. Final Decision About Acceptance or Rejection of Interventions During the Following Panel Discussion With the Indian Team
Step 8	**Long-Term Feedback**	Final Summary About the Findings and Formulated Recommendations by the Austrian Team Linked With the Relevant Background Literature Long-Term Feedback About the Implementations of the Indian Team After six Months

Table 3 Implementation process

After the last project in 2016, when surgery of leprosy and HIV patients was performed, the need for systematic changes in the hospital came up. The idea of

implementing checklists to improve the routine of the hospital was the beginning and expanded during the planning process over patient registration to a check-up of the total management of the hospital.

Step 1: Defining the Objective

The starting point of the project was to summarize struggles in the system which were recognized by the team at the last stay. One big problem, at first sight, were lacks in the continuity of quality as for example unsystematic maintenance of surgical devices and emergency equipment and fragmentary patient registration because of missing patient wristbands and checklists at the surgery department. These problems resulted in a concern about patient safety in total. Because of the limited resources, known through previous cooperation, the focus was laid on the aspect that the actions should be affordable and – if possible - cost saving.

Performing research for patient safety checklist shows an overcapacity of guidelines in the surgical field like “Surgical Safety Checklist” (World Health Organization, 2009a) and similar lists of the different nations on the one hand (Canadian Patient Safety Institute, 2009b), and educational curricula with general knowledge like the importance of focus groups for patient safety projects on the other hand (Canadian Patient Safety Institute, 2009a, World Health Organization, 2011). Facility checklist include strict demands like e.g. the diameter of the traps should be 40 mm (Provincial Infectious Diseases Advisory Committee, 2013) and which kind of antiseptic is the best use for which facility (Government of South Australia, 2013), while the first step in our case was to check if there is any disinfectant available. So, the main challenge concerning this project was that there are no fitting guidelines how to perform a basic checkup on the essential parts of a hospital with affordable measures. The same problems occur with the topic quality management. Searching for quality management checklists lead to theoretical background literature like the “seven quality management principles” (International Organization for Standardization, 2015) and “six aims of improvement” (Institute of Medicine Committee on Quality of Health Care in America, 2001) (see chapter 2.1.). But although these papers provide a good overview of the topic in general, unfortunately, key points as “customer focus” or “leadership” (table 1) are not giving

an explanation about the application of quality management. Therefore, it was necessary to create an own guideline using elements of different checklists.

The most suitable checklist for our project was found in the “Mindestanforderungen an QM Systeme V 3.5" [minimum requirements of quality management systems V 3.5] of the Austrian Federal Ministry of Health. It divides quality management into 6 minimum effort fields and offers handy subcategories:

- Structure (responsibility, information flow, documentation, and data policy)
- Process (definition, tools and error management of processes)
- Risky areas (patient safety and staff safety: prevention of error e.g. hygiene and error management)
- Patient-centeredness (feedback, information, rights and consent, access)
- Employee orientation (education, advanced training, staff satisfaction)
- Quality of results (ongoing reporting, continues aspiration for improvement)

(Bundesministerium für Gesundheit, 2014)

It also has many intersections with the mentioned literature of international quality standards above.

To receive similar tangible checklist items for patient safety, the idea came up to search for common struggles within this topic and to create a checklist concerning these risk fields. Landefeld et al. performed a survey in the South of India to find barriers to improved patient safety and found five main issues:

- Limited resources
- The fragmented structure of the health care system
- Punitive atmosphere
- Inadequate education
- Patients' behavior

(Landefeld et al., 2015)

This survey was later used as a starting point for the semi-structured interviews. At the preparatory stage, the roots of points 2-5 were searched. The fragmented structure and therefore the information flow was found to be an important source of systematic failures (Kohn et al., 2000). It also has intersections with point 2-3 of the top five risks of the WHO:

Top 5 Priority Risk Areas
Injection Handling
Transitions of Care in Case of Reconciliation
Correct Site Surgery
Handovers
Hand Hygiene

Table 3 Data adapted from five high 5s priority risk areas (Word Health Organization, n.d. cited in Leotsakos et al., 2014)

The factor of “punitive atmosphere” of Landefeld et al. points towards the effort to perform a basic check-up of the error management, as an important factor for patient safety (Landefeld et al., 2015). Within group discussions, the need of defining the responsibility within a company was seen as an essential systematic condition, which has to be set properly before error management can happen.

Furthermore, as already mentioned in the top 5 priority risk areas of the WHO above and the chapter 2.3., hygiene is an important issue in India. Because it is an essential part of medical care to prevent the patient and the staff from harm, this field became one of the top three basic check-up points of this project.

So, the main objectives of the project were defined as to check on…

1. …the continuity of information flow, to avoid mix up and resulting harm and near misses, because this source of errors is assumed to be very important for systematic failures (Kohn et al., 2000).
2. …the awareness of the staff about his/her respective responsibility, as a basement for error management.
3. …patient safety with a particular attendance on hygiene because it is a well-known problem, that the number of healthcare-associated infections in India is high (Rosenthal et al., 2006, Gupta et al., 2006) and the awareness for preventive measurements low (Kermode et al., 2005b, Pathak et al., 2013b).

Other factors mentioned above (e.g. injection handling, patient behavior, hand hygiene, …) were postponed to a later stage of the project as factors for measurement of the initial situation.

Step 2: Overall Project Run-off

After step one was performed and the objective was defined, the following proceeds had to be planned. Therefore, a measurement tool had to be chosen.

Because the objectives consist of behavioral, equipment and knowledge-based factors, the necessity of more than one measurement method was given. Since data about e.g. healthcare-associated infections or consumption of disinfectant are not available, an outcome-based analysis was not possible. The decision was made between the tools observation, interview, and questionnaire.

Observations offer the direct opportunity to measure behavior and document the availability and usage of equipment. The advantage of this tool is that the subjective bias of the investigated staff is eliminated and the information reflects the current happening without being dependent on the active cooperation of the respondent. The interview method, in contrast, offers the possibility to go deeper into the topic and answer questions which cannot be investigated by observation. Using a questionnaire is the cheapest measurement and is free of the bias of the interviewer. Compared to the others it is easier to gain big samples. But it has also some disadvantages: Low rate of return, inflexibility, time intensive and subjective bias of the respondent. Moreover, the omission of replies enables interpretation. (Kothari, 2004).

Step 3: Creating Measurement Tools

Because the three main objectives (information flow, responsibility, and patient safety) are parts of different processes and it was the goal of the project to perform a systematic basic check-up, it was necessary to close the gaps between the main objectives. Therefore, the conjunction of information flow, responsibility and patient safety to the “the seven quality management principles” of the ISO (2015) and the “six aims of improvement” of the IOM (2001) was reviewed and sub-targets were added. Within group discussions based on these standards, a list of focuses was set.

1. The first step of the seven quality management principles was the “customer focus”, which was interpreted as the wish of the patient to gain the best treatment on the one hand and to avoid harm on the other hand.

Focus: Do the patients receive the needed treatment? Are safety standards fulfilled? (hygiene, patient registration)

2. The importance of “leadership” should be involved via determining goals.

   Focus: What are the main goals of the leadership and where are points of intersections with the project goals?

3. “Engagement of people” as an important factor for the performance of the hospital. Because patient safety is a positive factor for high employee engagement (Lowe, 2012), group discussions about this topic were performed with members of the different job fields. Another important factor is the positive assessment of the own health care service, which was tried to be respected by the general effort of every project member to communicate in positive phrases and motivation.

   Focus: How is it possible to incorporate every staff member into the implementation process and to have a positive atmosphere of change?

4. “Process approach” is an essential step towards understanding the interrelations within the hospital and one of the top three check-up contents. To understand and monitor these processes a list of questions was made up to either observe or ask for every link of the working procedure (Appendix I). It includes the inpatient section, the outpatient clinic and specialized areas as pharmacy, laboratory, and x-ray. Every part contains the top three check-up fields: information flow, responsibility and patient safety.

   To simplify a complete survey of the quality and continuity of every step, these three factors were complemented by the “six aims of improvement” by the IOM (Institute of Medicine Committee on Quality of Health Care in America, 2001).

   Focus: Who is responsible? Is there a documentation about this process? How does this task affect the patient safety?

5. The principle of “improvement” as the factor of continuous enhancement was integrated into the project through long-term cooperation with feedback from both sides.

6. The principle of evidence-based decision making was followed by involving research knowledge into the discussions about the relevance of change and

into the solution finding. The translation of knowledge between clinicians on the one side, to economists on the other side, was made after the stay in form of an essay comparing the found problems with research findings of the consequences and possible solutions.

Focus: Are there current research findings about this topic available?

7. Relationship management regarding the balance of interests between the patient and the hospital was evaluated through interviews with the staff and part of the group discussion about solution finding. The interests of the patients were collected from the view of the staff members and could be part of following projects. The interests of the leadership were gathered by interviews with the head of the DTMC Trust.

   Focus: What kinds of interest interfere with the certain process and how is it possible to balance both sides?

These questions built the foundation for the observation and interview checklist (appendix I). Despite the self-designed checklist, further forms were used for the following topics:

- Information flow: discharge (Arundel, 2011) and handover (Blackpool Teaching Hospitals NHS Foundation Trust, 2016)
- Patient safety: “Surgical Safety Checklist” (World Health Organization, 2009a), “five moments for hand hygiene” (World Health Organization, 2006b) and washing facility checklist, which was consulted because of the practicability of contents, although it is addressing doctors’ offices (Österreichische Ärztekammer, 2015)

The interviews also included the following topics: general satisfaction with the daily routine, recognized problems, safety struggles concerning the patient or one’s own person, identification of the patient and information flow. Research results about the top five main issues in India (Landefeld et al., 2015) and the top five risky areas of the WHO (n.d. cited in Leotsakos et al., 2014) were brought up by the interviewer and similarities were queried.

Step 4: Perform the Measurement

The conduction of the measurement was planned to be performed in two-person teams, which should increase the efficiency of the observation. The interviews

should happen after the observations to complete the gained information and check on the correctness of proceedings, which were observed.

Step 5: Finding Solutions

After the performance of the measurement would be completed solutions have to be found. Solutions to the problems should be based on international guidelines, research on Pubmed, Google Scholar on the one hand and group discussion within members of the different staff fields and the head of the DTMC trust on the other hand. Every suggestion had to fulfill the demand to have a good cost-benefit ratio, based on the outcome of studies on the one hand, and costs of the new intervention compared to the current costs on the other hand.

Step 6: Prioritization and Procedural Planning

To increase the probability of change, aims were divided into short-term and long-term goals. Umar et al. recommend this approach of “little steps” to increase the sustainability of projects (Umar et al., 2009). But how is it possible to decide which intervention has to be conducted immediately and which one should be postponed? Although multi-criteria-decision-analysis exists in other economic fields, there is a lack of systematic approaches to transparent factors in healthcare and prioritization often happens through voting within team discussions (Baltussen and Niessen, 2006). It would be possible to leave the long-term goals completely out of this project to avoid overstraining. But defining the long-term goals is an important part of quality management in the sense of having a future direction (see chapter 2.1. Quality Management, p.3) and is a positive trigger for sustainable coordination and improvement. As already mentioned, this separation is likely to be very subjective and therefore it was necessary to determine factors to rely on. This process was based on decision-making tools modified from the HFMEA. It includes a hazard scoring matrix which is relatively simple: The risk of an error is rated by the severity on the one hand and the probability of happening on the other hand. The Severity Rating includes “minor”, “moderate”, “major” and “catastrophic event”. The Probability Rating contains “remote”, “uncommon”, “occasional” and “frequent”. (VA National Center for Patient Safety, 2014). These components are combined in a matrix, which makes it possible to attach a ranking number to every suggestion:

	Severity				
Probability		Catastrophic	Major	Moderate	Minor
	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Table 4 Hazard scoring matrix. Data adapted from (VA National Center for Patient Safety, 2014)

This matrix was extended by the project team as follows: Within the project, an equal score was solved by considering the cost-factor. The less cost-intensive intervention was preferred. Suggestions with a ranking number smaller than “8” were skipped to the long-term goals. The only exception was if the suggestions would not increase or decrease costs. The other way around, if a short-term goal was estimated to be too costly to be implemented immediately, it does not lead to a skip towards long-term goals, because it was not seen as the team's decision to leave an important suggestion out. This valuation could only be made by the head of the DTMC Trust.

Step 7: The Final Decision About Implementation

At the end of the stay, a presentation with all the long-term and short-term goals was scheduled. Part of this presentation was meant to give feedback about the positive results. This final meeting was intended to offer time for discussion about all suggestions and the new input should be included in the end report, too. Afterward, a meeting between the stakeholder and the head of the DTMC was scheduled to discuss the interventions.

Step 8: Long-Term Feedback

A summary about the recommendations should be formulated by the Austrian team and send via email to India. This final report should include the relevant background literature, on which the suggestions are based on.

About six months later a meeting between the head of the DTMC Trust and the Austrian team was planned to talk about the ongoing of the implementations. Furthermore, it was agreed on continuous staying in contact and information exchange via email.

4.2. General Project Conduction

The following results were collected via observation and participation in the discussed project.

4.2.1. Overall Project Run-off

The planning process of step 1 and 2 and the overall project design itself took a half year and was performed by group discussions, conducted by the seven-headed team and email correspondence with the Indian team. The stay at the hospital in Kakkaveri lasted six days plus four days of preliminary discussion and debriefing with the head of the DTMC Trust.

The six days at the hospital were divided into:

Two Days of Observation and Interviews	Chapter 4.2.2.
One Day of Panel Discussion With Solution Finding of Immediate Problem Solving (= Plan),	Chapter 4.2.3. A) PDCA: Plan
Two Days of First Implementations (= Do) and Ongoing Observation (= Check)	B) PDCA: Do C) PDCA: Check
Last Day: Panel Discussion With Representatives of the Different Jobs With the Final Decision About Short-Term and Long-Term Goals or Decline of Suggestions. The Implementation of These Short-Term Goals was Done After This Final Meeting (= Act).	D) PDCA: Act

Table 5 Schedule of the stay

A first struggle occurred at the beginning of our stay when some reservation towards the act of observation arose. It needed some time to explain the goal of the intervention to every staff member as a constructive project, not a test which could be failed. Within this state, some of the interviews and observations showed discrepancies. This problem was partially solved during our stay when the teams got to know each other and the first team meeting with results was performed. Presenting the first findings and suggestions was the best way for us to explain the project to the team. After the following days of implementation and ongoing

observations, the final meeting with representatives of the different job fields was held and suggestions were evaluated.

A final report about the findings and recommendations linked with the relevant background was sent one week after the stay. Long-term feedback by the Indian team was not submitted within the appointed six months. Email correspondence after seven months showed satisfaction with the implementations which were accepted (final decision, table 3) and additionally the implementation of two suggestions, which were declined previously.

4.2.2. Initial Situation

The following information was collected by observations and interviews and represents the results of step 3 “perform the measurement” (table 3). The ongoing of the project was essentially dependent on the findings of this step. This evaluation of the main objectives information flow, responsibility and patient safety was conducted within the first two days of the stay.

I. Information Flow

This investigation included the patient registration, documentation, and handover.

The patient registration with name, age, admission date, identification and room number is performed and documented completely. There is also a system for archiving and finding the information about previous stays. Handovers are performed without a checklist, but they include the mandatory components as required in the handover checklist of the Blackpool Teaching Hospital (Blackpool Teaching Hospitals NHS Foundation Trust, 2016). Discharges were also performed without a checklist. There are no wristbands or similar signs for patient identification. The beds, documents and laboratory material are labeled properly. Because surgical interventions are rare, a checklist for surgery is not in use.

II. Responsibility

Systematic distribution and documentation of tasks are given concerning: duty planning, cleaning schedule, files/records with signatures of the responsible employee, general time schedule with visiting hours, rounds, nursing care and opening hours of the laboratory and pharmacy.

Despite these well-structured fields, there are two fields in which tasks are not coordinated properly. The first area is the cleaning of medical devices (such as the ECG devices) and the fundamental cleaning (e.g. wiping the inside of the cabinets). The second area is the emergency management, where no official algorithm is defined and no one is responsible for the administration of emergency medication on the ward. In case of an emergency, missing medication has to be picked up at the hospital's pharmacy.

III. Patient Safety

Because the findings of this objective make up the largest part of the evaluation, they were separated into two chapters "equipment and tools" and "behavior and knowledge" and subcategories were added.

1. Equipment and tools

a. Washing Facilities:

At the first observation day, a screening of every ward regarding the following hygienic basic equipment was performed: sink, soap, paper towels, garbage can and disinfectant dispenser. None of the 27 rooms we checked was fully-equipped as required by the Austrian General Medical Council (Österreichische Ärztekammer, 2015). Every patient room had a sink and a waste bin. The casualty department and the doctor's rooms provided sinks, garbage cans, textile towels and disinfectant, but especially the working field of the nurses and technicians lacked disinfectant. Because of that, it is not integrated into the working routine. Soap is exclusively available in high-risk areas like the examination rooms, nurses' station, and the doctors' room. The used soap is curd soap. There is no liquid soap in use. The waste separation is happening at the nurses' station and it is the nurses' task to separate it there by hand, even the needles.

	Sink	Soap	Disinfectant	Paper Towel	Waste Bin
Patient Rooms	100	0	0	0	100
Casualty Department	100	100	75	0	75
Examination and Treatment	100	33	33	0	100
Nurses‘ Area	100	33	0	0	100
Average Percentage (All Rooms)	**100**	**16**	**8**	**0**	**97**

Table 6 Availability of washing facilities in percentage

There was also no disinfectant dispenser available in the hallway, which makes it difficult to perform the “five moments for hand hygiene” (World Health Organization, 2006b). There is also no reminder for hand hygiene on the walls as recommended by the WHO (World Health Organization, 2009b).

b. Radiation Protection

Unnecessary radiation is restricted by the requirement of a doctor’s order for every X-ray. The awareness for preventing pregnant women from radiation was said to be part of the daily routine. There is an apron for the staff, but the protection for the patients is missing.

c. Safe Pharmaceuticals

The hospital’s pharmacy is responsible for the inventory of the medical products, taking care of the availability of essential medication, checking on the expiration date and storage at the right temperature. There is no distribution without a doctor’s prescription to prevent the patient from wrong dosage or medication.

d. Information Procurement

Important information to prevent the patient from harm is collected, including allergies and past medical history and is available for every involved staff member. The admission is conducted with a consent form which the doctor reviews with the patient. A first “suspected diagnosis” is made and has to be verified after 24h hours. During the stay, the vital parameters are documented on a temperature chart, just like the in- and outtake and the dosage plan of the medication. At the end of the stay, a discharge summary is handed out and follow-up appointments are determined. The awareness for data safety reaches the limit, that suggestions about putting signs on the doors of isolation rooms to inform about safety protective measurements were seen as interference towards the privacy policy.

A discharge checklist, as we brought along, does not exist. As mentioned in the chapter “information flow”, patient wristbands are not in use and this could be a source of harm.

e. Waste Management

The waste separation is performed very properly and exceeds the segregation of biomedical waste. The strict separation of paper, sharp, and plastic etc. is conducted at the nurses’ station.

The needle disposal is deficient because portable containers for sharps are unknown and the disposal cannot be performed immediately after the procedure at the patients’ room. This proceeding increases the risk of needlestick injuries due to extended exposure. Furthermore, it is common use to recap needles because it is estimated to be a safe practice.

f. Environmental Infection Prevention

The cleaning is scheduled and a daily wiping of the floors is performed with water and soap. The surfaces are well suitable for cleaning. There is also a schedule for washing textiles. Because studies showed that textiles are likely to be good breeding grounds for microorganisms, it had to be discussed if the number of curtains, towels, and rugs could be reduced (Ohl et al., 2012, Trillis et al., 2008). The bed sheets are changed on a regular basis.

As Park estimated that dengue fever is the third most frequent reason for hospitalization and mortality among children in India (Park, 1979 cited in Raheel et al., 2010), safety measures towards the transmission by mosquitos were checked. There were no mosquito screens on the windows and no nets around the beds.

The transmission of highly infectious diseases can be prevented by separating risky patients. The existence of isolation rooms was checked and confirmed.

To fulfill the demands of a sterile area for an operating theatre, the room partitioning has to provide the possibility for proper clothes and shoe change. A changing room exists and therefore the basic measure for reducing the number of pathogens, but the partitioning does not fulfill the sterile requirements.

The drinking water as an important source of bacteria (Suthar et al., 2009) was checked during our stay. Although the water treatment of the hospital fulfills a high

standard and the staff neglected the occurrence of diarrhea, the water was positive for multiple bacterial contamination.

g. Case of Emergency

The possibility of an emergency evacuation in case of fire is given because the hospital is built barrier-free. There is a fixed proceeding for patient transfer in case of an emergency, which exceeds the treatment options of the hospital. A defibrillator is not available, but until now, there was no demand for it.

2. Behavior and Knowledge

a. Hand Hygiene

Within the interviews, the indication for hand hygiene was queried and the common knowledge was that the indication is given before and after invasive procedures. “The 5 moments of hand hygiene” of the WHO (2006b) are not an integrated component of the daily work neither in mind nor in performance. Within the interviews, insecurity about the indication for alcoholic based disinfection was revealed. The general opinion was that soap use is as effective or even more effective as the usage of disinfectant. Although masks are available, the usage is not performed systematically. Furthermore, there was a discrepancy between statements within the interview that hand hygiene is performed frequently and the fact that no disinfectant was available at the workplace.

b. Infectious Material

Invasive procedures like drawing blood were observed and the safety demands of the WHO regarding disinfection, glove use and the availability of a post-exposure prophylaxis were fulfilled properly (World Health Organization, 2007, World Health Organization, 2010).

Although blood is recognized as potentially infectious, there was a lack of awareness regarding the infectivity of other body fluids such as urine or salivary aerosols. The use of gloves to transport urinary bottles was uncommon and the housekeepers did not wear gloves on our first day but changed this behavior during our observation the next days. Certain utensils of daily use such as the thermometer were disinfected every day, but the use of multidose vials and the reuse of syringes was part of the routine. Several case studies show the risk of hepatitis B (Kidd-

Ljunggren et al., 1999) and C transmission (Krause et al., 2003, Germain et al., 2005, Widell et al., 1999) due to the usage of multidose vials. The Centers for Disease Control and Prevention recommends that multidose vials should be dedicated to single-patient use (Centers for Disease Control and Prevention, 2010). The reuse of syringes is a common issue in India (see chapter “2.3.5. Safety Culture”, p.15). Claude et al. tested the technique of reusing syringes, while changing the needle as “the only part that can be contaminated” and blood contamination was revealed. This may be contributed to negative pressure inside of the syringes, when removing the needle. (Trépanier et al., 1990, p. 158) Although the reuse in Kakkaveri was restricted to multiple use on one patient, the combination of multidose vials and reuse of syringes was rated as a potential risk for cross-infection by the Austrian team.

The labeling of maintained equipment, e.g. humidifier with water for ventilation, was deficient.

c. Patient Education and Behavior

The information of this chapter is based on observations and interviews with the staff, not with the patients. The patients’ knowledge about transmission of infectious diseases is very fragmentary. On the one hand, there is an ambivalent fear of getting infected. This leads to the demand to separate the dining rooms of HIV positive and HIV negative patients and to separate the laundry, although this is no official recommendation. Centers for Disease Control and Prevention even advise refraining from sorting laundry before washing, because it puts the personnel at the risk of contamination due prolonged exposure (Centers for Disease Control and Prevention, 2015). On the other hand, asking the patients to take protective measures as masks might lead to a bad impression. He/she then thinks this hospital must be very dangerous if it is necessary to wear masks etc. and could be frightened away. The description of Landefeld et al. that patients want to receive an injection was confirmed by the staff (Landefeld et al., 2015). It is even a common phrase to say, “I am going to get an injection” instead of saying “I am going to the hospital”. This ambivalence also shows in drinking hygiene behavior. The observation showed that the patients did not have any concerns about using one cup for the whole ward. Of course, it has to be mentioned, that no staff member removed the single cup on

the water tank at the ward. This indirect approval is also a missed change for patient education.

The wearing of shoes is also not very common for patients. The isolation of patients also showed compliance problems because many people are accompanied by a “bystander”, long-term visitors, who do not follow isolation rules.

d. Error Management

There are many staff meetings and it was said to be no problem to bring up problems and failures. The atmosphere of punishment as mentioned by Landefeld et al. was not confirmed (Landefeld et al., 2015). To avoid blaming of individuals is one important step towards the prevention of future errors (Kohn et al., 2000). Therefore, the error management of the SFS Health Centre is valued as important achievement towards patient safety. Furthermore, the patients are asked to give feedback at the end of the stay to evaluate problems.

4.2.3. Step by Step Proceed: Plan-Do-Check-Act

This chapter includes the results of step 5, 6, 7 and 8 from finding solutions to final decision and long-term feedback (table 3).

The first recommendations were gained by a panel discussion with both teams. Afterwards the first interventions were conducted and checked. Thereby, information about the success and barrier towards implementation could be collected and findings were integrated into the final discussion. These steps follow the structure of “plan”, “do” and “check” of the PDCA.

Afterward, it was possible to go on with the prioritization and to perform the final decision, which completed the implementation process of this project.

A) PDCA: Plan

The first results of the observation and interview were discussed within a panel and solutions were searched. It was tried to keep it short to avoid getting lost in detail. Therefore, the three main objectives were focused on (information flow, responsibility and patient safety) and examples for each field were given. The Austrian team also gave positive feedback about areas, where the checklist criteria were fulfilled or even surpassed (see chapter 2.2.2). The following chapters I-III will focus on fields in which certain requirements were lacking.

I. Information Flow

Wristbands for identification were recommended by the Austrian team, but the opinion about the necessity was not shared by the Indian team: On the one hand, the number of patients which are treated was said to be too small to need these tools. On the other hand, the function of the wristband was seen to be fulfilled by the bystanders of the patients.

II. Responsibility

The lacking administration of emergency medication and distribution of cleaning the cabinets and medical devices was addressed by the Austrian team. Although these problems were said to be recognized already, there was less understanding of the necessity of change by the entire Indian team.

Because emergency situations were said to be rare, the motivation for a change was small. The necessity was judged differently by the nurses (necessity = high) and by higher hierarchies as doctors and the chief of the nurses (necessity = low). Arguments by the Austrian team that “every emergency counts” did not convince.

The issue of cleaning of the cabinets and medical devices was recognized before, but there was a misunderstanding about who is responsible for the cleaning. The conception of urgency was not high enough to solve this problem before, but within this discussion, first conversation about future task distribution started.

III. Patient Safety and Hygiene

a. Recapping:

The safety of different procedures was discussed. Most of the needle stick injuries in Indian hospitals occur during recapping (Sharma et al., 2010). The WHO recommends avoiding recapping, whenever possible (World Health Organization, 2010). This information was new to the Indian team and a systematic failure due to official instructions. The resume was, that “no recapping” is now a rule for every staff member.

b. Needle Disposal at the Nurses’ Station:

Despite the recapping of needles, the unsafe collection and disposal is the most common cause for needle stick injuries (World Health Organization, 2003). These include handling the needle and collision with other people (Sharma et al., 2010). Long distance to the garbage can lead to a risk accumulation due to extended exposure. Portable sharps disposal container were recommended by the Austrian team, which were completely unknown to the Indian team. Although the general response was positive, there was still some uncertainty about the necessity of this implementation.

c. Water for the Patients:

Patients should be prevented from sharing cups. The potential exchange of saliva enables the transmission of droplet associated infections as cytomegalovirus and oral bacteria contributing to respiratory infections (Adler, 1988, Villarejos et al., 1974, Raghavendran et al., 2007). Minding the high proportion of immune-compromised HIV and TB patients at the hospital, who are vulnerable for pneumonia

and cytomegaly this risk was stated to be untenable by the Austrian team. The cup sharing was firstly dismissed by the Indian team as “unproblematic because the water is dowsed into the mouth without touching the cup”, which was disproved by observation. In the end, the need of change was accepted, and the following solution formulated: Water bottles will be available at the room for every patient and left cups at the ward will be removed.

d. Hand Hygiene:

The preference of soap towards disinfectant was discussed. The WHO reviewed different studies about the use of plain soap in healthcare and concluded that this practice often fails to remove pathogens and is even suspected to lead to a paradoxical increase of microorganisms due to skin irritation and lesions. There is a strong recommendation towards disinfectant or antibacterial soap, dependent on the indication. Nevertheless the usage of plain soap is a major progress over the washing with water alone (World Health Organization, 2009b), which must not be underestimated. Because struggles about the indication of disinfectant appeared, a training session about hand hygiene was planned for the next day.

B) PDCA: Do

Within one day staff members were informed about the new rules of “no-recapping” and “no cups at the ward” and water bottles were provided. First information about the costs of portable disposal containers was collected.

The training session was conducted and the lack of knowledge concerning the indications of hand hygiene as recommended by the WHO was confirmed (World Health Organization, 2006b). The concept of “visible dirty hands” was discussed and the advantages and disadvantages of soap and disinfectant (World Health Organization, 2009b, p. 78). The knowledge about how to perform a proper hand disinfectant was tested and well-known (World Health Organization, 2009b, p.155).

C) PDCA: Check

The observation showed successful implementation of the no-recapping rule. Water bottles were distributed and there were no more cups in the hallways of the wards.

The plans for purchasing portable disposal containers could not be implemented during our stay, because of the shortness of time. Despite the fact that disinfectant

solution was handed out and the observation of nurses carrying the bottles around was made, the disinfection was performed sporadically. The “five moments of hand hygiene” were never followed completely (World Health Organization, 2006b), but the general impression was that the engagement of the staff was high and that habits need more time to change. One big struggle towards this topic was the fact, that there was some resistance of the head of the nurses against handing out disinfectant. The background circumstances of this barrier could not be figured out during the stay, but there was a general opinion of the upper position employees that the nurses would not use the disinfectant.

D) PDCA: Act

The findings of the chapter 4.2.2. were prioritized by the hazard scoring matrix (VA National Center for Patient Safety, 2014) and presented within a panel discussion with members of the different job fields and the head of the DTMC Trust.

The suggestions were divided into the four big topics: general hygiene, patient safety, staff safety and surgical safety. Special attention was given to keep the balance between positive and negative findings. The existing basis was put on the bottom of the pyramid, the short-term goals are placed in the middle and the long-term goals on the top. The short-term suggestions signed with “✓” were implemented immediately, “→” is planned to be implemented or further discussion and “X” were declined by the audience.

A) General Hygiene

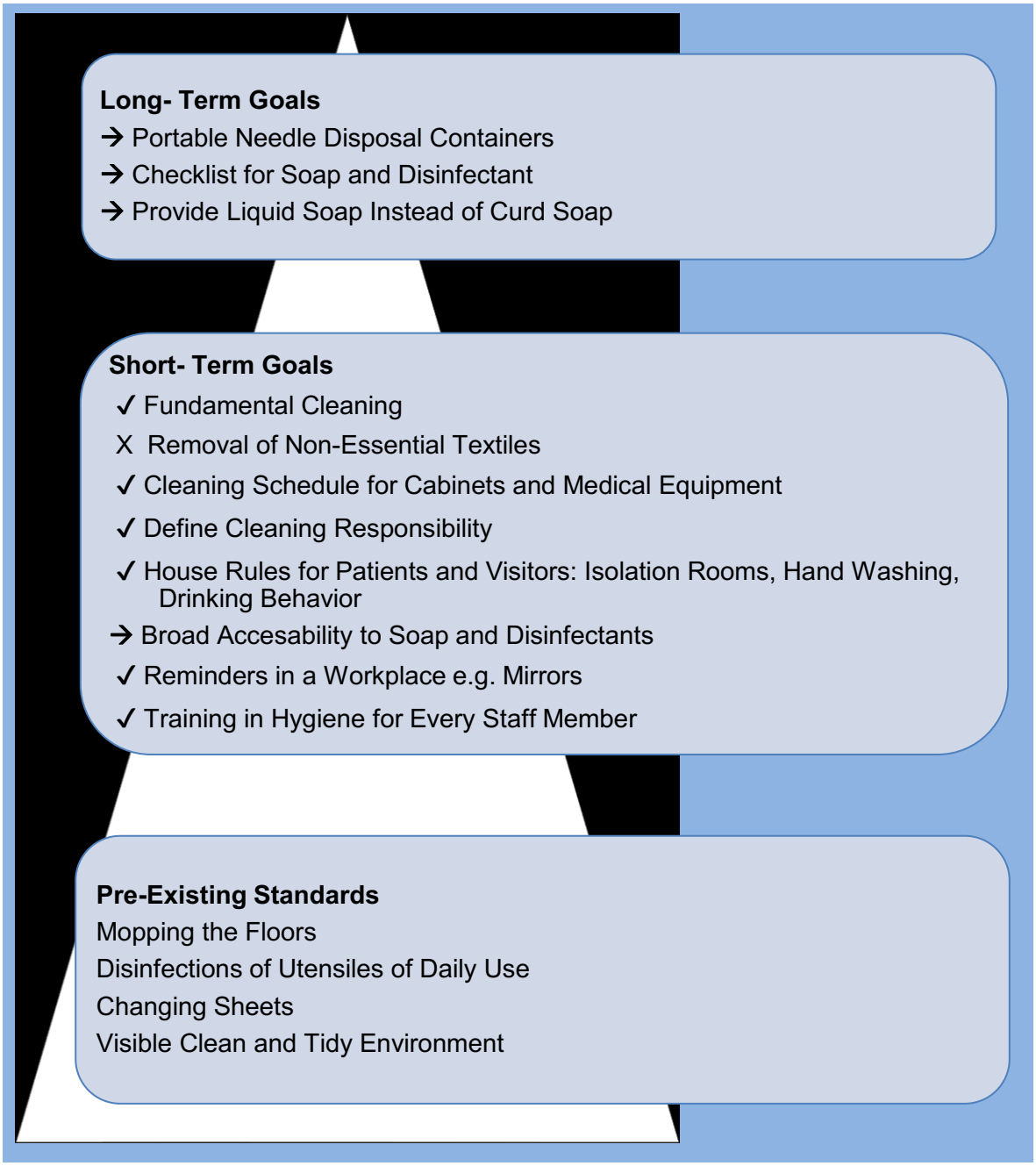

Figure 6 Suggestions concerning general hygiene

The removal of non-essential textiles (figure 6) was declined because the necessity of the existing textiles is given from the patients' side. Curtains for privacy instead of closing doors at the outpatient offer the advantage that family members can hear the patient during his examination. If there was a door, the separation would not be accepted. Rugs in front of every bathroom are also "essential" because many patients are not used to toilets (see chapter 2.3.) and used to shower afterward. If there is no rug, the patients will walk with wet feet through the room and spread the

water. The following suggestion to provide a towel for patients was declined because of costs. The implementation of paper towels was declined because the amount of waste would be very high. The recommendation to integrate the washing times of the curtains, towels, and rugs into the new cleaning schedule was accepted.

Although the need of broad accessibility to soap and disinfectant (figure 6) was seen, the financing is unclear at the moment and will be discussed between the head of the DTMC Trust and the stakeholders. The second point against fully equipped washing facilities with disinfectant and soap was the concern that patients could think they are allowed to take it home or that children could swallow the detergents.

The financing of needle disposal containers and liquid soap instead of curd soap (figure 6) has to be discussed with the stakeholders.

Checklist for the refill of soap and disinfectant (figure 6) will be implemented afterward, but the Indian team was not completely convinced of the importance of this bureaucratic step.

B) Patient Safety

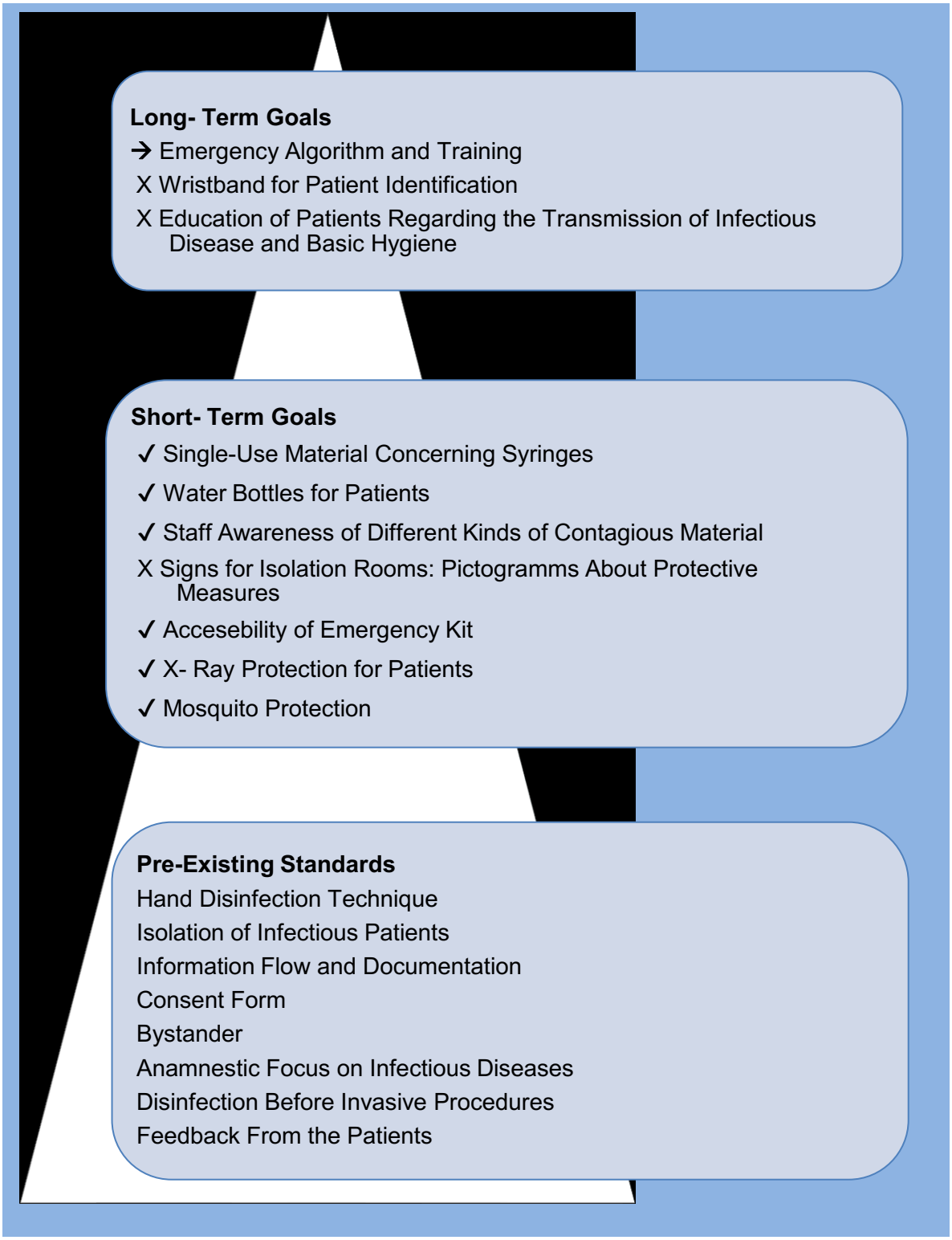

Figure 7 Suggestions concerning patient safety

Signs regarding protective measures (figure 7) were declined because of concerns due to privacy policy and stigmatization.

Wristbands were rejected (figure 7) because the necessity was not seen: Every staff member is familiar with the patients and it was estimated that patients would complain about carrying a wristband. The argumentation that a patient could be new at the ward and was getting unconscious was seen as unlikely to happen because the hospital has no focus on unstable patients.

The same opinion was expressed concerning emergency training and this intervention was determined as low priority and future task.

The education of the patients concerning hygiene and disease transmission (figure 7) was assessed as a critical task, which could frighten off patients.

C) Staff Safety

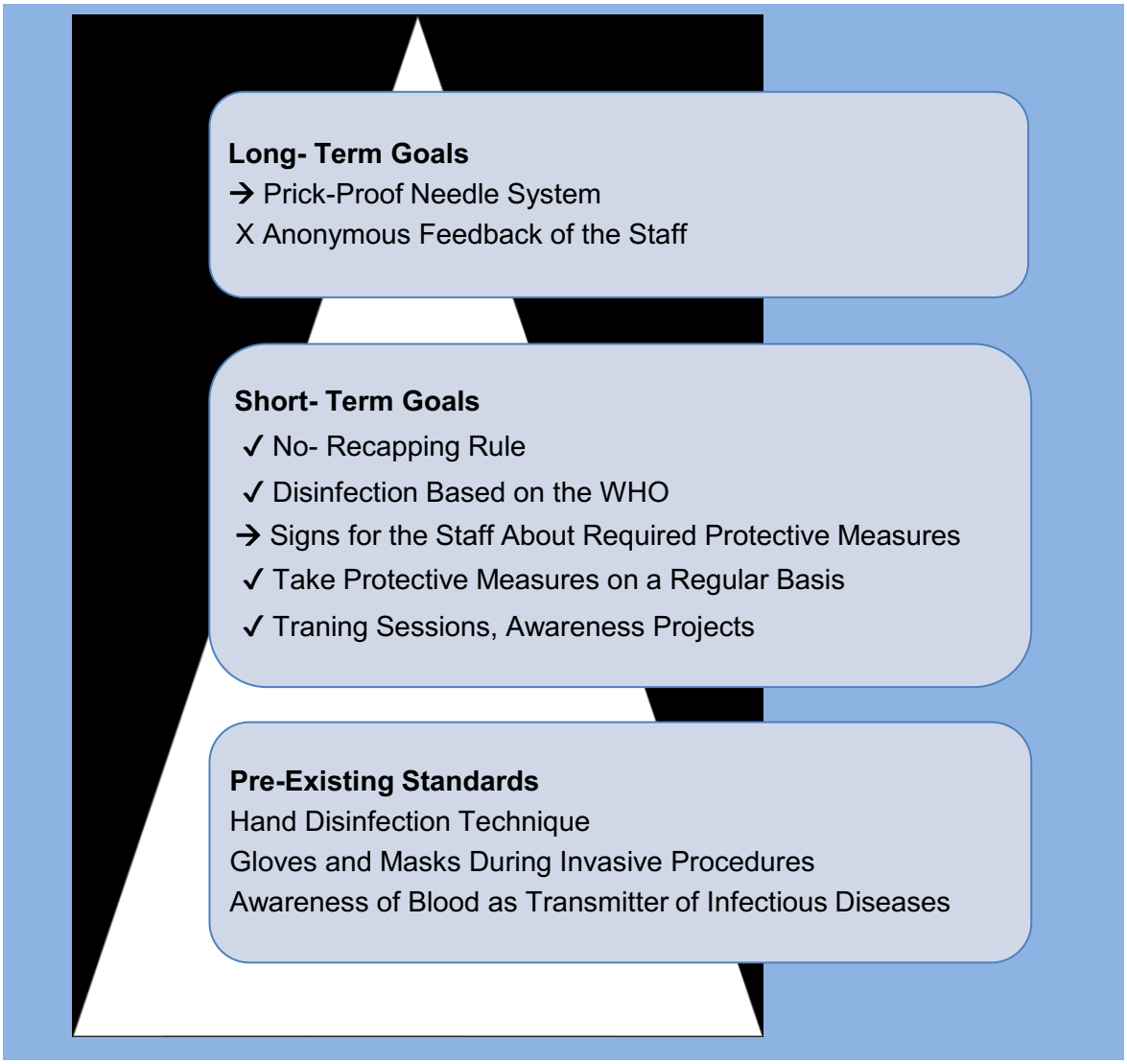

Figure 8 Suggestions concerning staff safety

The signs for the staff about protective measures (figure 8), as already mentioned regarding patient safety, was discussed again from the staff safety's point of view, and the same concerns were mentioned again. The agreement was to send further concrete suggestions for designing pictograms within the final report and re-discuss the implementation.

The prick-proof needle system (figure 8) was ranked within different interventions for needle safety to be the last one after eliminating recapping and needle disposal container.

The necessity of anonymous feedback (figure 8) was not understood, because the hierarchal structures are seen as flat.

D) Surgical Safety

Figure 9 Suggestions concerning surgical safety

Except for the defibrillator (figure 9), for which the financing of costs has to be planned and thus the implementation had to be postponed, all other “surgical safety” suggestions were accepted immediately.

5. Results II: Analytic Part

5.1. Success and Failures

36 suggestions were made and nearly 64% were accepted immediately. Further 22% are either determined as future intervention or skipped for later re-evaluation. 14% of the recommendations were declined.

The late feedback showed an increased success rate of almost 92%. “Education of patients regarding the transmission of infectious disease and basic hygiene” and the “removal of non-essential textiles” were implemented although they were declined previously.

5.2. Interviews “Factors Towards Improvement”

The results of this chapter are in the order by the frequency they were mentioned within the 12 interviews.

- The most frequently mentioned barrier towards improvement was the availability of equipment e.g. lacking disinfectant (9/12).
- Another mentioned problem was resistance within the staff against change, because of the requirement of adopting new structures and feared association with additional work e.g. regarding new checklists (8/12).
- Moreover, a frequently mentioned factor towards improvement was the behavior and compliance of the patient. An often given example was the determination of house rules which may lead to avoidance of the hospital (8/12).
- A further factor towards changes is the opinion that people involved think interventions are not necessary because it works the way it is. Examples were the awareness of contagious material and taking protective measurements (7/12).
- The lack of knowledge was also said to be a problem because recent guidelines or certain new tools are unknown. Furthermore, some rules are not understood by every staff member (5/12).
- The disagreement between the different hierarchies was mentioned in meaning of certain changings which are desired by one hierarchical level, but not taken seriously by another (5/12).

- The last barrier towards improvement was the circumstance that ideas exist, but the trigger for conducting the implementation and therefore the motivation are missing (4/12).

5.3. Correlation Between the Seven Collected Factors and the Success of Implementation

The seven collected factors of chapter 5.2. were checked on their appearance during the final decision (table 3) measured by their outcome concerning implementation (appendix II).

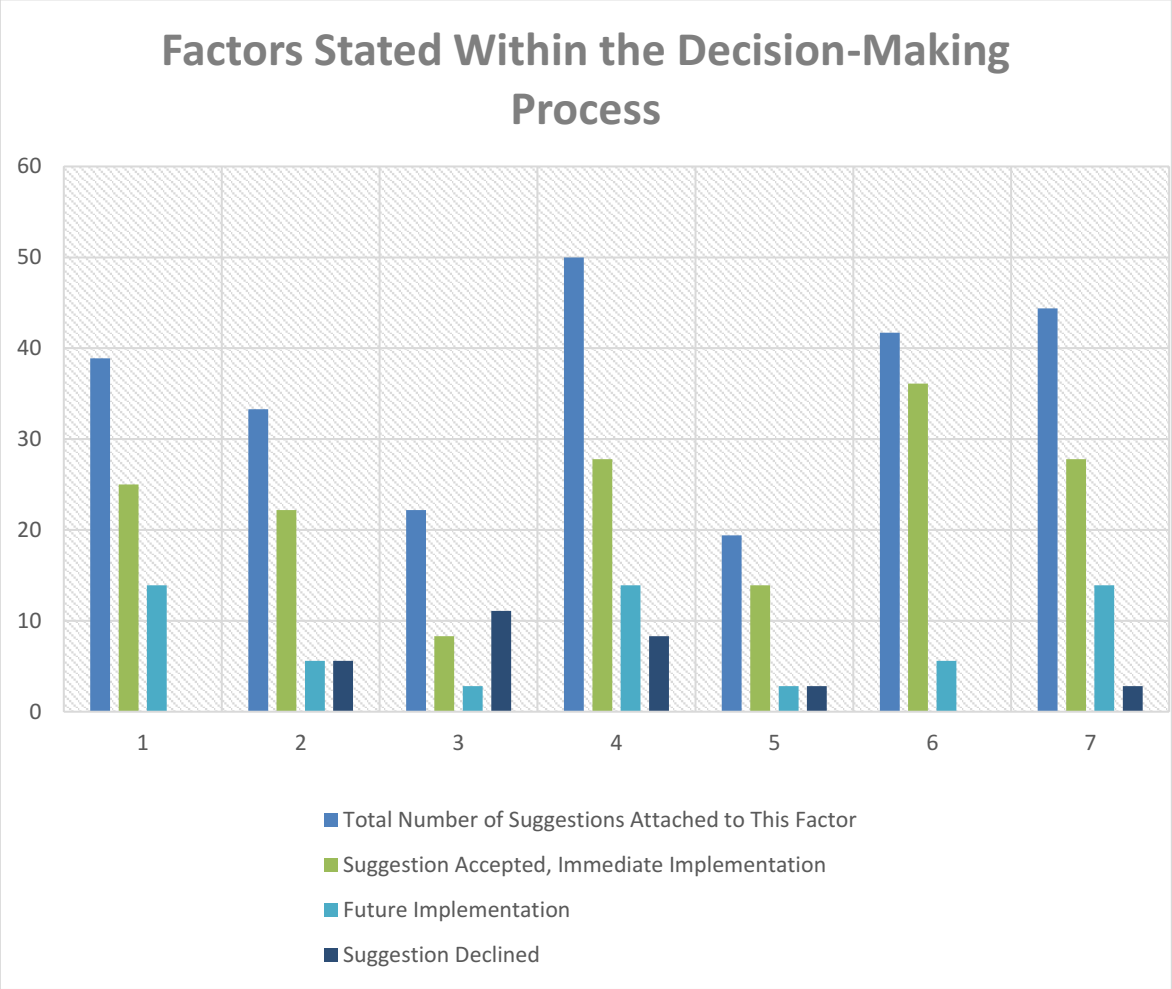

Figure 10 Percentages of factors stated within the decision-making process sorted by outcome 1= missing equipment, 2= staff resistance, 3= patient resistance, 4= low opinion about necessity, 5= disagreement between hierarchical levels, 6= missing trigger, 7= lack of knowledge

As you can see in figure 10, the factor of “low opinion about necessity” was attached to 50 % of the total suggestions. The most frequent reason to decline a suggestion was the factor of “patient resistance”, followed by the “low opinion of necessity” and “staff resistance”. The factor of the “missing trigger” was the leading characteristic

of the accepted factors with a proportion of 41,7%. No suggestion of the group “missing trigger” and “missing equipment” was declined. The factors of the “low opinion of necessity”, “lack of knowledge” and “missing equipment” showed the largest proportion of the successful decision group “future implementation”. To find out if these factors have a significant effect on the outcome of the decisions, it is important to take a look at the correlation factor (table 7 and figure 11).

	Correlation between the decision and appearance of the certain factor	P-Value
Missing Trigger	0,339	0,043*
Missing Equipment	0,32	0,057
Lack of Knowledge	0,198	0,248
Disagreement Between Hierarchies	-0,006	0,974
Staff Resistance	-0,057	0,742
Low Opinion on Necessity	-0,08	0,641
Patient Resistance	-0,558	0,000*

Table 7 Results of Spearman Correlation, statistically significant values = *

Results with a statistical significance were marked with a “*” in table 7 and darkened in figure 11. Four factors were observed to be negative factors towards improvement with a negative correlation factor (figure 11): the “resistance of staff”, “resistance of patients”, “low opinion of necessity”, and “disagreement within hierarchies”. The negative effect size of the “patient resistance” measured with the help of Cohen is ‘large’ (Cohen, 1988) and showed a high statistical significant value (p =0,001) (table 7). The negative correlation factor of “low opinion on necessity”, “resistance staff” and “disagreement between hierarchies” is beneath the effect size “small” and not statistical significant (table 7).

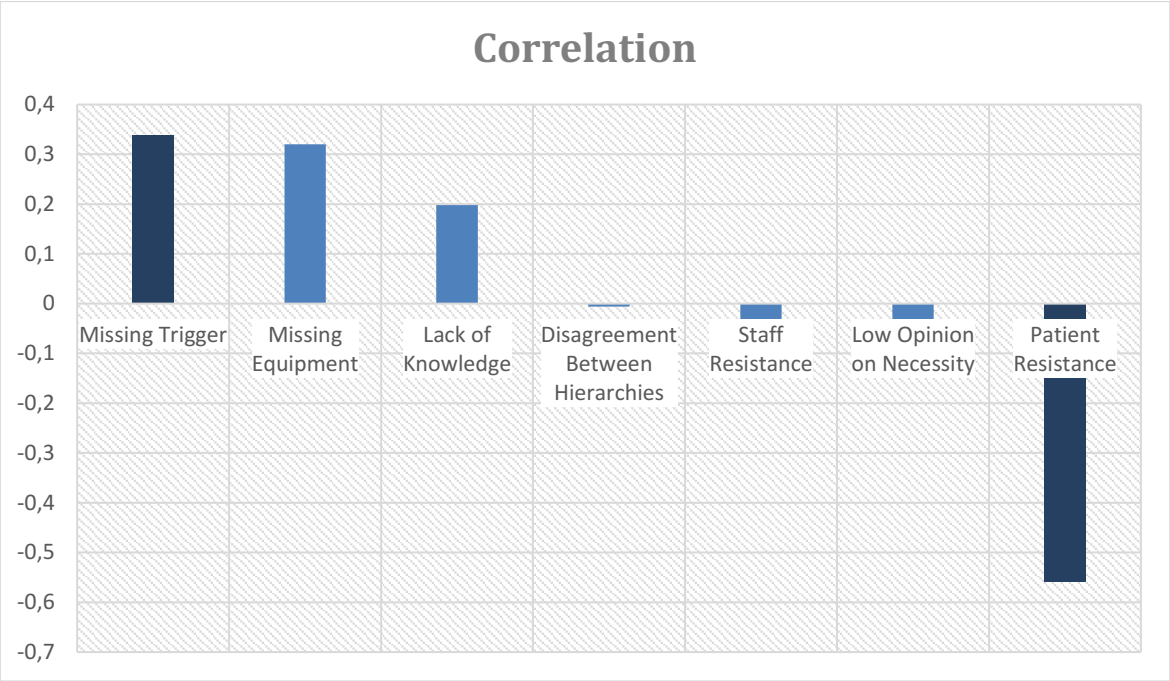

Figure 11 Results of Spearman Correlation

Three other factors which were mentioned in the interview, including the most frequent one, were not confirmed to have a negative impact (figure 11): the “missing equipment”, “missing trigger” and “lack of knowledge”.

In our case, these factors were even found to have a positive correlation towards success (figure 7). The effect size of the factors “missing equipment” and “missing trigger” is medium (table 7). The positive correlation of “missing trigger” showed a statistically significant result ($p = 0,043$) (table 7). The “lack of knowledge” has a small positive effect on the outcome (table 7).

6. Discussion

6.1. General Project Running

The expectation of this project to raise awareness for patient safety as an important part of quality management was surpassed by the implementation of 30 suggestions, with a success rate of almost 92%. Unfortunately, the difficulty of the planning process and conduction also surpassed the expected extend, because of struggles in finding practical oriented guidelines which include essential parts of quality management and patient safety at a realistic level. Many different guidelines and research results had to be consulted and, in the end, it was necessary to build up an own checklist, though it would have been preferred to use existing checklists.

The beginning on-site revealed some underestimated problems regarding reservation concerning the act of observation. These struggles may on the one hand be contributed to missed communication at the beginning of the project, on the other hand, be caused by the act of observation itself, to which the subject wants to react to (Franke and Kaul, 1978).

The general atmosphere between the teams was ambivalent extending from enthusiastic happiness about our presence to a diffuse kind of skepticism. Some of the employees, especially hierarchical-lower-positioned, brought up much motivation and engagement in showing their work on the one hand and insecurity concerning what they are allowed to show us and maybe a little bit fear of embarrassing themselves. Other staff members, particularly employees with more power, showed themselves very open for recommendations and agreed on many findings but tried to withhold information at the same time. Except for the head of the DTMC, there was less information given about the root causes of findings. The Austrian team, in turn, struggled with the effort of how to create a working atmosphere at eye level. The fear of unintentional paternalism led to uncertainty about the right level of directness concerning suggestions and perhaps inefficient communication. All these difficulties may be caused by the situation itself: a short stay and a foreign team with a different cultural background.

The cultural dimensions of Hofstede make it possible to compare the Austrian and the Indian culture and to understand appeared communication problems. The

Austrian “power distance index” is extremely opposite to the Indian value (Austrian Ranking: 76, Indian Ranking: 17-18 of 76 countries). This measure stands for “the extent to which the less powerful members of institutions and organizations within a country expect and accept that power is distributed unequally (Hofstede et al., 2010, p.61).” Countries with a high value as Austria are characterized by unafraid employees, no autocratic structures and decision making by discussion. It is a typical characteristic of wealthier countries. India, with it’s low “power distance index”, tends to have employees which are afraid of disagreeing with their boss. Structures are paternalistic and there is less request for discussion and worker participation, even from the staff side itself. These different characteristics show a likelihood of tensions. The Austrian team tried to involve all staff members, to build an atmosphere without hierarchies. This approach of active participation could possibly have led to overstraining the employees. Within the performed discussions a demand for clear recommendations instead of debating was brought up by the Indian team, but the Austrian team held on to the course of joint elaboration.

The next value of Hofstede, which will be compared, is the “uncertainty avoidance index”. Austria shows a high value of 70, while India reaches an Index of 40. The “uncertainty avoidance index” is defined as “the extent to which the members of a culture feel threatened by ambiguous or unknown situations (Hofstede et al., 2010, p.191).” Countries with a high value as Austria are in the need of rules, even if they do not work. The believing in experts and technical solutions is high and every process must be specified. In contrast, Indian people attach great importance to common sense, avoid rules whenever possible and have a higher tolerance for chaos. Countries with a low index are better in inventing than implementation. This of course directly interacts with the project. It may be, in turn, an argument for the Austrian approach to avoid the implementation of already fixed rules “from above” and use discussion and collaborative, own solution finding. Another good proceeding for this challenge might be one of the factors which were gained within the analytical part of this thesis: the missing trigger. Once again it has to be emphasized how important it is to build upon already “invented” ideas instead of enforcing guidelines.

Another factor of Hofstede (2010) showing widely diverging values for Austria and India is the “indulgence versus restraint”. It describes “a tendency to allow relatively

free gratification of basic and natural human desires related to enjoying life and having fun (Hofstede et al., 2010, p.281).” Austria with a high value of 63 is characterized by a feeling of personal life control, optimism, and less moral discipline. A collaboration between Austria and a country like India (low “indulgence versus restraint” index: 26) could offer the opportunity to increase the engagement of people and getting away from “having no control for what happens”. But of course, it is not possible to change attitudes in this short time and it is possible that this optimistic mood of the Austrian team was seen as naivety by the Indian team and maybe even decreased the credibility. The Austrian team tried to appeal to the Indian ethical responsibility (a factor which is commonly high in countries with a low index) to convince the staff of the necessity of patient safety implementations. This approach could be one of the important steps towards the success rate of 92%. Unfortunately, the overall communication showed a different result. After the departure of the Austrian team the correspondence lacked. The target date for feedback was surpassed and email correspondence progressed slowly. This may be a sign for cultural tensions, which could be bridged during the stay, but not be removed in long-term. Nevertheless, the cooperation between the DTMC Trust and GHD will be continued and precisely because of this misunderstanding, projects as presented are such an important chance to overcome cultural differences and to enhance cultural exchange.

6.2. Low Opinion About the Necessity

As the factor of “low opinion about necessity” was attached to 50 % of the total suggestions (appendix III) it is rated as the most important barrier towards previous improvement. This factor could be the counterpart to the “lack of awareness”, a known problem in India, which was discussed in chapter 2.3.3..

The opinion about the necessity of all checklists (surgical safety checklist, regular maintenance of all equipment, checklist for soap and disinfectant) was low (appendix II). The finding of the underuse of checklist, does fit worldwide struggles towards this safety measurement. Borchard et al. found that the compliance concerning the usage of checklists varies between 12-100% (mean: 75%) (Borchard et al., 2012). Vivekanantham et al. called the decreased overall compliance regarding checklists “checklist fatigue”, which is caused by an overuse of checklists

(Vivekanantham et al., 2014). Therefore, the number of recommended checklists was kept small from the beginning to avoid overstraining. Despite the low opinion about this tool all the brought-up lists were accepted in the final discussion. Thus, the factor “low opinion about necessity” had no correlation towards the success of a project and may be solvable by explanation and persuasion. Therefrom, it is important to recognize this struggle within the planning process and to react towards it.

6.3. The Resistance of Staff vs. Resistance of the Patient

The usage of wristbands was declined inter alia because the patient may have a negative opinion towards wearing a sign or number. This feared conflict with the dignity of the patient was also described by Andrew F. Smith et al., who conducted an interview to check this hypothesis. The survey showed that the magnitude of patients even had a positive attitude towards wristband identification, contrary to the expectation of the staff (Smith et al., 2011). Because this study was conducted in the UK it would be helpful to perform an equal survey in India, to exclude the error of cultural diversity concerning this topic. If this rejection happened without patient complain the resistance would be due to the staff, not the patient. The non-statistically significant tendency seen within the analysis that the resistance of the staff has a negative influence on the outcome could be higher than measured. To avoid this bias, communication problems between the patients and the staff have to be solved before a new evaluation can be performed. Zwick et al found out that staff resistance is more likely to occur, if the benefits of the intervention may not be gained by the staff (Zwick, 2002) and therefore it is important to explain the intersections between patient and staff safety to the employees.

The late feedback shows that two suggestions which were attached to the factor “patient resistance” were implemented afterward. This may be a sign that this barrier can be removed as soon as it is recognized and communication problems are solved.

6.4. Disagreement Between Hierarchies

There was a lack of accessibility concerning emergency medication and a defibrillator, which coincides with the low awareness about basic life support among nursing, dental and medical students in South India found by Aroor et al. Aroor et

al. (2014). The interviews about solution towards this problem showed that although the nurses were aware of the need for regular training, some of the doctors did not see the need for emergency training for nurses. The same problem occurred regarding the accessibility of disinfectant. Some of the doctors did not see the necessity to provide disinfectant for the nurses. This disagreement between hierarchies did not show a correlation towards the success of an implementation within the performed analysis. This may be contributed to the fact that the decision about implementation was made within a team discussion with representatives of the different job fields. Maybe this problem was already solved through this proceeding. Although this factor did not have a negative outcome in this given setting, it has to be considered as a barrier towards improvement in the daily routine. This suspicion is confirmed by the fact, that this subject was found to be attached to 19,4 % of the suggestions (appendix III) and therefore, may be a reason why these interventions were not implemented before. More interviews or evaluation via questionnaire would be necessary to answer this question.

6.5. The Missing Equipment

The lack of resources was a positive factor in this survey, but this finding is flawed concerning the decision making process, because it was part of the project to support the financing of the needed utensils. Despite the factor of “missing knowledge” this characterization was attached to the majority of successful future implementations and shows that although it has a positive impact on accepting an idea, the realization may be difficult and therefore postponed until later. The fact that 38,9 % of the total suggestions were positive towards this characteristic (appendix III) also shows that it plays an important role as a barrier towards improvement, because it impeded these interventions in the past.

6.6. Lack of Knowledge

The lack of knowledge as a factor for safety is a present parameter in today’s literature (see chapter 2.3.5.) and occurred as an important factor for taking protective measurement in India (Kermode et al., 2005b, Pathak et al., 2013a). During the training sessions of this project the knowledge towards the right disinfection technique of the nurses was graded as excellent, but insecurity about the right indication appeared. Because the performance of the disinfection was still

observed to be rare after distribution of disinfectant and training, it was presumed to be a multifactorial problem of lack of awareness, compliance, missing knowledge and equipment, which has to be further assessed. Nair et al. performed a study concerning hand hygiene among medical and nursing students in India and found out that only 9% had good knowledge and the majority had a poor attitude towards it (Nair et al., 2014). But before a cause analysis towards missing hand hygiene can start, the first step will be to provide the right equipment. During this project, the lack of knowledge was detected to be the second frequently attached characteristic of the total suggestions and thus it is an important barrier towards improvement. Apart from that, it was also found to have a not statistically significant positive impact on the success of a suggestion. Although the first observation did not show major changes, the attitude towards these suggestions was positive. Therefore, it may be a good starting point for projects to find problems, which are based on a lack of knowledge.

6.7. Missing Trigger

If a problem was already recognized by the staff and has been not implemented yet because of missing motivation or trigger, these suggestions showed a good succession rate within the project. The effect size of the positive correlation was medium and the result statistical significant ($p= 0.043$). This positive effect matches to the second and third principle of the International Organization for Standardization: leadership and engagement of people. The goals of the leadership were already defined before, which is an important part of quality management. The missing point the “engagement of people” as a positive performance factor might be triggered by the Austrian team. (International Organization for Standardization, 2015)

With 41,7 % of the total suggestion fulfilling this characteristic this factor is the third important barrier towards the previous improvement (appendix III).

6.8. Special Findings in Context to India

6.8.1. Drug Administration

The finding that drugs are restricted to be distributed only in combination with a prescription is a major step towards patient safety. The usage of antibiotics without a prescription is a known problem in India (Saradamma et al., 2000) and a serious issue considering the rising amount of resistant bacteria (Raghunath, 2008). The finding of Landefeld et al. regarding patient safety issues because of uncontrolled drug dosage was therefore not confirmed, because the hospital's pharmacy is responsible for checking the right prescription and distribution (Landefeld et al., 2015).

6.8.2. Unsafe Injections

Minding the fact that almost 77% of the given injections in India are estimated to be unsafe, it was no surprise to find struggles concerning this topic (Pandit and Choudhary, 2008). But while recapping had only one barrier to face - the "missing knowledge" - the reuse of syringes showed five different obstacles (appendix II). It shares this number of impediments ≥ 5 with the interventions "disinfection based on WHO", "take protective measures" and "broad accessibility of disinfectant and soap". All these interventions are necessary for a safe injection. If the reuse of syringes puts the patient in danger, as long as one syringes is dedicated to one patient, is not easy answerable. Most of the studies deal with the cross-infection caused by the reuse on different patients and there had to be an evaluation of the infection rate of the particular hospital to investigate mix up events. If the rules are followed strictly and as long as syringes are exchanged regularly, it may be possible to consider studies about the reuse on single patients in context to insulin injections. Several surveys were performed to evaluate the risk of bacterial infection in this setting, because it's a typical area for reutilization of equipment. Border et al. analyzed the injections behavior of 254 patients, who reused plastic syringes for an average of 1.5 days and found minimal growth of bacteria in 11% of the cultures (Borders et al., 1984). He also found out that only 2% of the participants showed a local sensitivity reaction and that no bacterial growth was found in follow- up quantitative cultures (Borders et al., 1984). Comparing this survey to our setting in South India it must be paid attention on the fact that the time and the temperature

differs because the length of reuse in Kakkaveri was dependent on the duration of stay and used syringes were not stored in a refrigerator. Furthermore, case studies as e.g. conducted by Paily described the occurrence of complications as a perinephric abscess in context to syringe reuse (Paily, 2004). Additionally, it is not possible to conclude on the bacterial growth in other drugs without further research. Drugs as insulin may have an bacteriostatic effect on the growth (Schuler et al., 1992), which of course influences the outcome of such trials.

During the discussion of implementing single use material, the most frequently mentioned barrier was the estimation that it does not harm the patient to reuse material as long as there is no mix-up between the patients. Minding the fact that immunocompromised patients are treated in the SFS and the effort of decreasing near-miss events lead to the decision of eliminating the reuse of syringes. The possible near miss of a mix-up was also discussed and although there are safety measures to avoid this error, it was valued as unnecessary threat to the patient. Another reason for the reuse of syringes is that there is a lot of struggle concerning the amount of disposal. The fee for waste disposal is a relevant burden on the budget of the SFS Health Centre. The misuse of single-use equipment was solved in Kakkaveri, because the risks of reuse were explained and a support for the financing was offered. The disagreement between the hierarchies had to be solved by panel discussion with the head of the DTMC Trust.

6.8.3. Informed Consent

The concept of the informed consent is part of the daily routine and every admission includes a consent form which is available in English and Tamil. This is by no means a matter considering a study of Yousuf R M et al., who found the tendency within Indian doctors to disclose medical information and disrespect the autonomy of the patients (Yousuf et al., 2007).

6.8.4. Bystander

The concept of having a bystander, a relative or friend of the patient who joins the admission, seems to be an Indian phenomenon, which is not present in today's literature (N.U., 2011). Therefore, it will not be further analyzed but mentioned as a tool for patient registration in India. The bystander is able to identify the patient, which is used as an alternative to wristbands.

6.9. Limitations

The limitation towards the descriptive part of the study is the subjectivity of observation, which cannot be eliminated, especially if the observer is part of the observed project. Because only one project was observed and discussed it limits itself towards a descriptive case study. Despite the planning time of a half a year, the conduction on-site was short and long-term feedback was not received, which limits the amount of information.

The analytic part of the thesis is limited by the sample number of 36 decisions and 12 Interviews. The gained information quality during the interviews is dependent on the subjectivity of the respondents and, because it was a semi-structured interview, the experience of the interviewer. There were also some problems concerning communication because the interviews were performed in English and some of the staff member only spoke Tamil (especially the housekeepers). If necessary, translation by locals was performed, but it was still difficult to check on the understanding of the interviewee.

Further struggles occurred regarding controverse content of information e.g. about staff resistance, which was very dependent on the hierarchical level. Because it was not possible to decide which opinion reflects the reality best, it was decided to include all opinions into the analytic part. Because all the analyzed information was collected in one hospital setting it could be moreover strongly depending on this setting. Because of these basic conditions, it is not possible to generalize the gained findings without further research.

7. Conclusion

This project towards improving patient safety and quality management was performed by focusing on the fields information flow, defined responsibility, and hygiene. Despite the own checklist orientated on the particular priority risks, checklists for discharge (Arundel, 2011), handover (Blackpool Teaching Hospitals NHS Foundation Trust, 2016), Surgical Safety Checklist (World Health Organization, 2009a), “five moments for hand hygiene” (World Health Organization, 2006b) and a washing facility checklist (Österreichische Ärztekammer, 2015) were used to evaluate the current status.

The prioritization was performed via an adapted hazard scoring matrix (VA National Center for Patient Safety, 2014), which was complemented by the factor costs. A division into long-term and short-term goals and the involvement of representatives of the different job fields was also part of gaining suggestions. This proceeding showed a success rate of 92%.

The interviews of factors towards improvement showed seven elements: “missing equipment”, “resistance of the staff”, “resistance of the patient”, “low opinion of necessity”, “disagreement between hierarchies”, “missing trigger” and “lack of knowledge”.

The final decision about implementation showed that 50% of the problems were attached to the factor “low opinion of necessity”, which was interpreted as a lack of awareness.

The correlation between the success of implementation and the mentioned factor showed significant results for the resistance of the staff ($p= 0.001$) and the missing trigger ($p=0.043$).

The “resistance of the patient” was revealed to have a correlation with the rejection of a suggestion. Because this factor was gained by interview with the staff, not with the patient, it is necessary to verify this factor by future evaluation. The size of this effect as ranked by Cohen was large (Cohen, 1988). Further research should be made to find out about the opinion of the patient and it is recommended to include this step in developing projects. If the patient is correctly assessed as negative towards improvements, it would be necessary to put more effort in educational work. If the opinion of the patient was misjudged by the staff, the clarifying of this

misunderstanding could be a great opportunity to eliminate the number one barrier at no cost.

The “missing trigger” as an attribute of a matter which has not improved yet was a positive factor towards the acceptance of a suggestion. This shows the importance of incorporating the people on-site and of actively asking for previous ideas for change.

These results should be investigated with greater samples and in different settings to gain generalizable information, which could increase the efficiency of implementations.

Bibliography

ADLER, S. P. 1988. Cytomegalovirus Transmission among Children in Day Care, Their Mothers and Caretakers. *The Pediatric infectious disease journal,* 7, pp. 279-285.

AHMED, N. U., ALAM, M. M., SULTANA, F., SAYEED, S. N., PRESSMAN, A. M. & POWERS, M. B. 2006. Reaching the Unreachable: Barriers of the Poorest to Accessing Ngo Healthcare Services in Bangladesh. *Journal of health, population, and nutrition,* 24, p. 456.

ANTONY, J., KUMAR, M. & MADU, C. N. 2005. Six Sigma in Small-and Medium-Sized Uk Manufacturing Enterprises: Some Empirical Observations. *International Journal of Quality & Reliability Management,* 22, pp. 860-874.

AROOR, A. R., SAYA, R. P., ATTAR, N. R., SAYA, G. K. & RAVINANTHANAN, M. 2014. Awareness About Basic Life Support and Emergency Medical Services and Its Associated Factors among Students in a Tertiary Care Hospital in South India. *Journal of emergencies, trauma, and shock,* 7, p. 166.

ARUNDEL, A. 2011. *Smart Discharge Protocol* [Online]. Available: http://www.ihi.org/resources/Pages/Tools/SMARTDischargeProtocol.aspx [Accessed 04/03 2018].

BAKER, G. R., NORTON, P. G., FLINTOFT, V., BLAIS, R., BROWN, A., COX, J., ETCHELLS, E., GHALI, W. A., HÉBERT, P. & MAJUMDAR, S. R. 2004. The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada. *Canadian medical association journal,* 170, pp. 1678-1686.

BALARAJAN, Y., SELVARAJ, S. & SUBRAMANIAN, S. 2011. Health Care and Equity in India. *The Lancet,* 377, pp. 505-515.

BALTUSSEN, R. & NIESSEN, L. 2006. Priority Setting of Health Interventions: The Need for Multi-Criteria Decision Analysis. *Cost effectiveness and resource allocation,* 4, p. 14.

BANDA, K., SARKAR, R., GOPAL, S., GOVINDARAJAN, J., HARIJAN, B. B., JEYAKUMAR, M. B., MITTA, P., SADANALA, M. E., SELWYN, T. & SURESH, C. R. 2007. Water Handling, Sanitation and Defecation Practices in Rural Southern India: A Knowledge, Attitudes and Practices Study. *Transactions of the royal society of tropical medicine and hygiene,* 101, pp. 1124-1130.

BARACH, P. & SMALL, S. D. 2000. Reporting and Preventing Medical Mishaps: Lessons from Non-Medical near Miss Reporting Systems. *BMJ: British medical journal,* 320, p. 759.

BATES, D. W., CULLEN, D. J., LAIRD, N., PETERSEN, L. A., SMALL, S. D., SERVI, D., LAFFEL, G., SWEITZER, B. J., SHEA, B. F. & HALLISEY, R. 1995a. Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. *Jama,* 274, pp. 29-34.

BATES, D. W., O'NEIL, A. C., PETERSEN, L. A., LEE, T. H. & BRENNAN, T. A. 1995b. Evaluation of Screening Criteria for Adverse Events in Medical Patients. *Medical care*, pp. 452-462.

BECKMANN, U., BALDWIN, I., DURIE, M., MORRISON, A. & SHAW, L. 1998. Problems Associated with Nursing Staff Shortage: An Analysis of the First 3600 Reports Submitted to the Australian Incident Monitoring Study (Aims-Icu). *Anaesthesia and intensive care,* 26, p. 396.

BERWICK, D. M. 1989. Continuous Improvement as an Ideal in Health Care. pp. 53-56.
BERWICK, D. M. 2002. A User's Manual for the Iom's 'Quality Chasm'report. *Health affairs,* 21, pp. 80-90.
BERWICK, D. M. 2003. Improvement, Trust, and the Healthcare Workforce. *BMJ Quality & Safety,* 12, pp. 448-452.
BLACK, N. 2001. Evidence Based Policy: Proceed with Care. *BMJ: British Medical Journal,* 323, p. 275.
BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST. 2016. *Handover Checklist for Patient Transfer* [Online]. Available: https://www.whatdotheyknow.com/cy/request/283677/response/696559/attach/html/25/CORP%20PROC%20444%20v4.pdf.html [Accessed 04/02 2018].
BORCHARD, A., SCHWAPPACH, D. L., BARBIR, A. & BEZZOLA, P. 2012. A Systematic Review of the Effectiveness, Compliance, and Critical Factors for Implementation of Safety Checklists in Surgery. *Annals of surgery,* 256, pp. 925-933.
BORDERS, L. M., BINGHAM, P. R. & RIDDLE, M. C. 1984. Traditional Insulin-Use Practices and the Incidence of Bacterial Contamination and Infection. *Diabetes Care,* 7, pp. 121-127.
BROOK, R. H., MCGLYNN, E. A. & CLEARY, P. D. 1996. Measuring Quality of Care. pp. 966-970.
BUNDESMINISTERIUM FÜR GESUNDHEIT 2014. Mindestanforderungen an Qualitätsmanagementsysteme
BURTON, M., COBB, E., DONACHIE, P., JUDAH, G., CURTIS, V. & SCHMIDT, W.-P. 2011. The Effect of Handwashing with Water or Soap on Bacterial Contamination of Hands. *International journal of environmental research and public health,* 8, pp. 97-104.
BUTLER, P. W. 2008. Using Leadership Development Programs to Improve Quality and Efficiency in Healthcare. *Journal of Healthcare Management,* 53, p. 319.
CALLUM, J. L., KAPLAN, H. S., MERKLEY, L. L., PINKERTON, P. H., RABIN FASTMAN, B., ROMANS, R. A., COOVADIA, A. S. & REIS, M. D. 2001. Reporting of near-Miss Events for Transfusion Medicine: Improving Transfusion Safety. *Transfusion,* 41, pp. 1204-1211.
CANADIAN PATIENT SAFETY INSTITUTE 2009a. Information, Rationale, and Faq for the Surgical Safety Checklist.
CANADIAN PATIENT SAFETY INSTITUTE 2009b. Surgical Safety Checklist & Scorecard.
CENTERS FOR DISEASE CONTROL AND PREVENTION. 2010. *Questions About Multi-Dose Vials* [Online]. Available: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html [Accessed 05/09 2018].
CENTERS FOR DISEASE CONTROL AND PREVENTION. 2015. *Guidelines for Environmental Infection Control in Health-Care Facilities (2003)* [Online]. Available: https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/laundry.html [Accessed 05/05 2018].
CHASSIN, M. R. & GALVIN, R. W. 1998. The Urgent Need to Improve Health Care Quality: Institute of Medicine National Roundtable on Health Care Quality. *Jama,* 280, pp. 1000-1005.

CHAUDHURY, N., HAMMER, J., KREMER, M., MURALIDHARAN, K. & ROGERS, F. H. Provider Absence in Schools and Health Clinics. 2004. Northeast Universities Development Consortium Conference, HEC Montreal, pp. 1-22.
CLANCY, C. M. & CRONIN, K. 2005. Evidence-Based Decision Making: Global Evidence, Local Decisions. *Health affairs,* 24, pp. 151-162.
COCH, L. & FRENCH JR, J. R. 1948. Overcoming Resistance to Change. *Human relations,* 1, pp. 512-532.
COHEN, J. 1988. *Statistical Power Analysis for the Behavioral Sciences 2nd Edn,* Erlbaum Associates, Hillsdale, pp. 79-81.
CORRIGAN, J. M., GREINER, A. C. & ADAMS, K. 2004. *The 1st Annual Crossing the Quality Chasm Summit: A Focus on Communities: Report of a Summit,* National Academies Press, p. 2.
CROSBY, P. B. 1979. Quality Is Free: The Art of Marketing Quality Certain. *New York: New American Library,* 1, pp. 1-309.
CULYER, A. J. 2001. Equity-Some Theory and Its Policy Implications. *Journal of medical ethics,* 27, pp. 275-283.
DAS, J., HOLLA, A., DAS, V., MOHANAN, M., TABAK, D. & CHAN, B. 2012. In Urban and Rural India, a Standardized Patient Study Showed Low Levels of Provider Training and Huge Quality Gaps. *Health affairs,* 31, pp. 2774-2784.
DATTA, S., SINGH, Z., BORATNE, A., SENTHILVEL, V., BAZROY, J. & DIMRI, D. 2011. Knowledge and Practice of Handwashing among Mothers of under Five Children in Rural Coastal South India. *International journal of medicine and public health,* 1, pp. 33-38.
DEMING, W. E. 2000. *Out of the Crisis,* The MIT Press, pp. 1-524.
DEOGAONKAR, M. 2004. Socio-Economic Inequality and Its Effect on Healthcare Delivery in India: Inequality and Healthcare. *Electronic Journal of Sociology,* 11.
DIAMOND, M. J. 2005. *Introducing Financial Management Information Systems in Developing Countries,* International Monetary Fund.
DOCTOR TYPHAGNE MEMORIAL CHARITABLE 2017.
DOCTOR TYPHAGNE MEMORIAL CHARITABLE TRUST. 2018. *Dtmctrust.Org* [Online]. Available: http://dtmctrust.org/gallery_view.php?sel=SFS-HEALTH-CENTRE [Accessed 07/06/2018] Reprinted with permission.
DRUCKER, E., ALCABES, P. G. & MARX, P. A. 2001. The Injection Century: Massive Unsterile Injections and the Emergence of Human Pathogens. *The Lancet,* 358, p. 1991.
ELHENCE, P., SHENOY, V., VERMA, A. & SACHAN, D. 2012. Error Reporting in Transfusion Medicine at a Tertiary Care Centre: A Patient Safety Initiative. *Clinical chemistry and laboratory medicine,* 50, pp. 1935-1943.
EPSTEIN, R. M., FISCELLA, K., LESSER, C. S. & STANGE, K. C. 2010. Why the Nation Needs a Policy Push on Patient-Centered Health Care. *Health affairs,* 29, pp. 1489-1495.
ERICKSON, S. M., WOLCOTT, J., CORRIGAN, J. M. & ASPDEN, P. 2003. *Patient Safety: Achieving a New Standard for Care,* National Academies Press, p. 2.
FAN, S., CHEN-KANG, C. & MUKHERJEE, A. 2005. *Rural and Urban Dynamics and Poverty: Evidence from China and India,* IFPRI Washington, DC, USA, pp. 1-50.
FORD, J. D., FORD, L. W. & D'AMELIO, A. 2008. Resistance to Change: The Rest of the Story. *Academy of management Review,* 33, pp. 362-377.

FORD, L., KALUZNY, A. D. & SONDIK, E. Diffusion and Adoption of State-of-the-Art Therapy. Seminars in Oncology, 1990. Elsevier, pp. 485-494.
FRANKE, R. H. & KAUL, J. D. 1978. The Hawthorne Experiments: First Statistical Interpretation. *American sociological review*, pp. 623-643.
FRAZIER, A. L., COLDITZ, G. A., FUCHS, C. S. & KUNTZ, K. M. 2000. Cost-Effectiveness of Screening for Colorectal Cancer in the General Population. *Jama,* 284, pp. 1954-1961.
GARVIN, D. 1983. Quality on the Line. *Harv. Bus. Rev.*, pp. 65-75.
GERMAIN, J.-M., CARBONNE, A., THIERS, V., GROS, H., CHASTAN, S., BOUVET, E. & ASTAGNEAU, P. 2005. Patient-to-Patient Transmission of Hepatitis C Virus through the Use of Multidose Vials During General Anesthesia. *Infection Control & Hospital Epidemiology,* 26, pp. 789-792.
GOVERNMENT OF SOUTH AUSTRALIA 2013. Environmental Cleaning Guidelines for Healthcare Settings.
GRAHAM, I. D. & TETROE, J. 2007. Cihr Research: How to Translate Health Research Knowledge into Effective Healthcare Action. *Healthcare Quarterly,* 10, pp. 20-22.
GUPTA, E., MOHANTY, S., SOOD, S. & DHAWAN, B. 2006. Emerging Resistance to Carbapenems in a Tertiary Care Hospital in North India. *Indian Journal of Medical Research,* 124, p. 95.
HAY, S. I., GETHING, P. W. & SNOW, R. W. 2010. India's Invisible Malaria Burden. *Lancet,* 376, p. 1716.
HOFSTEDE, G., HOFSTEDE, G. J. & MINKOV, M. 2010. *Cultures and Organizations - Software of the Mind: Intercultural Cooperation and Its Importance for Survival* pp. 57-300.
HUGHES, R. G. 2008. Patient Safety and Quality: An Evidence-Based Handbook for Nurses pp. 1146-1184.
INSTITUTE OF MEDICINE COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century,* Washington (DC), National Academies Press (US)

Copyright 2001 by the National Academy of Sciences. All rights reserved., pp. 5-6.
INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES 2007. *India National Family Health Survey (Nfhs-3), 2005-06,* International Institute for Population Sciences, p. 34.
INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. 2015. *Quality Management Principles* [Online]. Available: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/pub100080.pdf [Accessed 02/20 2018].
ISHIKAWA, K. 1976. Guide to Quality Control, Asian Productivity Organisation. *Hong Kong: Nordica International*, pp. 1-226.
JINDAL, N., JINDAL, M., JILANI, N. & KAR, P. 2006. Seroprevalence of Hepatitis C Virus (Hcv) in Health Care Workers of a Tertiary Care Centre in New Delhi. *Indian Journal of Medical Research,* 123, p. 179.
JURAN, J. M. 1981. Product Quality-a Prescription for the West, Part I. *Manage. Rev.,* 70, pp. 8-14.
KERMODE, M., JOLLEY, D., LANGKHAM, B., THOMAS, M. S. & CROFTS, N. 2005a. Occupational Exposure to Blood and Risk of Bloodborne Virus Infection among Health Care Workers in Rural North Indian Health Care Settings. *American journal of infection control,* 33, pp. 34-41.

KERMODE, M., JOLLEY, D., LANGKHAM, B., THOMAS, M. S., HOLMES, W. & GIFFORD, S. M. 2005b. Compliance with Universal/Standard Precautions among Health Care Workers in Rural North India. *American journal of infection control,* 33, pp. 27-33.

KIDD-LJUNGGREN, K., BROMAN, E., EKVALL, H. & GUSTAVSSON, O. 1999. Nosocomial Transmission of Hepatitis B Virus Infection through Multiple-Dose Vials. *Journal of Hospital Infection,* 43, pp. 57-62.

KOHN, L. T., CORRIGAN, J. M. & DONALDSON, M. S. 2000. To Err Is Human. pp. 1-312.

KOTHARI, C. R. 2004. *Research Methodology: Methods and Techniques,* New Age International, pp. 95-122.

KRAUSE, G., TREPKA, M. J., WHISENHUNT, R. S., KATZ, D., NAINAN, O., WIERSMA, S. T. & HOPKINS, R. S. 2003. Nosocomial Transmission of Hepatitis C Virus Associated with the Use of Multidose Saline Vials. *Infection Control & Hospital Epidemiology,* 24, pp. 122-127.

KRISHNA, A. 2004. Escaping Poverty and Becoming Poor: Who Gains, Who Loses, and Why? *World development,* 32, pp. 121-136.

LAHARIYA, C., SUBRAMANYA, B. & SOSLER, S. 2013. An Assessment of Hepatitis B Vaccine Introduction in India: Lessons for Roll out and Scale up of New Vaccines in Immunization Programs. *Indian journal of public health,* 57, p. 8.

LAMB, B. W. & NAGPAL, K. 2009. Importance of near Misses. *BMJ,* 339, p. b3032.

LANDEFELD, J., SIVARAMAN, R. & ARORA, N. K. 2015. Barriers to Improving Patient Safety in India: Focus Groups with Providers in the Southern State of Kerala. *Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine,* 40, p. 116.

LEAPE, L. L. 2000. Institute of Medicine Medical Error Figures Are Not Exaggerated. *Jama,* 284, pp. 95-97.

LEONARD, F. S. 1982. The Incline of Quality. *Harv. Bus. Rev.*, pp. 163-171.

LEOTSAKOS, A., ZHENG, H., CROTEAU, R., LOEB, J. M., SHERMAN, H., HOFFMAN, C., MORGANSTEIN, L., O'LEARY, D., BRUNEAU, C. & LEE, P. 2014. Standardization in Patient Safety: The Who High 5s Project. *International journal for quality in health care,* 26, pp. 109-116.

LITTLE, P., EVERITT, H., WILLIAMSON, I., WARNER, G., MOORE, M., GOULD, C., FERRIER, K. & PAYNE, S. 2001. Observational Study of Effect of Patient Centredness and Positive Approach on Outcomes of General Practice Consultations. *Bmj,* 323, pp. 908-911.

LLOYD, G. E. R., CHADWICK, J. & MANN, W. N. 1983. *Hippocratic Writings,* Penguin UK, pp. 1-384.

LOCALIO, A. R., WEAVER, S. L., LANDIS, J. R., LAWTHERS, A. G., BRENNAN, T. A., HEBERT, L. & SHARP, T. J. 1996. Identifying Adverse Events Caused by Medical Care: Degree of Physician Agreement in a Retrospective Chart Review. *Annals of internal medicine,* 125, pp. 457-464.

LOHR , K. N. & SCHROEDER , S. A. 1990. A Strategy for Quality Assurance in Medicare. *New England Journal of Medicine,* 322, p. 21.

LOWE, G. 2012. How Employee Engagement Matters for Hospital Performance. *Healthcare Quarterly,* 15, pp. 29-39.

MADHOK, R., ROY, N. & PANESAR, S. 2012. Patient Safety in India: Time to Speed up Our Efforts to Reduce Avoidable Harm. *The National medical journal of India,* 25, p. 129.

MADHOK, R., VAID, S., CARSON-STEVENS, A., PANESAR, S., MATHEW, J., ROY, N., SANGAL, A., DATAR, N., STROBL, J. & STORR, J. 2014. Promoting Patient Safety in India: Situational Analysis and the Way Forward. pp. 217-223.

MCMICHAEL, C., WATERS, E. & VOLMINK, J. 2005. Evidence-Based Public Health: What Does It Offer Developing Countries? *Journal of public health,* 27, pp. 215-221.

MEINGAST, M., ROOSTA, T. & SASTRY, S. Security and Privacy Issues with Health Care Information Technology. Engineering in Medicine and Biology Society, 2006. EMBS'06. 28th Annual International Conference of the IEEE, 2006. IEEE, pp. 5453-5458.

MOONEY, G. H. 1983. Equity in Health Care: Confronting the Confusion. *Effective health care,* 1, pp. 179-185.

MORRIS, S. K., BASSANI, D. G., AWASTHI, S., KUMAR, R., SHET, A., SURAWEERA, W. & JHA, P. 2011. Diarrhea, Pneumonia, and Infectious Disease Mortality in Children Aged 5 to 14 Years in India. *PLoS One,* 6, pp. 1-7.

MURRAY, C. J. & LOPEZ, A. D. 1997. Global Mortality, Disability, and the Contribution of Risk Factors: Global Burden of Disease Study. *The lancet,* 349, pp. 1436-1442.

N.U. 2011. palliumindia. Available: http://palliumindia.org/2011/11/where-is-the-bystander/ [Accessed 05/06 2018].

NADEEM, M. N., VASEEM, A. & MAQDOOM, M. 2018. A Cross-Sectional Study Evaluating the Awareness of Pharmacovigilance among Mbbs Interns of a Teaching Hospital in South India. *International Journal of Basic & Clinical Pharmacology,* 5, pp. 2468-2475.

NAIR, S. S., HANUMANTAPPA, R., HIREMATH, S. G., SIRAJ, M. A. & RAGHUNATH, P. 2014. Knowledge, Attitude, and Practice of Hand Hygiene among Medical and Nursing Students at a Tertiary Health Care Centre in Raichur, India. *ISRN preventive medicine,* 2014, pp. 1-4.

NASHEF, S. A. 2003. What Is a near Miss? *The Lancet,* 361, pp. 180-181.

NATIONAL HEALTH SYSTEMS RESOURCE CENTRE 2016. National Health Accounts Estimates for India 2013-14.

OATES, J., WESTON, W. W. & JORDAN, J. 2000. The Impact of Patient-Centered Care on Outcomes. *Fam Pract,* 49, pp. 796-804.

OHL, M., SCHWEIZER, M., GRAHAM, M., HEILMANN, K., BOYKEN, L. & DIEKEMA, D. 2012. Hospital Privacy Curtains Are Frequently and Rapidly Contaminated with Potentially Pathogenic Bacteria. *American journal of infection control,* 40, pp. 904-906.

OLIVER, A. & MOSSIALOS, E. 2004. Equity of Access to Health Care: Outlining the Foundations for Action. *Journal of Epidemiology & Community Health,* 58, pp. 655-658.

OOMMEN, T. K. 1989. India:'Brain Drain'or the Migration of Talent? *International Migration,* 27, pp. 411-425.

OPENSTREETMAP FOUNDATION. 2018. *Openstreetmap.Org* [Online]. Available: https://www.openstreetmap.org/search?query=kakkaveri#map=4/27.14/55.20 [Accessed 07/06/18] © OpenStreetMap-Mitwirkende. CC BY-SA (licence); Reprinted with permission.

ÖSTERREICHISCHE ÄRZTEKAMMER 2015. Kundmachung Der Österreichischen Ärztekammer Nr. 3/2015.

OULTON, J. A. 2006. The Global Nursing Shortage: An Overview of Issues and Actions. *Policy, Politics, & Nursing Practice,* 7, pp. 34S-39S.

PAI, M., GOKHALE, K., JOSHI, R., DOGRA, S., KALANTRI, S., MENDIRATTA, D. K., NARANG, P., DALEY, C. L., GRANICH, R. M. & MAZUREK, G. H. 2005. Mycobacterium Tuberculosis Infection in Health Care Workers in Rural India: Comparison of a Whole-Blood Interferon Γ Assay with Tuberculin Skin Testing. *Jama,* 293, pp. 2746-2755.

PAILY, R. 2004. Perinephric Abscess from Insulin Syringe Reuse. *The American journal of the medical sciences,* 327, pp. 47-48.

PAKENHAM-WALSH, N. & BUKACHI, F. 2009. Information Needs of Health Care Workers in Developing Countries: A Literature Review with a Focus on Africa. *Human resources for health,* 7, p. 30.

PANDIT, N. & CHOUDHARY, S. 2008. Unsafe Injection Practices in Gujarat, India. *Singapore medical journal,* 49, p. 936.

PARK, K. 1979. The Dengue Syndrome. *Park's Textbook of Preventive and Social Medicine. Jabalpur: Banarasidas Bhanot,* 16, pp. 186-188.

PATHAK, R., CHAUDHARY, C., PATHANIA, D., AHLUWALIA, S. K., MISHRA, P. K. & KAHLON, A. S. 2013a. Hepatitis B Vaccine: Coverage and Factors Relating to Its Acceptance among Health Care Workers of a Tertiary Care Center in North India. *International Journal of Medicine and Public Health,* 3.

PATHAK, R., CHAUDHARY, C., PATHANIA, D., AHLUWALIA, S. K., MISHRA, P. K. & KAHLON, A. S. 2013b. Hepatitis B Vaccine: Coverage and Factors Relating to Its Acceptance among Health Care Workers of a Tertiary Care Center in North India. *International Journal of Medicine and Public Health,* 3, pp. 55-59.

PATI, N. T., SETHI, A., AGRAWAL, K., AGRAWAL, K., KUMAR, G. T., KUMAR, M., KAANAN, A. T. & SARIN, S. K. 2008. Low Levels of Awareness, Vaccine Coverage, and the Need for Boosters among Health Care Workers in Tertiary Care Hospitals in India. *Journal of Gastroenterology and hepatology,* 23, pp. 1710-1715.

PHIMISTER, J. R., OKTEM, U., KLEINDORFER, P. R. & KUNREUTHER, H. 2003. Near-Miss Incident Management in the Chemical Process Industry. *Risk Analysis,* 23, pp. 445-459.

PRENTICE, J. C. & PIZER, S. D. 2007. Delayed Access to Health Care and Mortality. *Health services research,* 42, pp. 644-662.

PROVINCIAL INFECTIOUS DISEASES ADVISORY COMMITTEE 2013. Best Practices for Hand Hygiene Facilities & Infrastructure of Healthcare Settings. 4th ed.

PURI, P. 2014. Tackling the Hepatitis B Disease Burden in India. *Journal of clinical and experimental hepatology,* 4, pp. 312-319.

RAGHAVENDRAN, K., MYLOTTE, J. M. & SCANNAPIECO, F. A. 2007. Nursing Home-Associated Pneumonia, Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia: The Contribution of Dental Biofilms and Periodontal Inflammation. *Periodontology 2000,* 44, pp. 164-177.

RAGHUNATH, D. 2008. Emerging Antibiotic Resistance in Bacteria with Special Reference to India. *Journal of biosciences,* 33, pp. 593-603.

RAHEEL, U., FAHEEM, M., RIAZ, M. N., KANWAL, N., JAVED, F. & QADRI, I. 2010. Dengue Fever in the Indian Subcontinent: An Overview. *The Journal of Infection in Developing Countries,* 5, pp. 239-247.

RAJARAMAN, D., VARADHARAJAN, K. S., GREENLAND, K., CURTIS, V., KUMAR, R., SCHMIDT, W.-P., AUNGER, R. & BIRAN, A. 2014. Implementing Effective Hygiene Promotion: Lessons from the Process Evaluation of an Intervention to Promote Handwashing with Soap in Rural India. *BMC public health,* 14, p. 1179.

RAO, K. D., BHATNAGAR, A. & BERMAN, P. 2012. So Many, yet Few: Human Resources for Health in India. *Human resources for health,* 10, p. 19.

REASON, J. 1990. *Human Error,* Cambridge university press, pp. 1-302.

REASON, J. 2016. *Managing the Risks of Organizational Accidents,* Routledge, p. 202.

REELER, A. V. 1990. Injections: A Fatal Attraction? *Social Science & Medicine,* 31, pp. 1119-1125.

REELER, A. V. 2000. Anthropological Perspectives on Injections: A Review. *Bulletin of the World Health Organization,* 78, pp. 135-143.

REID, S. 2012. Estimating the Burden of Disease from Unsafe Injections in India: A Cost–Benefit Assessment of the Auto-Disable Syringe in a Country with Low Blood-Borne Virus Prevalence. *Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine,* 37, p. 89.

ROSENTHAL, V. D., MAKI, D. G., SALOMAO, R., MORENO, C. A., MEHTA, Y., HIGUERA, F., CUELLAR, L. E., ARIKAN, Ö. A., ABOUQAL, R. & LEBLEBICIOGLU, H. 2006. Device-Associated Nosocomial Infections in 55 Intensive Care Units of 8 Developing Countriesdevice-Associated Infections in the Intensive Care Unit. *Annals of internal medicine,* 145, pp. 582-591.

ROTHSCHILD, J. M., LANDRIGAN, C. P., CRONIN, J. W., KAUSHAL, R., LOCKLEY, S. W., BURDICK, E., STONE, P. H., LILLY, C. M., KATZ, J. T. & CZEISLER, C. A. 2005. The Critical Care Safety Study: The Incidence and Nature of Adverse Events and Serious Medical Errors in Intensive Care. *Critical care medicine,* 33, pp. 1694-1700.

SAHA, S., BEACH, M. C. & COOPER, L. A. 2008. Patient Centeredness, Cultural Competence and Healthcare Quality. *Journal of the National Medical Association,* 100, p. 1275.

SARADAMMA, R. D., HIGGINBOTHAM, N. & NICHTER, M. 2000. Social Factors Influencing the Acquisition of Antibiotics without Prescription in Kerala State, South India. *Social science & medicine,* 50, pp. 891-903.

SARAPH, J. V., BENSON, P. G. & SCHROEDER, R. G. 1989. An Instrument for Measuring the Critical Factors of Quality Management. *Decision sciences,* 20, pp. 810-829.

SCHULER, G., PELZ, K. & KERP, L. 1992. Is the Reuse of Needles for Insulin Injection Systems Associated with a Higher Risk of Cutaneous Complications? *Diabetes research and clinical practice,* 16, pp. 209-212.

SELVARAJ, S. & KARAN, A. K. 2009. Deepening Health Insecurity in India: Evidence from National Sample Surveys since 1980s. *Economic and Political Weekly*, pp. 55-60.

SHARMA, R., RASANIA, S., VERMA, A. & SINGH, S. 2010. Study of Prevalence and Response to Needle Stick Injuries among Health Care Workers in a Tertiary Care Hospital in Delhi, India. *Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine,* 35, p. 74.

SHEIKHTAHERI, A. 2014. Near Misses and Their Importance for Improving Patient Safety. *Iranian journal of public health,* 43, pp. 853-854.

SHOJANIA, K. G., DUNCAN, B. W., MCDONALD, K., WACHTER, R. & MARKOWITZ, A. 2001. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. *Evid Rep Technol Assess (Summ),* 43, p. 668.

SIMARD, E. P., MILLER, J. T., GEORGE, P. A., WASLEY, A., ALTER, M. J., BELL, B. P. & FINELLI, L. 2007. Hepatitis B Vaccination Coverage Levels among Healthcare Workers in the United States, 2002-2003. *Infection Control & Hospital Epidemiology,* 28, pp. 783-790.

SINGH, N., BHANDARI, L., CHEN, A. & KHARE, A. 2003. Regional Inequality in India: A Fresh Look. *Economic and Political Weekly*, pp. 1069-1073.

SINGH, R. B., SINGH, V., KULSHRESTHA, S. K., SINGH, S., GUPTA, P., KUMAR, R., KRISHNA, A., SRIVASTAV, S. S., GUPTA, S. B. & PELLA, D. 2005. Social Class and All-Cause Mortality in an Urban Population of North India. *Acta cardiologica,* 60, pp. 611-617.

SMITH, A. F., CASEY, K., WILSON, J. & FISCHBACHER-SMITH, D. 2011. Wristbands as Aids to Reduce Misidentification: An Ethnographically Guided Task Analysis. *International Journal for Quality in Health Care,* 23, pp. 590-599.

STEWART, M. 2001. Towards a Global Definition of Patient Centred Care: The Patient Should Be the Judge of Patient Centred Care. *BMJ: British Medical Journal,* 322, p. 444.

SUTHAR, S., CHHIMPA, V. & SINGH, S. 2009. Bacterial Contamination in Drinking Water: A Case Study in Rural Areas of Northern Rajasthan, India. *Environmental monitoring and assessment,* 159, p. 43.

TRÉPANIER, C. A., LESSARD, M. R., BROCHU, J. G. & DENAULT, P. H. 1990. Risk of Cross-Infection Related to the Multiple Use of Disposable Syringes. *Canadian journal of anaesthesia,* 37, pp. 156-159.

TRILLIS, F., ECKSTEIN, E. C., BUDAVICH, R., PULTZ, M. J. & DONSKEY, C. J. 2008. Contamination of Hospital Curtains with Healthcare-Associated Pathogens. *Infection Control & Hospital Epidemiology,* 29, pp. 1074-1076.

UMAR, N., LITAKER, D. & TERRIS, D. D. 2009. ' *Quality Management in Healthcare,* 18, pp. 295-304.

UNAIDS. 2016. *Country Factsheets India* [Online]. Available: http://www.unaids.org/en/regionscountries/countries/india [Accessed 03/10 2018].

VA NATIONAL CENTER FOR PATIENT SAFETY 2014. The Basics of Healthcare Failure Mode and Effect Analysis.

VAN DAM, K., OREG, S. & SCHYNS, B. 2008. Daily Work Contexts and Resistance to Organisational Change: The Role of Leader–Member Exchange, Development Climate, and Change Process Characteristics. *Applied psychology,* 57, pp. 313-334.

VILLAREJOS, V. M., VISONÁ, K. A., ALVARO, G. D. & ANTONIO, R. A. 1974. Role of Saliva, Urine and Feces in the Transmission of Type B Hepatitis. *New England Journal of Medicine,* 291, pp. 1375-1378.

VINCENT, C., NEALE, G. & WOLOSHYNOWYCH, M. 2001. Adverse Events in British Hospitals: Preliminary Retrospective Record Review. *Bmj,* 322, pp. 517-519.

VIVEKANANTHAM, S., RAVINDRAN, R. P., SHANMUGARAJAH, K., MARUTHAPPU, M. & SHALHOUB, J. 2014. Surgical Safety Checklists in Developing Countries. *International Journal of Surgery,* 12, pp. 2-6.

WALSHE, K. & RUNDALL, T. G. 2001. Evidence-Based Management: From Theory to Practice in Health Care. *The Milbank Quarterly,* 79, pp. 429-457.
WIDELL, A., CHRISTENSSON, B., WIEBE, T., SCHALÉN, C., HANSSON, H. B., ALLANDER, T. & PERSSON, M. A. 1999. Epidemiologic and Molecular Investigation of Outbreaks of Hepatitis C Virus Infection on a Pediatric Oncology Service. *Annals of internal medicine,* 130, pp. 130-134.
WORLD BANK. 2014. *Purchasing Power Parities and Real Expenditures of World Economies, Summary of Results and Findings of the 2011, International Comparison Program* [Online]. Available: http://pubdocs.worldbank.org/en/150971487105181565/Summary-of-Results-and-Findings-of-the-2011-International-Comparison-Program.pdf [Accessed 05/01 2018].
WORLD HEALTH ORGANIZATION 2000. *The World Health Report 2000: Health Systems: Improving Performance,* World Health Organization.
WORLD HEALTH ORGANIZATION 2003. Aide-Memoire for a Strategy to Protect Health Workers from Infection with Bloodborne Viruses.
WORLD HEALTH ORGANIZATION 2005. World Alliance for Patient Safety: Who Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action.
WORLD HEALTH ORGANIZATION 2006a. *The World Health Report 2006: Working Together for Health,* World Health Organization.
WORLD HEALTH ORGANIZATION 2006b. Your 5 Moments for Hand Hygiene.
WORLD HEALTH ORGANIZATION 2007. Post-Exposure Prophylaxis to Prevent Hiv Infection.
WORLD HEALTH ORGANIZATION 2008. Establishing and Monitoring Benchmarks for Human Resources for Health: The Workforce Density Approach. *Spotlight on Health Workforce Statistics,* 6, pp. 1-2.
WORLD HEALTH ORGANIZATION 2009a. Surgical Safety Checklist.
WORLD HEALTH ORGANIZATION 2009b. WHO Guidelines on Hand Hygiene in Health Care.
WORLD HEALTH ORGANIZATION 2010. WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy.
WORLD HEALTH ORGANIZATION 2011. Patient Safety Curriculum Guide: Multi-Professional Edition.
WORLD HEALTH ORGANIZATION 2015a. Regional Strategy for Patient Safety in the Who South-East Asia Region (2016-2025). pp. 1-46.
WORLD HEALTH ORGANIZATION 2015b. Regional Strategy for Patient Safety in the WHO South-East Asia Region (2016-2025).
WORLD HEALTH ORGANIZATION 2016. The Health Workforce in India: Human Resources for Health Observer Series No. 16. *The Health Workforce in India: Human Resources for Health Observer Series No. 16.*
WORLD HEALTH ORGANIZATION. 2017a. *Facts on Patient Safety* [Online]. Available: http://www.who.int/features/factfiles/patient_safety/patient_safety_facts/en/index8.html [Accessed 04/28 2018].
WORLD HEALTH ORGANIZATION 2017b. Global Tuberculosis Report 2017
WORLD HEALTH ORGANIZATION. 2018. *WHO | World Alliance for Patient Safety* [Online]. Available: http://www.who.int/patientsafety/worldalliance/en/ [Accessed 04/30 2018].

WRIGHT, L. B. 2002. *The Analysis of Uk Railway Accidents and Incidents: A Comparison of Their Causal Patterns* [Online]. University of Strathclyde. Available: http://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.269869 [Accessed 05/15 2018].

WYATT, H. 1984. The Popularity of Injections in the Third World: Origins and Consequences for Poliomyelitis. *Social Science & Medicine,* 19, p. 913.

YOUSUF, R., FAUZI, A., HOW, S., RASOOL, A. & REHANA, K. 2007. Awareness, Knowledge and Attitude Towards Informed Consent among Doctors in Two Different Cultures in Asia: A Cross-Sectional Comparative Study in Malaysia and Kashmir, India. *Singapore medical journal,* 48, p. 559.

ZINN, C. 1995. 14,000 Preventable Deaths in Australian Hospitals. *BMJ (Clinical research ed.),* 310, p. 1487.

ZWICK, T. 2002. Employee Resistance against Innovations. *International journal of Manpower,* 23, pp. 542-552.

Appendix

Appendix I: Checklist for Observation and Interview

Inpatient Sector

Doctor:

1. Do the patients come spontaneously for an inpatient stay or do they have an appointment?

2. Does the hospital plan in advance for the needed capacity?

3. What are questions you typically ask patients when they arrive at the ward?

4. Do you always perform an examination? If so, what kinds of exams do you perform?

5. Do patients get any form of identification?

6. Who decides which room the patient gets? How is this decided? Does an infectious disease play a role? Do wards have a room schedule? How do you find the patients?

7. Do you document the treatment plan?

Doctor's Order:

Does the hospital use medical charts? Or how do you document your visit with the patient? What does it include? (e.g. success/efficacy of the therapy, treatment history)

Do you document examinations, blood samples, and medications?

Which vital parameters are normally measured?

How are interventions dealt with?

Do you have a fixed procedure for discharging patients? How does it work? (e.g. a discharging letter, final examination, or the organization of social services and support systems)

Nurse:

1. What kind of questions do you ask the patients? (anamnesis)

2. What kind of information do you write down?

- Name/ date of birth/ address/ emergency contact

- Social anamnesis

- Allergies

- Religion

- Medication

- Dietary habits

- Physical restrictions (e.g. status of teeth, etc.)

- Bowel movements, digestion

- Number of births

- Pain

Time Management: Are There Certain Times for …?

- Bed rest and visitors
- Bathing, cleaning, giving medication
- Rounds? (With or without doctors? Bandage change and observation?)
- Wake up/ Meals (Is there a meal for patients?)
- Mobilization of patients
- Examinations/ drawing blood/ laboratory/ imaging (X-ray) and other interventions

Responsibility: Who…?

…measures the blood pressure and temperature? How often do you check these readings?

…gives the patients their medication?

…draws blood?

…puts in an IV/ gives an infusion?

…takes care of changing bandages/ wound observation

Is there someone responsible for patient safety during the night? Do you have an observation plan?

Hygiene at the Unit:

Is there someone responsible for cleaning the beds? If so, how often are the sheets changed? What kind of cleaning products do you use?

Is there a time schedule for cleaning the surfaces and the patient's environment? (e.g. items in the room)

Do you have a cleaning plan for the bathrooms and for the floors of the unit? If so, how often do you clean? Which cleaning products do you use?

How do you clean the oxygen device? What kind of water do you use? How often do you change the water? Where do you document the maintenance?

Do you have disinfectant dispensers? Soap? Sinks?

General Information:

How many people work at each ward? Is someone in charge of the ward?

What kind of functional areas do you have? Who is responsible for the different tasks? Is the division always the same or does the responsibility change?

What kind of working positions do you have? (Student nurses? Cleaning staff?) Who is responsible for which area and how long are the shifts?

What is the patient/nurse ratio?

Does every employee have an education in first aid?

Out-Patient Clinic

Do the patients come spontaneously or do they have an appointment?

Who is the first person that talks to the patients and who decides if it's an emergency or not? (Triage?)

Do you have an admission form? Does the patient get an identification number or a wristband?

If it's not the first admission, do you try to get previous files/data?

Doctor: What are questions you typically ask patients when they arrive? What kind of physical examination do you perform?

Doctors' order: What kind of interventions do you perform? (Blood sample, taking vital parameters, wounds and bandages) How do you communicate those tasks?

How do you decide whether there is an admission needed or not? And if you discharge the patient, how do you do this? Is there a final talk with the patient? What kind of information does it include? Do you write a letter for the general practitioner? Do you ask about the social circumstances?

Do you make follow-up appointments?

Is there a suggestion box at the out-patient clinic for patients and staff?

Hygiene

Is protection available, e.g. disposable gloves, aprons/ skirts, masks?

When do you use such protection?

Are there disinfectant dispensers, soap, sinks, mirrors, and disinfectant for the devices?

Is someone responsible for checking the time for the disinfectant to work?

Are there instruments you use more than once? Is there someone in charge of the sterilization of used instruments? If so, is there a plan?

If there is time left between treating two patients in row – do you clean the working environment or do you have other cleaning schedules? How often do you clean?

Do you clean everything at the same time for example: The floor and the examination lounger in a row?

Is there someone who is responsible for the maintenance of the devices?

Do you have opening hours for the different departments? (Laboratory, Pharmacy? Visitors?)

Could you show us the waste disposal of your ward? Where do you dispose your needles? Where do you dispose infective material? Does the cleaning staff use gloves?

Surgery:

Who takes care of the maintenance of the ventilator? Is there a regular maintenance schedule? How often do you change the masks and the tubes/ hoses?

Can you show us were you store your catheters and surgery equipment? Is there material that you use more than once? How do you clean it/ Where do you dispose of it?

Where do you get the water for cleaning instruments or for the oxygen?

Do you have sinks, mirrors, and disinfectant dispensers?

Do you clean the rooms between two interventions?

Does everybody know which infectious diseases a patient has, when it comes to an intervention? Do you talk about that? What happens when somebody gets in contact with infectious material?

ICU:

Can you show us the oxygen bottles/ the masks and your monitoring? Is everything ready to go? Where does the oxygen connection end? Do you use water here?

How often do you perform an ECG? Can you show us your equipment? How often do you clean it? Who is responsible for that?

Do you have a form for patients at the ICU?

Are there rules or special equipment to protect the patients at the ICU? (Masks, scrubs?) What about visitors? Are they allowed to come here?

How do you notice if someone is getting worse? Is there an alarm bell?

Do you separate between surgical and non-surgical patients?

Pharmacy

How do you order medications? What medications do you keep in stock? How does it get to the patient? Do you need a prescription for every medication? Is there an expiration date on the package and who checks on that? Do patients have to pay for the medication they take?

Do you have a fridge for certain medications?

What kind of bandages do you have and where do you store them?

Do you produce medications on your own? (Creams? Syrup? Mixtures?)

Do you have a list of the inventory?

Laboratory

Where do you store the vials for the blood samples?

Are the blood samples labelled?

Do you use protection in the laboratory, e.g. gloves, soap, etc.?

Is someone responsible for the maintenance of the lab equipment?

Is there a cleaning plan for the laboratory?

X-Ray

Do you have lead aprons to protect from radiation?

Do you ask women if they are pregnant before they undergo an X-ray? (What about pregnant staff?)

What do you tell a patient before the procedure?

Appendix II: Factors Stated Within The Decision-Making Process

	Missing Equipment	Staff Resistance	Patient Resistance	Low Opinion of Necessity	Disagreement Between Hierarchies	Missing Trigger	Lack of Knowledge
Fundamental Cleaning		✔				✔	
New Cleaning Schedule		✔					
Define Responsibility						✔	
House Rules for Patients and Visitors			✔			✔	
Reminders in a Workplace				✔			
Training in Hygiene		✔			✔	✔	
Single-use Material Concerning Syringes	✔			✔	✔	✔	✔
Water Bottles			✔				
Awareness Contagious Material				✔		✔	
Emergency Kit	✔				✔		✔
X-Ray Protection	✔						✔

Mosquito Protection	✔						
No Recapping							✔
Disinfection Based on the WHO	✔	✔		✔	✔	✔	✔
Take Protective Measures	✔	✔	✔	✔	✔	✔	✔
Training Sessions		✔				✔	
Surgical Safety Checklist				✔			✔
Regular Maintenance of all Equipment	✔			✔			✔
Equipment Organization		✔				✔	
Maintenance of the Ventilator	✔					✔	
Functional Room Partitioning		✔		✔			✔
Reducing Textiles				✔		✔	✔
Mosquito Screen Operating Theatre	✔			✔		✔	
Portable Needle Disposal Container	✔			✔			✔

Checklist for Soap and Disinfectant				✔			
Liquid Soap	✔					✔	
Broad Accessibility of Disinfectant and Soap	✔			✔	✔	✔	✔
Emergency Algorithm and Training		✔		✔			
Prick Proof Needle System	✔						✔
Signs for Protective Measures		✔	✔	✔			✔
Defibrillator	✔						✔
Anonymous Feedback of the staff				✔	✔		
Removal of Textiles			✔				✔
Wristband for Patient Identification			✔	✔			
Patient Education		✔	✔				
Signs for Isolation Rooms		✔	✔	✔			
In Total	14	12	8	18	7	15	16

xxx

Accepted	9	8	3	10	5	13	10
Future Implementation	5	2	1	5	1	2	5
Declined	0	2	4	3	1	0	1

Table 8 Factors stated within the decision-making process

Appendix III: Percentage of Suggestions Attached to the Respective Factor

	Missing Equipment	Staff Resistance	Patient Resistance	Low Opinion of Necessity	Disagreement Between Hierarchies	Missing Trigger	Lack of Knowledge
Total Number of Suggestions Attached to This Factor	38,9	33,3	22,2	50	19,4	41,7	44,4
Suggestion Accepted, Immediate Implementation	25	22,2	8,3	27,8	13,9	36,1	27,8
Future Implementation	13,9	5,6	2,8	13,9	2,8	5,6	13,9
Suggestion Declined	0	5,6	11,1	8,3	2,8	0	2,8

Table 9 Percentage of suggestions attached to the respective factor