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INFLUENCE OF STAKEHOLDERS IN DECISION MAKING PROCESSES IN HOSPITALS WITH REGARD TO PATIENT SAFETY CULTURE

DOCTORAL THESIS

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ANNOTATION

This doctoral thesis focuses on the influence that stakeholders have in decision making processes in healthcare and patient safety culture. The aim of this doctoral thesis is to show how stakeholders do have an influence in decision making processes with regard to patient safety culture by differentiating self-awareness and awareness of others (scope: Germany). This research is based on a dependency model between stakeholders in decision making process and patient safety culture.

To define patient safety, a literature review was combined with the results of six semi-structured expert interviews. The common result is that patient safety culture is not easy to define. It is a wide term and a universal definition does not exist. Authors like Kohn, Wachter, Naji, Pronovost, Ball, Leape, Berwick and Dixon-Woods were considered in the research. All authors did not agree on one definition; the same result derived from expert interviews, where the experts did not agree on one universal definition. However, there are common elements in defining patient safety which are: reduction of harm for the patient, building of culture of safety, reduction of the risk for the patient and reporting of errors.

In order to analyze the influence of different stakeholders in Germany in the decision making process, a quantitative questionnaire was developed. The answers were measured on a 5-point Likert scale and the most important stakeholders were involved. The main result is that there is no clear definition of patient safety culture and that stakeholders (nurses, physicians and management) influence patient safety culture. Further there is a significant difference between self-awareness and awareness of others. Nurses and physicians consider themselves less influential than others. This is due to the fact that the closer the stakeholders are to the patient, the more the stakeholders are afraid to make mistakes.

These results show that it is a complex topic but also that there are clear significant influencers which than can help to improve the patient safety culture by optimizing the decision making process in every hospital. This doctoral thesis contains of 173 pages, 38 figures, 13 tables and 4 appendices and in total, 220 sources are used in bibliography.

**Keywords:** healthcare management, hospital management, decision making process, patient safety, patient safety culture
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LIST OF ABBREVIATIONS

AIG: American International Group

BSC: Balanced Scorecard

et al.: et alii (and others)

e.g.: exempli gratia (for example)

IOM: Institute of Medicine of National Academies

PSIs: Patient Safety Indicators

SDM: Shared decision making

SEU: Subjective Expected Utility

WHO: World Health Organization
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Introduction

Actuality of the topic

Safe care is about doing the right things right. That means that the right decisions have to be made in hospitals. The price to pay when errors occur is often high, on both, a human and a health-system level. One example of lack of patient safety is that globally, every fourth hospital is not fulfilling the hygienic standards. The Institute of Medicine (IOM) (IOM is a nonprofit organization, located in the USA, that provides global guidance on issues related to biomedical science, medicine, and health) essay “To Err is Human” in 1999 was the starting point of growing awareness and new initiatives on patient safety in the USA and around the world. The present-day discussion in Germany shows that there is still a gap between the goal of safe health care set in 1999 and reality. The overall goal is to eliminate preventable patient harm through improved systems and find solutions to previously “unpreventable” errors. Improvement in patient safety is also a major aim of hospital management these days. Nearly 10 years after “to Err is human”, RAND Europe (RAND stands for research and development) estimated that in 27 European Union member states, between 8% and 12% of patients admitted to hospital suffer from adverse effects while receiving healthcare. A report from the National Patient Safety Foundation, based in the USA, stated that 15 years after the IOM released “To Err is Human”; the work to make care safer for patients has progressed at a rate much slower than anticipated. They further state that safety issues are far more complex and pervasive than initially appreciated. In addition to the need for improved patient safety, the hospitals in Germany have a liquidity dilemma. That means the cost pressure is very high but they also feel pressure to improve patient safety.

From management perspective, one potential way to find a possible solution and/or improvement is to ensure that the right decisions are made. Speaking of business decisions, management research has shown that involvement of the right stakeholders is essential in order to achieve a certain goal.

Authors who intensively researched patient safety like Kohn, Wachter, Leape, Berwick, and Pronovost did not solve this problem how to influence decisions with regards to patient safety culture.

The fundamental conception of this doctoral thesis is to consider decisions in German hospitals, the involved stakeholders and their relevance to patient safety culture. The focus of this thesis is to analyze and understand how much stakeholders in decisions influence patient safety culture and therefore to derive recommendations for hospital management. Hence, this
A doctoral thesis is a chance to understand the influence of stakeholders in investment decisions in hospitals with regards to patient safety, further even a chance to improve patient safety and if nothing else to better understand the interest of the different stakeholders and to improve the work of managers in hospitals.

Aim

The aim of this doctoral thesis is to show how stakeholders influence decision making processes with regard to patient safety culture by differentiating self-awareness and awareness of others and to develop a conceptual framework for hospital management to understand and improve decision making processes and therefore patient safety culture.

Tasks

In order to accomplish this aim, the following research tasks were stated:

- analyze the theoretical aspects of “decision-making processes”, “patient safety” and “patient safety culture”
- analyze the existing systems and tools in hospital
- derive definition of patient safety culture from experts, hospital managers by conducting semi-structured expert interviews
- measure the influence in decision making process with regards to patient safety culture of relevant stakeholders by quantitative questionnaire
- identify the specifics of decision making processes for hospitals
- develop a dependency model with stakeholders in decision making processes
- develop a conceptual framework for hospital managers.

Research Object

Selected private, public and church-owned hospitals in Germany.

Research Subject

Stakeholders (nurses, physicians, management, buyers of investment goods in hospitals, biomedical engineers) in the decision making process and their impact on patient safety culture.
Main Hypotheses and Thesis for Defense

The key research questions for this research are: Is there a relation between involving different stakeholders in the decision making process in hospitals and improving patient safety culture? How to define patient safety culture? Is there a difference between self-awareness and awareness of others? These research questions lead to the main hypothesis driving the overall research:

Main hypothesis:

Involving different stakeholders in decision making processes in hospitals influences patient safety culture by differentiating self-awareness and awareness of others.

Thesis for defense:

- There is a difference between self-awareness and awareness of others regarding the role and consideration of patient safety culture in decision making processes.
- Self-awareness shows a higher influence on patient safety culture in decision making process than awareness of others.
- Physicians and nurses consider themselves more important than Administrative Stakeholders (Management, Buyer and Biomedical Engineers).

Methodology

From a theoretical perspective, state-of-the-art scientific literature concerning the following topics was reviewed and evaluated: decision making, decision-making concepts, group decisions, risk management in healthcare, patient safety, patient safety culture, and risk management systems in healthcare.

Based on this in-depth literature review and a subsequent empirical analysis of prerequisites, status quo, perceptions, and demands as well as experience reports, this doctoral thesis is following an exploratory approach: on the basis of lessons learned from the literature review and semi-structured expert interviews, a dependency model has been developed. The robustness of this dependency model has then been tested with questionnaires for relevant stakeholders. So, overall a mixed methods approach is applied. This indicates that both qualitative and quantitative data was collected simultaneously through the applied research methods. These research methods were semi-structured expert interviews and structured questionnaires. “Semi-structured” indicates both, open- and closed-ended questions. In order to determine the status quo of patient safety as well as define patient safety culture, semi-
structured expert interviews (within hospitals in Germany) were conducted. In this context, an expert is defined by the existence of at least three of the defined criteria.

All six expert interviews were conducted either per phone or personally. An introduction to the research topic was followed by structured and open questions and finalized by enquiring data about the hospital.

After conducting the semi-structured expert interviews, analyzing and evaluating those, the results are the operationalized definition of patient safety culture. Based on this definition, the dependency model is further advanced and taken as a basis for the development of the structured questionnaire. The structured questionnaire used consisted of and an introduction to the research topic, structured questions based on comparable questions applying a 5-point-Likert-scale as well as an inquiry of personal and key hospital data. With this questionnaire, 114 stakeholders from Germany were interviewed, either in person or via email.

All empirical data were analyzed by content analysis and statistical evaluation - predominantly via SPSS. Wherever applicable, quantitative analysis of both quantitative and qualitative data was realized. Parametric tests were applied. Hereinafter an overview of the evaluation methods applied:

- Content analysis – catchwords in the answers to open questions of expert interviews and questionnaires are evaluated and summarized,
- Expert interview content certification scheme in order to evaluate the status quo of patient safety based on expert interviews,
- Parametric tests on the quantitative data from questionnaires conducted from stakeholders – correlation analysis, regression analysis, t-test to test the differences between groups, variance analysis via SPSS.

**Novelty**

1) adjusted and further developed definition of patient safety culture,
2) differentiation of self-awareness and awareness of others with regards to considering patient safety culture in decision making process,
3) developed dependency model to show correlation between stakeholders and patient safety culture,
4) the conceptual framework, developed by the author, reflecting, how hospital managers can improve patient safety culture with focus on decision making processes.
Approbation of Results of Research (Publications, Conferences)

The main results have been provided to the scientific community for use and further research.

International Scientific Conferences:

Conferences, in which the results of the research have been reported on:


7. Ehrnsperger, Barbara: “Patient safety in healthcare: how experts are defining it, preliminary results” in Multidisciplinary Scientific Conference on Management, Marketing, and Economics, Academic Conferences Association z.s. and Czech Technical University, the Czech Republic, Prague, December 9-10, 2016;


Publications:

Papers have been published in conference proceedings and in journals.


Content of Doctoral Thesis

The aim of this research is to show how stakeholders influence the decision making processes with regard to patient safety culture by differentiating self-awareness and awareness of others.

Chapter 1 is devoted to the comparative analysis of theoretical decision making and patient safety. First part focuses on different decision-making concepts, starting with general decision making and then being more specific by analyzing theory about group decisions and further theoretic concepts about decisions in health care. The second part of chapter 1 is the comparative analysis about risks in healthcare. Risk is very closely related to quality and therefore quality in healthcare is also included into this theoretical research. More specifically this chapter is concluded with the analysis of patient safety culture and the investigation regarding the definition of patient safety in literature. Authors like Kohn, Wachter, Naji, Pronovost, Ball, Leape, Berwick and Dixon-Woods have been considered in the research.

Chapter 2 outlines and summarizes the existing systems and regulations in hospitals with regards to patient safety. One of the key elements in this chapter is the analysis of the factors driving patient safety resulting in: professionalism in hospitals, regulations in hospitals and economic environment. Chapter 2 also analyzes barriers and hurdles determining why patient safety is not as good as it should be. The highest barrier is lack of patient safety culture.

Chapter 3 starts with an overview of the research conducted, beginning with the quantitative semi-structured expert interviews and going in detail on the results of how experts define patient safety and patient safety culture. To define patient safety culture, the literature review
was combined with the results of six semi-structured expert interviews. The overall result is that patient safety and patient safety culture are not easy to define. It is a wide term and a universal definition does not exist either in literature or as a result of expert interviews. However, there are common elements in defining patient safety culture which are: reduce harm for the patient, reduce medication errors, reduce the risk for the patient and report errors. In the next step the quantitative questionnaire is outlined to collect data from relevant stakeholders in Germany. The answers have been measured on a 5-point Likert scale and all stakeholders (nurses, physicians, biomedical staff, buyers and management) have been involved. In total data from 114 stakeholders was collected with the following distribution: 30 physicians, 67 nurses, 3 biomedical engineers, 12 managers, 2 buyers of investment goods in hospitals. The last three groups were aggregated into administrative stakeholders or management. The relevant population is 656,650 workers in German hospitals, sample size represents 0.01%. The main result is that there is no clear definition about patient safety culture and that stakeholders (nurses, physicians and management) have influence on patient safety culture. Further there is a significant difference when differentiating during the evaluation of self-awareness and awareness of others, namely, there is a difference in how a certain group of stakeholders perceives themselves compared to how others perceive this group. Nurses and physicians consider themselves less influential than others. This might be due to the fact that the closer the stakeholders are to the patient, the more they are afraid to make mistakes. These results show that the topic is complex, but also indicate that there are clear significant influencers which than can help to improve patient safety culture by changing the decision making process in every hospital.

Limitations

In the course of the configuration of the empirical research, some limitations either arouse or were set in order to specify the underlying conditions:

- Limitation to care provider “hospital” instead of investigating other care providers like outpatient centers, day-care centers, elderly homes;
- Limited to hospitals without considering influence of “health care environment” including government and regulations;
- The research was conducted without considering the patients’ view;
- Decision making process was analyzed based on investment in an infusion pump which is an investment decision, not an actual procedure on the patient;
- Geographic scope of the research is Germany, which is a developed country, where everybody has access to health care system and is financially fully covered.
- Additional factors, such as individuality of hospitals, external influence factors on stakeholder’s situation, restricted number of experts interviewed and stakeholders surveyed might set further limits to the present research.
1. THEORETICAL FOUNDATION OF DECISION MAKING & PATIENT SAFETY

Health is a basic human right and taking the World Health Organization (WHO) definition into account, health care has to provide more than just curative services. The modern health systems of today have evolved over more than a century with the expectations and the demands drastically changing during this time. Still, the main aim of any health system has remained the same: to provide adequate, high-quality care to those who need it. Unfortunately, many system structures and actors have not changed with them. The task and responsibility to design a framework, set standards and define goals within which boundaries the health system and its actors perform lies with the decision makers in the hospitals and the health policies they set forth. This thesis focuses on the decisions in the hospitals and on how these decisions can influence patient safety.

1.1 Theoretical Analysis of Decision Making

Decision theory is theory about decisions. The subject is not a much unified one. To the contrary, there are many different ways to theorize about decisions¹, and therefore also many different research traditions. This chapter attempts to reflect some of the diversity of the subject. Modern decision theory has developed since the middle of the 20th century through contributions from several academic disciplines. Although it is now clearly an academic subject of its own right, decision theory is typically pursued by researchers who identify themselves as economists, statisticians, psychologists, political and social scientists or philosophers or clearly management science. There are some differences between these disciplines. A political scientist is likely to study voting rules and other aspects of collective decision-making. A psychologist is likely to study the behavior of individuals in decisions, and a philosopher the requirements for rationality in decisions. In management science, decisions are analyzed with regards to economic results. However, all of these views have common aspects, and the subject has gained from the variety of methods that researchers with different backgrounds have applied to the same or similar problems which is summarized in the following chapter.

In general, human choice behaviors during social interactions often deviate from the predictions of game theory. This might arise partly from the limitations in the cognitive abilities necessary for recursive reasoning about the behaviors of others. In addition, during

iterative social interactions, choices might change dynamically as knowledge about the intentions of others and estimates for choice outcomes are incrementally updated via reinforcement learning. Some of the brain circuits utilized during social decision making might be general-purpose and contribute to isomorphic individual and social decision making\(^2\). Overall, decision theory is a wide area in science, with a long tradition. The first idea of decision making theory reaches back over hundreds of years and is still relevant at present. For the topic of this thesis, in respect to how decisions are made in hospitals it is substantial to understand the theoretical foundations.

Until the 1990s, most game theorists relied on equilibrium analysis to predict strategies. Players are considered to be in equilibrium when they correctly forecast what others will do and pick a utility-maximizing strategy. In the history of decision sciences, the theory of games, developed by J. von Neumann and O. Morgenstern,\(^3\) represents such a milestone. All the approaches in the 1950s and 1960s were based on mathematical models and algorithms to decision-making and problem-solving in the fields of management\(^4\). The modern theory of individual decision-making under risk, as formulated by Bernoulli in 1738\(^5\), axiomatized by J. von Neumann and O. Morgenstern and generalized by Savage\(^6\), has emerged from a logical analysis of games of chance, not from a psychological analysis of choice behaviour. The theory has been developed primarily as a normative model that describes the behaviour of an idealized rational person\(^7\), not as a descriptive model that explains the behaviour of real people. As one noted economist put it, the theory "has a much better claim to being called the logic of choice than a psychology of value"\(^8\).

Rational models were discussed from the classical economists (e.g. Adam Smith) with a view on rational behavior of agents which maximize their utility – the homo oeconomicus. A more scientific approach of Pascal and de Fermat shows a calculation of probabilities and Bernoulli laid the foundation of risk science by examining random events\(^9\). Decision theory is the study of how choices are and should be made in a variety of different contexts. Decision theory

provides a rational framework for choosing between alternative courses of action when the consequences resulting from this choice are imperfectly known. This framework is in particular important for hospital management, because decisions are made without knowing the consequences for patient safety.

The tension between logical and psychological considerations and the interaction between normative and descriptive arguments have characterized decision theory from its early days. Bernoulli and Cramer introduced concave utility functions in order to explain for money to rationalize risk aversion and reconcile individual differences in risk bearing with the concept of mathematical expectations. Similarly, the modern theory of personal probability, developed by Ramsey\(^{10}\), De Finetti\(^{11}\) and Savage\(^{12}\), can also be viewed as an attempt to generalize decision theory so as to permit individuals to assign different probabilities to the same event - if they do not have the same information or if they hold different beliefs. Hence, the normative analysis of value and belief has been extended to accommodate psychological considerations. On the other hand, it has been widely believed that an adequate normative theory of choice must also provide an acceptable descriptive model because (i) people are generally effective in pursuing their goals and (ii) more effective individuals, organizations and modes of action are more likely to survive than the less effective ones. Indeed, the expected utility model has been extensively used to explain personal, economic and political decisions\(^{13}\). These applications have been based on the assumption\(^{14}\) that the axioms of rational choice (e.g., transitivity, substitution) represent an acceptable idealization of human behaviour and that the expected utility model\(^{15}\), which follows from these axioms, provides a reasonable approximation of individual decision making under risk or uncertainty.

This position has been challenged by two lines of evidence. The first, initiated by the French economist Maurice Allais\(^{16}\), indicates that the axioms of independence and substitution, which underlie the expected utility model, are consistently violated in a predictable manner. The second line of evidence came from psychological experiments showing that the preference order between prospects depend critically on the manner in which they are represented or framed. This work challenges not only the axioms of expected utility theory but the more


\(^{13}\) Lee; Seo: Strategic Decision Making, 2016.

\(^{14}\) Lee; Seo: Strategic Decision Making, 2016.

\(^{15}\) Lee; Seo: Strategic Decision Making, 2016.

\(^{16}\) Lee; Seo: Strategic Decision Making, 2016.
fundamental principle that preferences are independent of the manner in which the choices are described. This theory follows closely the work of Tversky and Kahneman.\textsuperscript{17,18}

The options among which one must choose are defined by their possible outcomes and the probabilities (or contingencies) with which they occur. The outcomes and the contingencies associated with a particular choice can be described or framed in different ways. The frame that a decision maker adopts is controlled partly by the formulation of the problem, and partly by the decision maker's norms, habits and personal characteristics.\textsuperscript{19} Alternative frames for a decision problem may be compared to alternative perspectives on the same visual scene.\textsuperscript{20} Veridical perception requires that the perceived relative height of two neighbouring mountains, say, should not reverse with changes of vantage point. Similarly, rational choice requires that the preference between options should not reverse with changes of the frame. Because of imperfections of human perception and decision, however, changes of perspective often reverse the relative apparent size of objects and the relative desirability of options.

1.1.1 Decision Making Concepts
There are several ways to differentiate the various disciplines of decision-making.\textsuperscript{21} Common is the distinction between prescriptive/normative and descriptive/positive decision-making. The overview of Laux\textsuperscript{22} shows the distinction between the two main theories and in more detail that the prescriptive theory is underlined with tangible guidelines and models.

Laux model was based on the research of Dillon\textsuperscript{23} who initially developed the two dimensions of descriptive and normative/prescriptive decision making theory:

- Descriptive (e.g. Laux, Salinger)
- Prescriptive / Normative (e.g. Savage, Kahnemann and Tversky)

\textsuperscript{17} Tversky, Amos; Kahneman, Daniel: The Framing of Decisions and the Psychology of Choice The Framing of Decisions and the Psychology of Choice, 1981.
\textsuperscript{18} Kahnemann, Daniel; Tversky, Amos: Prospect theory: an analysis of decision under risk, in: Econometria (March), 1979, pp. 263–291.
The field of decision making can be loosely divided into two parts: the study of prescriptive models and the study of descriptive models. Prescriptive decision scientists are concerned for making optimal decisions. Descriptive decision researchers are concerned with the bounded way in which the decisions are actually made.

The descriptive theory does not focus primarily on the decision making problem and how to resolve it; it aims to describe the decision in reality. How the person made the decision and the influencing factors based on irrational acting. The foundation for the descriptive decision making is rooted as well in the behavioral and social science. The canonical theory of choice—Subjective Expected Utility (SEU)—owes its inception to the work of Savage, building on previous contributions by De Finetti, Ramsey and von Neumann and Morgenstern. It offers a homogenous treatment of both decisions under “risk”—situations in which the decision maker has knowledge of, or holds firm beliefs regarding, the objective probabilities of all events pertinent to the success of his or her actions—and decisions under

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29 Ramsey, Frank: Truth and probability, 1931.
“uncertainty”—in which he or she does not. In its non-normative incarnation, it proposes at the very least that agents can be described as if:

- associating with the possible consequences of the acts available to them two numerical quantities:
  - “utility” corresponding to the degree to which they would desire the outcome to occur and
  - “subjective probability” corresponding to their degree of confidence in the occurrence of the outcome given the performance of the act, a degree of confidence which may or may not be given by a corresponding assessment of objective probabilities;
- being such that their preferences between acts, and hence their dispositions to choose certain acts over others, are determined by these quantities in such a way that acts are ranked by their subjective expected utility.

Ontologically bolder incarnations of the view have it that agents are so describable because they really do have degrees of belief and desires, introspectively familiar psychological states, that determine their preferences and choices in such a manner.

A number of important formal results, known as “representation theorems”, show that this claim about describability can be derived from a set of prima facie plausible general principles, aka “postulates” or “axioms”, pertaining to the agents’ preferences over acts. Furthermore, not only are these axioms collectively sufficient to derive SEU’s claim, but a significant proper subset of them also turn out to be individually necessary. Unsurprisingly then, much of the work on assessing the empirical adequacy of SEU has focused on the testing of the aforementioned axioms. Such tests could, in the best case, undermine a key reason to endorse the claim and, in the worst, provide grounds to reject it.

Prescriptive theory commands people, how they should make decisions. Prescriptive theories warn that if we do not follow their rules we will suffer dire consequences. The theory assumes a logical, mathematical, and statistical view of the world, and idealizes decision

makers as superhuman, rational, emotionless beings. The foundation of the prescriptive concept is the subjective expected utility (SEU) theory, a doctrine of choice based on psychology (subjective), probability theory (expected) and economics (utility). SEU is not empirical, and humans more often than not disregard the SEU hypothesis. SEU provides the goals for algorithmic procedures to decision making. Some of the roots of the SEU theory are in the theory of inductive inference and in statistical decision theory, also called subjective decision theory.

Important developments in decision theory took place over the recent decades: the trend to a behavioral approach was supported by psychological science. Kahnemann and Tversky did contribute a lot to this recent development. A good example of their work is published in the famous book “Thinking Fast and Slow”. Kahnemann differentiates two systems:

- System 1 operates automatically and quickly, with little or no effort and no sense of voluntary control.

- System 2 allocates attention to the effortful mental activities that demand it, including complex computations. The operations of system 2 are often associated with the subjective experience of agency, choice, and concentration.

In a normal situation, the human structure is based on system 1 and will only use system 2 if it is really necessary.

Agency Theory applies to situations where one or more persons (the principals) engage another person or persons (the agents) to perform some service on their behalf, which includes delegating some decision-making authority to the agent. “If both parties to the relationship are utility maximizers then there is good reason to believe the agent will not always act in the best interests of the principal”. Agency Theory predicts that the agency conflict may be reduced when the owner is involved in management. Principal-agent conflict may be less pronounced in the case of smaller organizations where it is more likely that the principal and agent will have a close relationship. On the other hand, it is also true that managers in small firms may be more isolated from the market discipline due to a closer relationship with their principals. Such isolation may result in entrenchment. Entrenchment is, in turn, likely to have a negative

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38 Kahnemann, Daniel: Thinking, Fast and Slow, 2011.
impact on performance. Furthermore, isolation from market disciplines and entrenchment-induced inertia is likely to encourage a weak culture and weak leadership as well as a myopic strategy. The agency theory is a supposition that explains the relationship between principals and agents in business. Agency theory is concerned with resolving problems that can exist in agency relationships due to unaligned goals or different aversion levels to risk. The most common agency relationship in finance occurs between shareholders (principal) and company executives (agents).

1.1.2 Group-Decision Making

Group decision-making had a tradition of research in social psychology\(^{39}\). Reviews have underlined the fact that small group research in social psychology has waned over the years, but has been revitalized within the domain of organization, as Steiner\(^ {40}\) had partially predicted. The trend is indeed to use teams in organizations more heavily. The current assumption is that groups make better decisions than individuals\(^ {41}\). For historical reasons, there is also probably a desire to avoid the dominance of autocratic individuals who decide for everyone else\(^ {42}\). Thus, teams making important strategic decisions are seen as crucial to the sustainability of organizations. Therefore the use of teams in organizations has become prevalent\(^ {43}\), and strategic decisions require being made by teams given the high stakes involved. Nevertheless, both advantages and disadvantages of team decision-making have to be considered. Decisions made by teams are thought to be advantageous for at least two reasons: the pooling of knowledge, expertise, and skills, and the commitment to the team and to its decisions (e.g. team cohesion)\(^ {44}\). First, the pooling of knowledge, skills, and expertise is critical to the quality of decisions taken by teams, and this pooling can only occur if team members share information. In turn, the more diverse team members are\(^ {45}\) the greater the potential amount of information could be pooled. Both pooling of knowledge and team diversity have been studied in interaction, i.e. to what extent diversity in teams influences the

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\(^{44}\) Stingl, Verena; Geraldi, Joana: Errors, lies and misunderstandings: Systematic review on behavioural decision making in projects, 2017.

\(^{45}\) Stingl, Verena; Geraldi, Joana: Errors, lies and misunderstandings: Systematic review on behavioural decision making in projects, 2017.
sharing of information. Second, it has been argued that team members have a greater propensity to support group decisions if they participated and are listened to thus reinforcing the commitment to present and future decisions. These decisions, taken and accepted by all members, have better chances to be successfully implemented.

These advantages may become disadvantages. The diversity of perspectives, skills, expertise, opinions, status, have to be integrated, which can lead to dissent, disagreement, or conflict. Although the conflict in itself is presumed to help decision quality⁴⁶, it can be detrimental as well, especially if group members get involved in personal disputes. In naturalistic environments, team members are confronted with uncertainty and ambiguity, which can be a source of stress. In turn, stress and autocratic leadership in a highly cohesive group that feels invulnerable can provide antecedents for what Janis has called “groupthink”⁴⁷ to describe defective decision-making. The group members favor unanimity above the realistic assessment of alternatives, thus suffering momentarily from a deterioration of mental efficiency, reality testing, and moral judgment. Despite these possible drawbacks, group decision-making is considered as one of the more important aspects of group performance⁴⁸ and of all managerial activities. The processes usually involved are gathering and sharing information, creating and identifying alternative courses of action, choosing among these alternatives by integrating the diverse perspectives of members, and finally implementing the decisions⁴⁹. The prescriptive approach mentioned earlier has recommended a certain number of steps, a number oscillating between four and eight. Janis & Mann⁵⁰ have extracted seven criteria from the extensive research literature on prescriptive decision-making: Based on these seven steps, Janis has extracted four steps, which he considers as a descriptive model of decision-making ((a) formulating the problem, (b) using information resources, (c) analyzing and reformulating, (d) evaluating and selecting), and which, when carefully followed, characterize vigilant decision-making, preventing decision-making groups from committing major mistakes⁵¹.

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⁴⁶ Guzzo; Dickson: Teams in organizations: recent research on performance and effectiveness, 1996.
⁴⁹ Guzzo, Richard; Dickson, Marcus: Teams in organizations: recent research on performance and effectiveness, 1996.
Researchers have attempted to empirically test either all or part of these. Because the prescriptive approach takes a long time in group decision-making processes and because strategic decision-makers in a naturalistic environment do not always have time to process all seven steps, some of the steps get truncated or overlooked. But one can argue that the core of group decision-making activities is alternative generation and alternative evaluation. Indeed, even when team members have to identify the problem or discuss the objectives (or the strategy), they go through a process of proposing several alternatives, of evaluating each of these alternatives, and of contributing to the discussion with the information they think could add value to the decision. Furnham summarizes decision-making as the process of generating alternatives and then choosing among them; Zander (1994) states that decision-making is the selection of a preferred solution from several alternative solutions.

Decisions in organizations are also made by humans and therefore reflect human behavior in organizations. According to March and Simon, these behaviors can be grouped into three classes:

a) Organization members are primarily passive instruments; performing their work and accepting direction, but not initiating actions

b) Organization members bring their own attitude, values and goals into the organization.

c) Organization members are decision makers and problem solvers.

The listed classification above reflects different types of decisions in organizations; therefore, a robust process must enable decision-making and decision execution. Group decision-making had a tradition of research in social psychology. Reviews have underlined the fact that small group research in social psychology has waned over the years but has been revitalized within the domain of organization psychology, as Steiner had partially

52 Stingl; Geraldi: Errors, lies and misunderstandings: Systematic review on behavioural decision making in projects, 2017.
53 Stingl; Geraldi: Errors, lies and misunderstandings: Systematic review on behavioural decision making in projects, 2017.
56 Laughlin, Patrick: Social choice theory, social decision scheme theory, and group decision-making, 2011.
predicted. The trend is indeed to use teams in organizations more heavily\textsuperscript{65,66,67}. This fact is used in business administration more and more since group work and group decisions are getting more important. The current assumption is that groups make better decisions than individuals\textsuperscript{68,69}. For historical reasons, there is also probably a desire to avoid the dominance of autocratic individuals who decide for everyone else\textsuperscript{70}. Thus, teams making important strategic decisions are seen as crucial to the sustainability of organizations\textsuperscript{71}.

The particular focus of this thesis is the decision to buy an investment good in the hospital, which is a strategic decision. A strategic decision is defined as an important decision that deals with complex and ambiguous issues and requires the commitment of a large amount of resources from the organization\textsuperscript{72}. The complexity and ambiguity surrounding a strategic decision is usually too overwhelming for only one person to deal with it, thus strategic issues are often handled by top management teams\textsuperscript{73}. Priem and Price\textsuperscript{74} point out that in strategic decision-making, the "correctness" of a possible solution is difficult to verify. In her study on strategic decision-making in high-velocity environments, Eisenhardt\textsuperscript{75} found that executive teams use real-time information, which gives them “an intimate knowledge of their business”. They simultaneously generate and evaluate multiple alternatives because of time pressure, which enables them to process strengths and weaknesses quicker and makes sure they don't

\textsuperscript{63} Levine, John; Moreland, Richard: Group Socialization: Theory and Research.
\textsuperscript{64} Steiner, Ivan: Paradigms and Groups, 1986.
\textsuperscript{65} Bettenhausen, Kenneth: Five years of group research: What we have learned and what needs to be addressed, in: Journal of Management 17 (2), 1991, pp. 345–381.
\textsuperscript{66} Guzzo, Richard; Salas, Eduardo: Team effectiveness and decision making in organizations, 1995.
\textsuperscript{70} Davis, James; Hinsz, Vinzent: Current research problems in group performance and group dynamics, in: Group decision making 25, 1982, p. 557.
\textsuperscript{71} Dooley, Robert; Fryxell, Gerald: Attaining decision quality and commitment from dissent: The moderating effects of loyalty and competence in strategic decision-making teams, in: Academy of Management Journal 42 (4), 1999, pp. 389–402.
\textsuperscript{73} Mintzberg, Henry; Raisinghani, Duru; Théorêt, André: The Structure of « Un-structured » Decision Processes, in: Administrative Science Quarterly 21 (June), 1976, pp. 246-275.
leave "a stone unturned". They focus their attention on their most experienced members' opinion. They are used to work with each other in turbulent conditions, but to deal with high-stakes decisions, they have to cope with anxiety, actively deal with conflict resolution, and build confidence.

One of the central aspects of team decision-making is information, whether information search or information processing. In fact, the quality of the information resources available to team members may determine whether decision-making will be successful or not. There is a high expectation for groups to perform in their decision tasks more effectively than individuals would, providing they share their respective knowledge, skills, expertise, and abilities. This suggests that diversity of group members is an important factor for the quality of the decisions, although it does not preclude homogeneous teams to have diverse perspectives to share. Each member does not have the exact same amount of knowledge or the exact same amount of information in his or her possession. In addition, due to limits on information processing capabilities, group members, experts or not, may not be able to evoke all the relevant information they would want to consider.

Despite the promising potential to have more information resources available in a decision-making team, there is evidence that this potential remains often unrealized. The major findings by Stasser and Titus are that the sharing of information is inhibited by two kinds of hindrance: a) group members discuss shared information (i.e. information known by all the group members before the discussion starts) more than unshared information (i.e. information held only by one member); b) the discussion is biased in favor of the initial or current preferences of the group members, as developed by group members, based on some subsets of information that they are aware of before the discussion. Stasser and his colleagues have continued to investigate the first hindrance. Stasser and Titus found that there is a better chance for unshared information to arise in the discussion if the amount of information available to group members is not too high and if unshared information constitutes two-thirds

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of the total amount of information available. Stasser, Taylor, & Hanna\(^{80}\) found that the larger the size of the group, the fewer chances for unshared information to be brought in the discussion, and structuring the discussions only helps to further discuss already shared information. Stewart & Stasser\(^{81}\) suggest that when expert roles are assigned, more of the unshared information is recalled and correctly recognized by group members after the discussion. The fact that experts bring the unshared information forth is seemingly crucial, as group members will not give credibility to unshared information if not provided by a designated expert\(^{82}\). Straus, Parker and Bruce\(^{83}\) confirm that groups are unable to take uniquely held information into consideration for the decision, even if it has been shared during the discussion.

The second hindrance to effective sharing of information in groups is what Schulz- Hardt\(^{84}\) have called the “confirmation bias”: it means that individuals request or seek only information that will support a pre-selected alternative; to be in a group accentuates the tendency to prefer supporting information rather than conflicting information. Schulz- Hardt found evidence of this phenomenon in their studies, but only within homogeneous groups. Indeed, heterogeneous groups, defined in this particular context as groups comprising either one or two minority members, had less of a confirmation bias. Due to processes such as divergent thinking\(^{85}\) or conversion theory, all stakeholders, even if they did not influence the whole decision of the group successfully, at least led the group to have a more balanced information search.

### 1.1.3 Decision Making in Healthcare

Healthcare delivery is undergoing a transformation from care in single settings and providers to care across multiple providers and settings. These new approaches to care delivery bring new complexities around how healthcare delivery needs to be structured and managed. For example, managing patients with chronic illness in a collaborative manner requires the

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82 Wittenbaum; Hollingshead; Botero: From cooperative to motivated information sharing in groups: moving beyond the hidden profile paradigm, 2004.
integration of processes of care delivery such as information exchange and decision-making over time and space and across providers of different skillsets and expertise. However, a substantial gap exists between how care delivery should be provided and how it is actually provided. Key elements of health care delivery such as support for collaborative care delivery and patient participatory medicine remain as challenges. A large part of the problem is that the healthcare delivery system is not designed to support the above-mentioned endeavors. Despite our best attempts at meaningful health-care transformation, we continue to struggle with unintended consequences from reform efforts. Examples of these unintended consequences include a continued prevalence of medical errors, despite dedicated efforts and initiatives to prevent them.

In fact, at times, the very solutions we implement to solve specific issues become the basis for further unanticipated problems. For example, the 1999 Institute of Medicine Study “To Err is Human” brought attention to the prevalence of medical errors. A follow-up Institute of Medicine (IOM) study in 2001 advocated increased use of information technology as a driver to healthcare reform, including the reduction in medical errors.

As a result, more Health Information Technology (HIT) strategies put in place to reduce medical errors. However, studies began to emerge suggesting HIT could in fact be causing further medical errors. In an ironic turn, the very technologies we designed and implemented to reduce classic errors led to a whole new category: technology-induced errors. A Complex Adaptive System (CAS) is a system that displays properties such as emergent behaviors, non-linear processes, co-evolution, requisite variety, and simple rules. As a system becomes more complex, the number of components and interactions between each component increases both within the system and between the system and its environment. Healthcare can be classified as a CAS because the various elements such as care delivery, education, and policy consist of a series of interacting parts that work in non-linear and evolving ways. Collaborative care delivery is a specific healthcare process that represents a CAS due to the fact there are multiple participants separated by time and space, and the rules of engagement for how they should work together may be emerging and evolve over the course of time.

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86 Kuziemsky, Craig: Decision-making in healthcare as a complex adaptive system, in: Healthc Manage Forum 1, 2016, pp.4-7.

87 Kohn, Linda; Corrigan, Janet; Donaldson, Molla: To err is human: Building a SaferHealth System, Bd. 6, 1999.
Many stakeholders and actors influence decisions in healthcare\(^\text{88}\). The following paragraph outlines the overall system of healthcare: a system is defined as an organized set of components, performing a unique behavior, where each component contributes to the system and all are interdependent. Groups of components may form subsystems and the whole system is affected if one component changes or is removed. Furthermore, the system has an environment with which it exchanges inputs and outputs.\(^\text{89}\). Following systems theory, a social system of its own right performs a task unique to the system and which no other system can perform; and it has autonomy not controllable externally\(^\text{90}\).

![Diagram of the healthcare system and its environment](source: Authors illustration, based on Güntert, 2008\(^\text{91}\))

As represented in the figure above, the components of the health care system are the patients, the service providers, the insurances, and government. Its environment is the economic, legal, historical and cultural structures of society\(^\text{92}\). The inputs are represented not only by resources but also by regulations and expectations of the people entering the health system, while the outputs comprise individual and public health, productivity and revenues, research and


medical advancement, among others. Typically, the components of the health care system are called actors and/or stakeholders. They are the ones forming relationships and exchanging fees and services. Consequently, they all follow their own sets of goals, adhere to specific principles and define their expectations according to their view of the system. Within such a system it is always a shared decision making. Shared decision making (SDM) is a process by which a healthcare choice is made jointly by the practitioner and the patient and is said to be the crux of patient-centered care. A number of surveys have shown that a significant proportion of patients would like to play an active role in decisions concerning their health. A process by which a healthcare choice is made jointly by the practitioner and the patient is defined as shared decision making (SDM).

The talent to solve problems is essential to management. Problems and making decisions are a constant component of a manager’s work. A manager’s job is to solve problems and to make decisions; in fact, a manager’s worth is assessed by how well she/he is able to do this. Healthcare managers, in particular, have to deal with a much larger number of and harder decision-making and problem-solving challenges. As concepts, problem-solving and decision-making could be regarded as a result of strategic thinking. It is well known that the process of strategic thinking ends with the action of making a decision. A decision can be defined as a choice made among given options.

Charles, Whelan and Gafni analyzed the three basic models of decision making in healthcare. The most common one, they say, is the Paternalistic Model. They describe the model as particularly one-sided and therefore stressful to both doctor and patient. This approach considers the ailment a problem that can be solved in the same manner as a

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94 Légaré, France; Dawn, Stacey; Kryworuchko, Jennifer; Graham, Ian; Turcotte, Stephane: Interventions for improving the adoption of shared decision making by healthcare professionals, in: Cochrane Database of Systematic Reviews (5), 2010, p. 46.
99 Toygar; Akbulut: An assessment of the decision-making and problem-solving skills of hospital administrators, 2013.
100 Toygar; Akbulut: An assessment of the decision-making and problem-solving skills of hospital administrators, 2013.
Without involving the patient or recognizing his/her personal preferences, the doctor will make the best decision for the patient based on his medical expertise. Some authors have argued let a patient may actually prefer this approach. However, this would require the preceding discussion of alternative decision-making models, which is normally not likely at the beginning of a doctor-patient relationship.

The Paternalistic Model is not a co-operation between doctor and patient, at all. While the focus is on the doctor in this particular model, the focus of the Informed Model is on the patient. The main thing the doctor has to do is to provide information. There is a doctor communicates comprehensively all treatment options and the benefits and risks associated with them. In the following deliberation, only the patient will make a final decision based on the information provided to him/her. The patient may be aided in his decision-making process by friends, relatives or his/her spouse, but not necessarily so. According to his/her own preferences, it may very well be that two patients with the same ailment decide on two different treatments in that model.\(^{101}\)

Therefore, Shared Decision-Making is the preferred method for many medical practitioners. This model focuses on an interaction between doctor and patient who go through all stages of the decision-making process together. Both sides can propose treatment preferences and explain the rationale behind them. This should establish an environment of mutual trust between the doctor and the patient.

Table 1. 1: Three decision-making models: paternalistic, shared and informed model

<table>
<thead>
<tr>
<th>Analytical stages</th>
<th>Paternalistic model</th>
<th>Shared model</th>
<th>Informed model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information Exchange</td>
<td>Flow: One way</td>
<td>Two way</td>
<td>One way</td>
</tr>
<tr>
<td></td>
<td>Direction: Doctor → Patient</td>
<td>Doctor → Patient → Doctor</td>
<td>Doctor → Patient</td>
</tr>
<tr>
<td></td>
<td>Type: Medical</td>
<td>Medical and personal</td>
<td>Medical</td>
</tr>
<tr>
<td></td>
<td>Minimum amount: Legal requirements</td>
<td>Anything relevant for the decision making</td>
<td>Anything relevant for the decision making</td>
</tr>
<tr>
<td>Deliberation</td>
<td>Doctor alone or with other doctors</td>
<td>Doctor and patient (plus potential others)</td>
<td>Doctor and patient (plus potential others)</td>
</tr>
<tr>
<td>Who makes the decision?</td>
<td>Doctors</td>
<td>Doctor and patient</td>
<td>Patient</td>
</tr>
</tbody>
</table>

Source: Authors design, based on Charles, Whelan and Gafni 1999, p. 781.

Shared decision-making (SDM) is a complicated procedure, though, especially because it includes both medical practitioners and patients. The choice of the treatment for an ailment is first and foremost up to the patients. This is of course not simple, as the patients may or may not have any medical expertise. Nevertheless, all of them will have some initial preference concerning the treatment, regardless whether it is well-informed or not. Therefore, the medical practitioners must transform their patients’ initial preferences into informed preferences.

Elwyn suggest the procedure that includes three talks with the patient about the options for treatment. This is the first talk is supposed to be a Choice Talk, i.e. the medical practitioner informs the patient about reasonable options for his/her treatment. Since this is a planning talk, the medical practitioner will not impose any ideas on the patient. After presenting the options, it is even better for the medical practitioner to step back and summarize the options and to offer choices.

This, however, may lead to a misconception on the side of patient. He or she may consider the medical practitioner as incompetent and incapable of offering a definite solution. Therefore, all options must be presented in the same well-informed way, including possible consequences of the treatment. The medical practitioner must monitor the patient's reaction carefully and be willing to offer more information if necessary. However, if the patient enquires of the medical practitioner what to do, closure of the talk should be deferred.
Another way of looking at it is the Option Talk. This talk should provide the patient with a structure on which to base his/her decision. Therefore, the conversation should take place in a structured way. Elwyn\textsuperscript{102} suggest the following steps:

a) Check knowledge. Even if some patients may appear well-informed, it is best to assume that they are not and to check their before the actual talk.

b) List options. This will provide structure to the following talk.

c) Describe options. This step is meant to generate dialogue and explore preferences. Here, the medical practitioner must point out the differences between the options (surgery or medication). The various points that speak for or against different options are the main focus of shared decision-making, as the authors point out. Both, harms and benefits must be made clear.

d) Provide patient decision support. The authors suggest to use such instruments as decision boards or option grids.

e) Summarize. According to the authors, the medical practitioner should make a list of the various options and determine whether the patient understood the point by asking for reformulations. This so-called “teach back method” has proven to be a good test for the occurrence of any misconceptions.

Only then, after the patient has been very clearly informed about the rationale behind each suggested treatment, is it possible for the patient to make a decision based on the shared information. However, not only the information should be shared. The patient good should not be left alone with the decision.

Therefore, the focus of the Decision Talk, is on preferences. After giving the patient time to reconsider, the medical practitioner elicits a preference and move the patient to making a decision, unless the patient is still in doubt and it is preferable to defer a decision. The following figure illustrates the framework of decisions in clinical practice.

\textsuperscript{102} Elwyn, Glyn; Frosch, Dominick; Thomson, Richard: Shared decision making: A model for clinical practice, in: Journal of General Internal Medicine 27 (10), 2012, p. 1364.
However, not all patients are capable of making such a decision that is required of them\textsuperscript{104}. The patient's capability to make decisions is usually judged by three criteria, following Appelbaum\textsuperscript{105}.

Criterion 1: Outcome

This is the most simplistic approach and judges' capability based on the outcome of the decision-making process.

Criterion 2: Status

The next approach is less simplistic, but not less questionable. The patient's capability this determined on the basis of his/her membership of a particular social group. Education, chronological or mental age, profession or other characteristics are used under the presence that a) the group is homogeneous and b) the characteristics shared by the members of the group are helpful in making such a decision. However, there is no empirical support for any of these assumptions.

Criterion 3: Functionality

It is one of the tasks of the talks mentioned above to determine whether a person understands, knowledge, and abilities our sufficient to make the required decision. This means that the medical practitioner/s present at the talk must evaluate the following abilities:

\begin{table}[h]
\begin{tabular}{|c|c|c|}
\hline
\textbf{Deliberation} & \textbf{Decision Support} & \textbf{Informed Preferences} \\
\hline
\textbf{Initial Preferences} & \textbf{Choice Talk} & \textbf{Option Talk} & \textbf{Decision Talk} \\
\hline
\end{tabular}
\end{table}

\textbf{Figure 1. 3: Decision-making framework in clinical practice}

\textit{Source: Authors illustration, based on Wong et al. 1999, p. 444\textsuperscript{103}.}

\textsuperscript{103} Wong, Jason; Clare, Ian; Gunn, Maria; Holland, Arvin: Capacity to make health care decisions: Its importance in clinical practice, in: Psychological Medicine 29 (2), 1999, p. 439.

\textsuperscript{104} Dastidar, Joyeeta; Odden, Andy: How Do I Determine if My Patient has Decision-Making Capacity?, in: The Hospitalist (8), 2011.

\textsuperscript{105} Dastidar, Joyeeta; Odden, Andy: How Do I Determine if My Patient has Decision-Making Capacity?, in: The Hospitalist (8), 2011.
Communication of a choice: If the patient is not capable of communicating his/her choice, he/she is certainly not capable of making such a decision. However, a mere expression of a choice does not indicate whether enough consideration has been given to the issues in question.

Understanding relevant information: It is a matter of course that provided information must be understood by the patient. However, in healthcare this standard is only applicable if explanations in broad terms and simple language are sufficient to convey the nature and purpose of the treatment. Even if the matter is explained in plain language, not all patients will be able to sufficiently weigh the risks and benefits of the different options presented to them. This is a basic requirement for a successful talk.

Reasoning and rational manipulation of information to arrive at a decision: The authors state that when a patient is required to make a health care decision, the mere appreciation of the information provided is not good enough. The patient must show factual understanding. The patient must recognize that he or she has an ailment that can be cured by a particular treatment. If the doctors recognize a lack of insight or a limited understanding, these might even be components of major psychiatric disorders.106

To avoid any trouble concerning one’s own decision as a patient, either of two possibilities will take place.

Advance health care statements: This means that patient needs to have made a valid statement in the case he/she is no longer capable to make such decisions. Advance statements of health care are most respectful of an individual’s right to self-determination because they are direct expressions of personal wishes.

Decision-making by proxy: Two general approaches have been adopted for proxy decision-making, ‘best interest’ and ‘substituted judgment.’107 The ‘best interest’ approach is based on the ethical principle of beneficence. The proxy — either a relative or some court-appointed proxy — make a decision that best reflects the person’s choice if he/she still had the capacity to do so. Decision-making may be made through informal proxies, such as family members or

106 Wong, Jason; Clare, Ian; Gunn, Maria; Holland, Arvin.: Capacity to make health care decisions: Its importance in clinical practice, in: Psychological Medicine 29 (2), 1999, p. 439.

carers, by proxies appointed by the patient through a legal mechanism, by court-appointed guardians, or by the court itself.

If a patient's capabilities seem dubitable, matters become complicated. Treating a patient without his/her consent or consent of a proxy is rarely possible. The following illustration shows the questions that need to be asked if a patient seems not to be capable to make a decision.

![Diagram](source)

**Figure 1.4: How to include a non-capable patient in decisions**

*Source: Authors illustration 2017*
The patient's interest is not the only main factor in decision-making on the side of the hospital. Some treatments are very expensive, and a doctor who enters a talk with a patient might be required to withhold information about expensive treatment alternatives due to a cost-effectiveness analysis (CEA). This very technical approach considers the additional cost per extra unit of “effect” in terms of, for example, quality-adjusted life-year (QALY) gained. The basis for this is the so-called incremental cost-effectiveness ratio (ICER). This ratio represents a threshold value that determines which interventions do not improve efficiency and which do.  

Cleemput et al. (2011) who researched the ICER found it to be insufficient as a measure for evaluating an intervention's value. Apart from any ethical discussions, there are fundamental differences and evaluation of the value of a quality-adjusted live-year between different healthcare systems. In a national health service system, as in the United Kingdom, where healthcare budgets are well-defined and social security systems, such as in Germany, where the maximum budget depends on the money paid into the system.

Additionally, no healthcare decision can be reduced to a simple equation. The ICER is not meant to take societal values into account.

On the other hand, neglecting economic considerations may be considered unethical, as spending resources on one treatment reduces the resources for another one. If it is the main purpose of the ICER to provide transparency, another method might suffice.

This could be the introduction of a modified a balanced scorecard. Authors Kaplan and Norton devised this rather simple, but effective instrument to take all aspects into account. The balanced scorecard (BSC) helps to establish the necessary balance between four crucial factors in a decision-making process.  

The BSC is rather a method than a clearly defined instrument. The authors explicitly state that it is not meant to be a strait jacket. It works with both financial and non-financial indicators that are included in a model that considers the at hand from four different points of view. In healthcare, these will be the patient's perspective, the feasibility of the treatment, the doctor's perspective and possibly also a financial perspective.

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To arrive at a truly balanced scorecard, it is important that the key figures of each perspective are connected to the financial objectives in a cause-effect relationship. If certain measures are too costly and drain the budget too much, the BSC will also yield the information that they cannot be realized, if the budget is fixed. However, the balanced scorecard can always be adapted to the present circumstances.

There are also theories, which are saying that there should be “No decision about me, without me”. This can only be realized by involving patients fully in their own care, with decisions made in partnership with clinicians, rather than by clinicians alone. Shared Decision Making is a process in which patients, when they reach a decision crossroads in their health care, can review all the treatment options available to them and participate actively with their healthcare professional in making that decision. With current, clinical information, relevant to their particular condition, about all the options available to them patients are helped to work through any questions they may have, explore the options available, and take a treatment

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route which best suits their needs and preferences. To achieve this, we are encouraging the development of new relationships between patients, nurses and clinicians, where they work together, in equal partnership, to make decisions and agree a care plan. In addition, we want to put Shared Decision Making not only at the care level, but also at the strategic and commissioning level, with patients involved in the co-design, co-commissioning and co-production of healthcare. Without these changes, one cannot achieve the required transformational culture change to support Shared Decision Making.

1.2 Theoretical Analysis of Risks in Healthcare
Medication error (ME) is defined as a failure in the treatment process causing harm to the patient. Also, the Institute of Medicine’s (IOM’s), development of the initial PSIs was based on the definition of patient safety. The IOM is based in the United States. Their definition is “freedom from accidental injury due to medical care, or medical errors”\textsuperscript{111}. The IOM report defined medical errors as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim...[including] problems in practice, products, procedures, and systems.”\textsuperscript{112} This definition excludes acts that do not achieve desired outcomes, but are not the result of negligence, outcomes resulting from underlying or comorbid illnesses, and outcomes known to be unavoidable risks of a procedure.

1.2.1 Quality and Risk Management in Health Care
A successful risk management program helps organizations prioritize strategies for risks that are likely to have the biggest impact on their business\textsuperscript{113}. In general, there are differences in how to approach quality in a healthcare system\textsuperscript{114}. A more traditional approach is characterized by being problem oriented, retrospective focus, participation by staff is limited and most of the times isolated and random events. On the other side, there is the more innovative approach to quality assurance which is most of the times a dual approach with a concomitant focus on problem identification and compliance with standards, full staff participation, planned and systematic, specific topic focused on a particular clinical area and

\textsuperscript{111} Institute of Medicine (IOM): Health IT and Patient Safety: Building Better Systems for Better Care, in: (November), 2011, p. 2.
\textsuperscript{114} Conklin, Analijn; Vilamovska, Anna-Marie; Vries, Hans de; Hatzichristou, Evi: Improving Patient Safety in the EU: Assessing the expected effects of three policy areas for future action, in RAND Corporation, 2008, p. 126.
based on well-developed nursing standards. The Marker Umbrella Model demonstrates that there are nine universal activities that constitute professional quality assurance practice. These nine activities apply to all professional services in all settings. The model directs quality practice by delineating what broad areas should be addressed and demonstrates the interdependent relationship of each\textsuperscript{115}. All nine activities should be implemented but not necessarily all at once. Each service should determine which three or four activities are initial priorities: develop the methods, mechanisms, and tools to carry out the activities; and then integrate both the activities and the methods into the quality assurance plan. Operationally, each nursing unit or professional service should create a unit quality assurance manual with all nine activities labelled. After the reporting mechanism has been summarized, the data being reviewed for the quarter, along with accomplishments, the manual can be thinned of obsolete data. This thinning process maintains the quality assurance manual in an orderly and current manner.

![Quality Assurance Programm](image)

**Figure 1.6: Quality Assurance Program including nine mandatory elements**

*Source: Author's illustration according to Marker, 1987\textsuperscript{116}*

The Marker Quality Assurance Umbrella Model operationally defines quality assurance (QA) as nine essential activities occurring at the hospital, department, division or nursing unit level. According to Marker, the Model advocates a dual approach: (1) data sources for early and consistent problem identification and (2) measuring compliance with the existing structures, processes, and outcome standards. The umbrella components consist of standards, continuing education, credentialing, performance appraisal, audit, concurrent monitoring, utilization review, risk management, and active problem identification. The Marker model offers nursing


and other disciplines a sophisticated and comprehensive approach\textsuperscript{117} to professional quality assurance.

The quality assurance umbrella model from Marker is still used in literature as well as for daily practice, for example in a book for nurses in 2008\textsuperscript{118}.

Gloving is part of quality system in hospitals and is recommended as a barrier protection for healthcare workers to reduce the risk of contamination during contact with body fluids, mucous membranes or the damaged skin of patients. When used properly, gloving may also reduce cross-transmission of micro-organisms from healthcare workers’ hands. In a study from Girou and Brunbuisson in a French university hospital a total of 101 observation periods were undertaken during which 120 healthcare workers were observed and performed 784 contacts with 30 patients infected or colonized with potentially pathogenic bacteria\textsuperscript{119}. This study demonstrates that failure to change or remove contaminated gloves is a major component of poor hand hygiene compliance. The improper use of gloves was associated with healthcare workers missing more than half the opportunities for hand hygiene.

Risk is a probability/threat of damage, injury, liability loss that is caused by vulnerabilities and that may be avoided through pre-emptive action/s. Interaction of humans with health systems pose a threat to them mainly because of the; complex technology, intensely complex procedures, high demand on services, time pressure, high expectations from the service users, hierarchical by nature of training and responsibilities. W.H.O estimates show that in developed countries as many as 1 in 10 patients is harmed while receiving hospital care.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{117} Storey, John: Factors affecting the adoption of quality assurance technologies in healthcare, in: Journal of Health, Organisation and Management 27 (4), 2013, pp. 498–519.
\item \textsuperscript{118} Kämmer, Karla: Pflegemanagement in Altenpflegeeinrichtungen, 2008, pp.481–483.
\item \textsuperscript{119} Girou, Emmanuelle; Brunbuisson, Christian: Misuse of gloves : the foundation for poor compliance with hand hygiene and potential for microbial transmission ?, in, 2004, pp. 162–169.
\end{itemize}
\end{footnotesize}
Risk management for healthcare entities can be defined as an organized effort to identify, assess, and reduce, where appropriate, risk to patients, visitors, staff and organizational assets. Risk management in its best form may be to use it in a pro-active manner in identifying and managing the risks. However, in case an incident has happened; after the event handling, it should still be tackled in line with the risk management principles as outlined here. This review provides a concise material in risk management for healthcare professionals to quickly grasp the key concepts in risk management and implement them in the healthcare organizations where they work\textsuperscript{121}.


According to National Organizational Development Network Australia, risk management as a process uses a five step management decision-making model. Five Basic Steps of Risk Management:\(^{122}\):

**Step 1: Establish the context**

Establish the context: Context is very important in risk identification and management. ICU (Intensive care unit), O.R (Operation room), E.R (Emergency room), blood transfusion services, CCU (coronary care unit), medication management including medication administration are contextually high priority areas for risk management in relation to patient care.

**Step 2: Identify risks**

Identify Risks: Risk identification is the process whereby the healthcare professional and the healthcare employees become aware of the risks in the health care services and environment. The risks identified are entered in the Risk Management Tool (RMT) as depicted in Figure 2, also sometimes known as the Risk Register.

**Sources of risk identification**

- Discussions with department Chiefs, managers and staff
- Patient Tracer Activity (Tracing the journey of a patient from admission till discharge)
- Retrospective screening of patient records
- Reports of accreditation bodies
- Incident reporting system & Sentinel events
- Healthcare associated infections (HAI) reports
- Executive committee reports
- Facility management & safety committee report
- Patient complaints and satisfaction survey results
- Specialized committee reports (such as Morbidity and mortality committee, medication management and use, Infection control, blood utilization, facility management and safety committee).

**Step 3: Analyze risks**

Analyze Risks: Risk analysis is about developing an understanding of the risks identified. It includes the following:

- Level of the risk or Risk score,
- Underlying causes,
- Existing control measures.

Risk score is calculated by multiplying the likelihood score with the severity of impact score. Likelihood scoring is based on the expertise, knowledge and actual experience of the group scoring the likelihood. In assessing likelihood, it is important to consider the nature of the risk. Risks are assessed on the probability of future occurrence; how likely is the risk to occur? How frequently has this occurred?

Step 4: Evaluate risks

Evaluate risks: The purpose of risk evaluation is to prioritize the risks based on risk analysis score and to decide which risks require treatment and the mode of treatment. Risk evaluation can be classified as:

![Diagram of risk evaluation classification in hospitals](image)

**Figure 1. 8: Risk evaluation classification in hospitals**

*Source: Authors illustration according to Ali Yawar Alam, 2016*

Step 5: Treat/Manage Risks

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Risk Treatment: (Also known as Risk reduction, Risk mitigation): The decisions in risk treatment should be consistent with the defined internal, external and risk management contexts and taking account of the service objectives and goals. Risk treatment plan should have:

- Proposed actions
- Resource requirements
- Person/s responsible for action
- Timeframes (Dates for actions to be completed and date for review).

Controlling the Risk: The most effective methods of risk control are those which redesign the systems and processes so that the potential for an adverse outcome is reduced. Other methods of controlling the risk include reducing the likelihood of the risk and/or reducing the severity of the impact of the risk.

Reduce the Likelihood of the risk occurring - e.g. by preventative maintenance, audit & compliance programs, supervision, policies and procedures, testing, training of staff, technical controls and quality assurance programs.

Reduce the Severity of Impact of the risk occurring - through contingency planning (contingency plan is a back-up plan in case the identified risk actually takes place), disaster recovery plans, off-site back-up, emergency procedures, staff training, etc.

1.2.2 Characteristics and Definition of Patient Safety

Patient safety is a significant healthcare issue with substantial clinical and economic consequences. The question is what patient safety is. According to the US based Agency for Healthcare Research and Quality (AHRQ), “patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events124.

The patient safety movement was brought to the medical mainstream by a report of the U.S. Institute of Medicine To Err is Human125, with the goal to eliminate preventable patient harm through improved systems and find solutions to previously “unpreventable” errors126. A

125 Kohn, Linda; Corrigan, Janet; Donaldson, Molla: To err is human: Building a SaferHealth System, Bd. 6, 1999.
Summary of definitions on patient safety and medication errors was made by Linda Norton in 2001\textsuperscript{127} from the Institute of Medicine (IOM) in USA. In her research, she defines Patient safety as "Applies to initiatives designed to prevent adverse outcomes from medical errors. The enhancement of patient safety encompasses three complimentary activities: preventing errors, making errors visible, and mitigating effects of the errors.” Researchers at the Agency for Healthcare Research and Quality (AHRQ) developed a set of Patient Safety Indicators (PSIs) for identifying suspected instances of compromised patient safety\textsuperscript{128}.

One general approach to profile patient safety is to identify adverse outcomes that are often preventable and then to look backward to ascertain how and why they occurred. This approach was used successfully in the Harvard Medical Practice Study and follow-up studies in Utah and Colorado, but the screening criteria in those studies necessitated nurse review of every record. Safety is the reduction of risk of unnecessary harm to an acceptable minimum, and hazard a circumstance, agent or action with the potential to cause harm. A circumstance is a situation or factor that may influence an event, agent or person(s), an event is something that happens to or involves a patient, and an agent is a substance, object or system that acts to produce change. Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. Healthcare-associated harm is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury\textsuperscript{129}.

Patient safety improvements demand a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice, and safe environment of care\textsuperscript{130}. Further, advancing patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach to safety in which safety is systematic and is uniformly applied across the total process and also includes management commitment\textsuperscript{131}. According to Ball, Kaminski and Webb\textsuperscript{132}, patient safety depends on the

\begin{itemize}
\item \textsuperscript{127} Norton, Linda: Medical and Medication Errors: A Partial Summary of Reports by the Institute of Medicine and the Quality Interagency Coordination Task Force, in: 7 (1), 2001.
\item \textsuperscript{128} Norton, Linda: Medical and Medication Errors: A Partial Summary of Reports by the Institute of Medicine and the Quality Interagency Coordination Task Force, in: 7 (1), 2001.
\item \textsuperscript{129} Runciman, William; Hibbert, Peter; Thomson, Richard; Van der Schaaf, Tjerk; Sherman, Heather; Lewalle, Pierre: Towards an International Classification for Patient Safety: the conceptual framework, 2009, Journal for Quality in Health Care, Vol 21 (1), pp. 18-26.
\item \textsuperscript{130} Hughes, RG (Agency for Healthcare Research and Quality); Clancy, CM: Working conditions that support patient safety., in: Journal Of Nursing Care Quality 20 (4), 2005, pp. 289–92.
\item \textsuperscript{131} Pronovost, Peter; Ravitz, Alan; Stoll, Robert; Kennedy, Susan: Transforming Patient Safety: A Sector-Wide Systems Approach, 2015.
\end{itemize}
actions and beliefs of the person highest on the health care ladder (as health care has a long tradition of being hierarchical). The understanding of errors is linked to the ability to maintain a “fair and just culture” one in which errors are quickly reported and addressed rather than hidden. However, such a culture is often difficult to construct, modify and maintain. Patient safety culture, which is also called patient safety climate, is an overall behavior of individuals and organizations, based on common beliefs and values which should be supported by hospital management.

Already in 2005, two authors of to err is human, Leape and Berwick, stated that the main reason for no measurable improvement is due to culture of medicine. Creating a culture of safety requires changes that physicians may perceive as threats to their autonomy and authority. Fear of malpractice liability, moreover, may create an unwillingness to discuss or even admit to errors. Other issues include a lack of leadership from management at the hospital and health plan level; and a scarcity of measures with which to gauge progress. All these articles are showing that patient safety depends on the culture. Consequently, improvement fully depends on the culture. There is a growing change trend in the number of articles on patient safety culture research; however there has been no objective and quantitative evaluation of the quality of the research so far. A project-by-project approach did not lead to widespread, holistic change. To generate holistic change, we need to embrace a wider approach to safety rather than focusing on specific, circumscribed safety initiatives – meaning culture. This requires clear guidance and support from management in hospital with priority to patient safety and clear role modeling, that reporting mistakes is something which no one is blamed for.

After understanding that the major influencer for patient safety is culture, the following paragraph further analyses what drives patient safety culture. The following explains which factors are influencing culture while aiming to improve patient safety and what can help management with regard to improving the safety of patients. An essential part of culture and

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135 Leape, Lucian; Berwick, Donald: Five Years After To Err is Human: What have We Learned?, in: Journal of the American Medical Association 293 (19), 2005, pp. 2384–90.

136 Leape, Lucian; Berwick, Donald M.: Five Years After To Err is Human: What have We Learned?, in: Journal of the American Medical Association 293 (19), 2005, pp. 2384–90.

137 Xuanyue, Mao; Yanli, Nie; Hao, Cui; Pengli, Jia; Mingming, Zhang: Literature review regarding patient safety culture, in: Journal of Evidence-Based Medicine 6 (1), 2013, pp. 43–49.
one key strategy to improve patient safety is enhancing transparency of performance on safety, clinical and service quality\textsuperscript{138}. This is of course not an easy goal since no one wants to actively show mistakes.

Already the IOM report in 1999 states, that if there is a safety culture where adverse events can be reported without people being blamed, they have the opportunity to learn from their mistakes and it is possible to make improvements in order to prevent future human and system errors, and thus promoting patient safety\textsuperscript{139}. Actively showing mistakes also supported by management by being transparent is part of the successful patient safety culture. By embracing safety as a core value, other industries have moved beyond competition to a stage of cooperation. Health care organizations should also make this shift. While some health care organizations have begun to work cooperatively with each other to advance patient safety, a commitment to share safety data and best practices is most evident among pediatric hospitals. For example, the Children’s Hospitals’ Solutions for Patient Safety (SPS) network (based in the USA) has seen significant improvements in patient safety metrics as a result of collaboration\textsuperscript{140}. Unfortunately, many other health care organizations, respectively their management, seem to believe that they must differentiate themselves based on their safety record. Organizations should not compete on safety; such competition slows progress in patient safety by blocking the free flow of information crucial to preventing harm.

In the decades since the Institute of Medicine (IOM) issued its landmark report, “To Err Is Human: Building a Safer Health System,” there have been a number of successful efforts undertaken to improve patient safety in the United States\textsuperscript{141}. Nevertheless, the nation remains far from realizing the vision of eliminating harm to patients from care that is meant to help them. The study from Ball, Kaminski and Webb describes the progress that has been achieved by one organization committed to developing a culture of high reliability. ProMedica Health System is a non-profit integrated health care delivery system headquartered in Toledo, Ohio.

\textsuperscript{138} Ball, Debra; Kaminski, Brian; Webb, Kevin: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve Safety, 2016.
\textsuperscript{139} Kohn, Linda; Corrigan, Janet; Donaldson, Molla: To err is human: Building a Safer Health System, Bd. 6, 1999.
\textsuperscript{141} Leape, Lucian; Berwick, Donald: Five Years After To Err is Human: What have We Learned?, in: Journal of the American Medical Association, 293 (19), 2005, pp. 2384–90.
In 2012, they set out to transform the cultural operating system with the goal of “zero events of harm”\textsuperscript{142}.

A study in 2015 states, that healthcare lacks robust mechanisms to routinely measure the problem and estimates of the magnitude vary widely. Further, this study states, that it is hard to gauge safety when healthcare uses multiple different measures for the same harm and provides limited investment in measurement, implementation and applied sciences. According to Pronovost, Cleeman, Wright and Srinivasan, a valid and reliable measurement system is essential to monitor progress, to do benchmarking, to hold clinicians accountable and to be able to compare and summarize measurements across different unit types\textsuperscript{143}. Culture is not only determined by the caregivers and the hospital management. The regulatory framework is also part of the overall safety culture and can help to improve patient safety. For example, the current reimbursement system can also work against safety improvement and, in some cases, may actually reward less-safe care, as Leape and Berwick state. For instance, some insurance companies will not pay for new practices to reduce errors, while physicians and hospitals can bill for additional services that are needed when patients are injured by mistakes\textsuperscript{144}. The complexity of the healthcare industry, with its vast array of specialties, subspecialties, and allied health professionals is also mentioned as a reason for slow improvement in patient safety.

The literature has no clear definition of patient safety. The figure below shows the flow of the theoretical review and also outlines key aspects and key literature of the research.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Overview literature review about patient safety improvement from 1999 to 2015}
\end{figure}

\textsuperscript{142} Ball, Debra; Kaminski, Brian; Webb, Kevin: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve Safety, in: People & Strategy, 39 (1), 2016, pp. 29–34.

\textsuperscript{143} Pronovost, Peter; Cleeman, James; Wright, Donald; Srinivasan, Arjun.: Fifteen years after To Err is Human: a success story to learn from., in: BMJ quality & safety (December), 2015.

\textsuperscript{144} Leape, Lucian; Berwick, Donald: Five Years After To Err is Human: What have We Learned?, 2005.
Safety depends on culture, not only on system improvements – this is the major reason for no incremental improvement of patient safety. Culture is not easy to change and it takes long time and full effort to change cultural behavior. For management, this means that if they want to improve patient safety they have to be aware of culture and even of cultural change. Success factors which are determining culture are transparency, peer learning, measurement and framework. Transparency, peer learning and measurement are factors which can be influenced and has to be driven by management. However, frameworks or even more implementation of new frameworks are part of decision-making processes in hospitals.

The following paragraph shows the complexity of the definition of patient safety and also outlines what the different definitions have in common. The simplest definition of patient safety is the prevention of errors and adverse effects to patients associated with health care. While health care has become more effective it has also become more complex, with greater use of new technologies, medicines and treatments. Health services treat older and sicker patients who often present with significant co-morbidities requiring more and more difficult decisions as to health care priorities. Increasing economic pressure on health systems often leads to overloaded health care environments. Every 10th patient in Europe experiences preventable harm or adverse events in hospital, causing suffering and loss for the patient, their families and health care providers, and taking a high financial toll on health care systems.

The urgency of improving patient safety is globally clear and prioritized. In order to develop the right initiatives and right systems, it is essential to understand what you want to improve. Further, when it comes to measuring results like "did we improve patient safety" the definition of patient safety has to be clear in order to compare results and to make it visible.

The simplest definition of patient safety is the prevention of errors and adverse effects to patients associated with health care. While health care has become more effective it has also become more complex, with greater use of new technologies, medicines and treatments. Health services treat older and sicker patients who often present with significant co-

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146 Shojania, Kaveh; Duncan, Bradford; Mcdonald, Kathryn: Safe but Sound: Patient Safety Meets Evidence-Based Medicine, 2002, JAMA The Journal of the American Medical Association 288 (4); pp.508-13.
morbidities requiring more and more difficult decisions as to health care priorities. Increasing economic pressure on health systems often leads to overloaded health care environments.

Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. Healthcare-associated harm is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury\(^\text{148}\). A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. In the context of the International Classification for Patient Safety (ICPS), a patient safety incident will be referred to as an incident. The use of the term ‘unnecessary’ in this definition recognizes that errors, violations, patient abuse and deliberately unsafe acts occur in healthcare and are unnecessary incidents, whereas certain forms of harm, such as an incision for a laparotomy, are necessary. The former are incidents, whereas the latter is not.

National Health Service (NHS) Statement: “The errors that occur in healthcare are rarely the fault of individuals, but are usually the result of problems with the systems they work in. Regardless, patients should be treated in a safe environment and be protected from avoidable harm. Patients should be treated in clean surroundings, with a minimal risk of infection. The equipment used should be in good working order and used in the correct way. Medicines should be given on time and in the correct doses. Tests, investigations and treatments provided to patients should be appropriate for their condition, with procedures performed correctly and in a timely and effective way. Care should be delivered in a co-ordinated way by competent healthcare staff who work in an effective team. This includes communicating patients' needs effectively. Some treatments or drugs are expected to cause harm, such as chemotherapies or certain drug therapies. Rare allergic reactions, for example, are "expected" in the sense that they will happen to a very small number of patients – we just can't predict which ones. Those cases are not considered patient safety issues.”

Patient safety practice is defined 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 diseases and procedures\(^\text{149}\).


Quality has been defined as ‘the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge’. The definition of patient safety has a different emphasis regarding AHRQ (Agency for Healthcare Research and Quality) 2001: ‘the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum’. Safety is often included as one of the components of quality, and many quality improvement activities both improve outcomes and prevent harm (for example, the introduction of information systems and standardized care processes).

The differences between quality and safety are relevant in primary health care. Safety and quality research in primary health care has generally been focused on issues to do with quality, such as access to healthcare services, differences in health outcomes for particular parts of the population and compliance with clinical guidelines. There has been much less research about issues concerning patient safety in primary health care, and ways of preventing unnecessary harm associated with the delivery of care.

In the literature you can find definitions of patient safety, however, there is no standard theoretical definition of patient safety. What is clear in all definitions is that defining patient safety is a very difficult task and no expert in literature does have the requirement to have the perfect and overall definition of patient safety. In the following there are five different definitions of patient safety of well-known researchers or associations like AHRQ which is the Agency for Healthcare Research and Quality:

(1) Patient safety is a significant healthcare issue with substantial clinical and economic consequences. The question what patient safety is. According to AHRQ, “patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events.”

(2) A Summary of definitions on patient safety and medication errors was made by Linda Norton in 2001. In her research, she defines Patient safety as "Applies to initiatives designed to prevent adverse outcomes from medical errors. The enhancement of patient safety encompasses three complimentary activities: preventing errors, making errors visible, and mitigating effects of the errors.”

150 AHRQ Patient Safety Network (AHRQ, PSNet.): Definition Patient Safety, Glossary.
151 AHRQ Patient Safety Network (AHRQ, PSNet.): Definition Patient Safety, Glossary.
(3) Patient safety is the reduction of risk of unnecessary harm associated with healthcare
to an acceptable minimum. Healthcare-associated harm is harm arising from or
associated with plans or actions taken during the provision of healthcare, rather than
an underlying disease or injury\textsuperscript{152}.

(4) According to Ball, Kaminski and Webb\textsuperscript{153}, patient safety depends on the actions and
beliefs of the person highest on the health care ladder (as health care has a long
tradition of being hierarchical). The understanding of errors is linked to the ability to
maintain a “fair and just culture” one in which errors are quickly reported and
addressed rather than hidden. However, such a culture is often difficult to construct,
modify and maintain\textsuperscript{154}. Patient safety culture, which is also called patient safety
climate, is an overall behavior of individuals and organizations, based on common
beliefs and values which should be supported by hospital management\textsuperscript{155}.

(5) A definition for patient safety has emerged from the health care quality movement
that is equally abstract, with various approaches to the more concrete essential
components. Patient safety was defined by the IOM as “the prevention of harm to
patients.”\textsuperscript{156} Emphasis is placed on the system of care delivery that (1) prevents
errors; (2) learns from the errors that do occur; and (3) is built on a culture of safety
that involves health care professionals, organizations, and patients\textsuperscript{157}.

The result of the literature review on patient safety shows that there is no universal definition
in literature. As a next step, the author is having a close look at the reality in hospitals. The
following chapter will give an overview on how the situation and progress on patient safety as
well as decision processes in hospital looks like.

\textsuperscript{152} Runciman, William; Hibbert, Peter; Thomson, Richard; Van der Schaaf, Tjerk; Sherman, Heather; Lewalle,
\textsuperscript{153} Ball; Kaminski; Webb: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve
Safety, 2016.
\textsuperscript{154} Ball; Kaminski; Webb: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve
Safety, 2016.
\textsuperscript{155} Nieva; Sorra: Safety culture assessment: a tool for improving patient safety in healthcare organizationP.,
2003.
\textsuperscript{156} Aspden, Philip; Corrigan, Jane; Wolcott, Julie: Patient safety: achieving a new standard for care., in: National
\textsuperscript{157} Aspden, Philip; Corrigan, Jane; Wolcott, Julie: Patient safety: achieving a new standard for care., in: National
1.2.3 Characteristics of Patient Safety Culture

Safety culture plays an important role in the approach towards greater patient safety in hospitals. Culture is part of organizations and therefore part of organizational theory. Organizational theory is the study of how organizations function and how they affect and are affected by the environment in which they operate.

Theories of organizations include bureaucratic theory, rational system perspective, division of labor, and also modernization of theory, which can be all three applied to hospitals:

1) The term ‘bureaucracy’ has been widely used with invidious connotations directed at government and business. Bureaucracy is an administrative system designed to accomplish large-scale administrative tasks by systematically coordinating the work of many individuals. Weber\textsuperscript{158} has observed three types of power in organizations: traditional, charismatic and rational-legal or bureaucratic. He emphasizes that bureaucratic type of power is the ideal one. And also recognizes that this ‘ideal bureaucracy’ does not exist in reality, but rather represents a selective reconstruction of the real world. Weber identifies the essential components of bureaucracy as follows: Official jurisdiction on all areas is ordered by rules or laws already implemented; there is an office hierarchy; a system of super- and sub-ordination in which higher offices supervise lower ones; the management of the modern office is based upon written rules, which are preserved in their original form; office management requires training and specialization; when the office is developed/established it requires the full working capacity of individuals; rules are stable and can be learned. Knowledge of these rules can be viewed as expertise within the bureaucracy (these allow for the management of society).\textsuperscript{159} This described hierarchy can be found in hospitals in Germany and as outlined in chapter two, can lead to barriers while improving patient safety culture.

2) Rational system perspective focuses on the formal structures of an organization and sees the organization as a group of people who work together to pursue specific goals. Taylor attempted to rationalize the individual worker by: dividing work between managers and workers – this is seen as physicians and nurses in hospitals; providing

\textsuperscript{159} Weber, Max: Economy and Society, Berkeley, Los Angeles, London 1978.
an incentive system (based on performance), scientifically trained workers – incentive for hospital workers is well established in German hospitals; developing a science for each individual’s responsibilities; making sure work gets done on time/efficiently.\textsuperscript{160} The time/efficiently part is regulated by health insurances who established diagnosis related groups (DRG).

3) The division of labor is the specialization of individual labor roles. Individuals, organizations, and nations are endowed with or acquire specialized capabilities and either form combinations or trade to take advantage of the capabilities of others in addition to their own. According to Adam Smith, the division of labor is efficient due to three reasons: occupational specialization, savings from not changing tasks, and machines taking the place of human labor. Occupational specialization leads to increased productivity and distinct skill. Also, Smith argued that human and physical capital must be similar or matched; if the skills of the workers were matched with technological improvements, there would be a major increase in productivity.\textsuperscript{161}

An organization is a tool people use to coordinate their actions to obtain something they desire or value – to achieve their goals. At the same time that organizational structure is evolving, so is organizational culture. Organizational culture is the set of shared values and norms that controls organizational members’ interactions with each other and with suppliers, customers, and other people outside the organization. An organization’s culture is shaped by the people inside the organization, by the ethics of the organization, by the employment rights given to employees, and by the type of structures used by the organization. Organizational culture shapes and controls behavior within the organization. It influences how people respond to situation and how they interpret the environment surrounding the organization.\textsuperscript{162}

Generally, approaches to organizational culture can be classified into two categories: (1) dimensions approach\textsuperscript{163} (2) interrelated structure approach\textsuperscript{164} (e.g. Schein, 1985; Hatch, 1993; Homburg & Pflesser, 2000; Allaire & Firsirotu, 1984)\textsuperscript{165}166167.

\textsuperscript{162} Jones, Gareth: Organizations and Organizational Effectiveness, in: Organizational Theory, Design, and Change, 2013, pp. 1–27.
\textsuperscript{164} Schein, Edgar: Organizational Culture and Leadership, San Francisco 1985.
\textsuperscript{165} Schein, Edgar: Organizational Culture and Leadership, San Francisco 1985.
The dimensions approach is one of the most prominent approaches to cultural constructs, in particular for quantitative research. Classic anthropological research designs have partly lost ground due to the paradigm of cultural dimensions by Hofstede and paved the way for new research contexts that required the quantitative measurement of cultures. Hofstede et al. (1990)\textsuperscript{170} and Sagiv & Schwartz (2007)\textsuperscript{171} emphasize that organizational culture dimensions considerably differ from national culture dimensions. Nevertheless, they are related to each other. Sagiv & Schwartz (2007)\textsuperscript{171} explain that organizations operate under pressure of societal values.

The interrelated structure approach of organizational culture is characterized by bidirectional links indicating interdependence, i.e. linear or recursive processes that illustrate certain relationships between domains of a model. While there exists a great variety of heavily cited models, it was chosen Schein (1985)\textsuperscript{172} and Hatch & Cunliffe (2006)\textsuperscript{173} as a starting point for

\textsuperscript{166} Hatch, Manry; Cunliffe, Ann: Organization Theory: Modern, Symbolic, and Postmodern Perspectives, 2006.
\textsuperscript{167} Hatch, Manry; Cunliffe, Ann: Organization Theory: Modern, Symbolic, and Postmodern Perspectives, 2006.
\textsuperscript{168} Schein: Organizational Culture and Leadership, 1985.
\textsuperscript{169} Schein: Organizational Culture and Leadership, 1985.
\textsuperscript{170} Hatch, Manry; Cunliffe, Ann: Organization Theory: Modern, Symbolic, and Postmodern Perspectives, 2006.
\textsuperscript{172} Schein: Organizational Culture and Leadership, 1985.
\textsuperscript{173} Hatch, Manry; Cunliffe, Ann: Organization Theory: Modern, Symbolic, and Postmodern Perspectives, 2006.
the development of a generic model of organizational culture. Both models are well-rounded and recognized in their respective fields, however are rooted in organization theory (Hatch & Cunliffe, 2006) or culture theory (Schein, 1985). A combination of both models provides richer insights in culture dynamics in organizations. In addition, the presented model consists of domains and relationships that are rooted in culture and organization research and establishes a more comprehensive link between these two fields of research. The figure above provides a visual representation of these models.

Research into high reliability organizations (HRO), which experience fewer accidents than expected, such as aircraft carriers and nuclear power plants, has highlighted the importance of a culture of safety. Safety is the number one priority for the organization and for each of the workers that work within the organization. These organizations have several features:

- High degree of autonomy but also interdependence. Individuals are empowered to act as independent operators but rely on others to perform tasks.
- Multiple cultures and teams that work interdependently. Individuals work as part of cohesive teams, such as doctors or nurses, but also rely on other teams to achieve complex tasks effectively.
- A prevailing attitude of chronic unease about potential safety threats. There are formal rules and procedures but the purpose is to create “heedful attention” to high-risk situations instead of routine compliance. There is usually one individual who takes an overall view of the situation and monitors the response to the situation.
- Training is a high priority. This includes clear required competencies that regularly assessed, often by participating in simulations.
- A collaborative structure takes over in situations of high risk. In high-risk situations, the formal hierarchical relationship dissipates, all team members increase situational awareness, and each individual constantly monitors both the situation and the actions of other team members. Feedback on performance is freely given and perceived. The overall aim is to maintain safety.

Healthcare is complex and requires a differentiation of professional roles, such as doctors, nurses, social workers. The more complex the process, and the larger the organization, the greater the need for more healthcare workers of different types, e.g. university hospital. This inevitably creates difficulties, with greater potential for errors to occur, because of the

requirement to coordinate, collaborate and cooperate. Most healthcare workers have had
different and separate trainings, and often hold a value system that is specific to their
professional group. It means that even different stakeholders might have differences in respect
to their understanding of patient safety culture. The problem of ‘too many hands’ involved in
healthcare, especially when it is complex, results in a collective lack of responsibility for
safety and little personal responsibility and feeling of accountability when adverse events
occur.

The Joint Commission's Center for Transforming Healthcare in the United States has stated
the six aspects of maintaining a patient safety culture\textsuperscript{176}:

1. \textit{Patient safety culture starts at the top}. It would be difficult to establish and maintain a
patient safety culture if it did not start at the highest level of the healthcare organization,
executive leadership must promote a culture of safety and make their commitment evident to
the rest of the organization. It has to be a tone set by leadership, not something you talk about
once in a while. Further, the physical visibility of management to staff is important. Board
members and executives must move from the meeting rooms to patient care units and connect
directly with physicians, nurses and patients. Increasing visibility shows both staff members
and patients that the leadership’s commitment to patient safety does not stop in the board
room or the C-suite.

2. \textit{Patient safety culture is driven by a vision}. Healthcare leadership must create a vision that
will drive the organization's patient safety culture. This requires executives and board
members to conduct a gap analysis to understand where the organization exists in the
spectrum of safety and where it wants to be.

3. \textit{Patient safety culture involves everyone at every level}. Once the gap analysis is completed,
hospital leadership can take steps to promote and develop a patient safety culture. Everyone
must be involved in developing the action plans necessary to close the gap and improve the
quality and safety for every patient. Action plans developed without the input and buy-in of
staff members and physicians will most likely fail. The first step towards establishing a true
culture of safety is a sense that every voice is heard no matter what level they are in the
organization.

\textsuperscript{176} Lambert, Matthew: 6 Elements of a True Patient Safety Culture, Clinical Leadership & Infection Control,
4. Patient safety culture requires some evolution. Patient safety culture is not a one-size-fits-all solution. Healthcare organizations are complex structures, comprised of many different units with different needs, different staff members and different patients. For example, some hospital units may have a good team structure, where staff members are supportive and willing to stop each other when they don't exercise patient safety. Other units might have staff members who are more hesitant to speak up when they see a colleague has not complied with patient safety protocols. The change in safety culture requires courage since some of the changes will be counterintuitive to traditional processes and protocols. It's important for organizations to look at safety culture not as a one-time fix or a few simple steps to improve quality.

5. Commitment to patient safety culture is consistent. One of the most common pitfalls that typically undermines the development of a patient safety culture is inconsistency in the leadership's commitment. A hospital board and executive leadership may say they are committed to patient safety, but they may cut funding for patient safety education programs at the first sign that the organization is in a difficult financial position, that kind of message clearly says to the rest of the organization that safety is not the first priority, and that can really disillusion employees. It is absolutely critical that the leadership remembers that medical errors are almost always the result of systematic flaws rather than individual incompetence. When medical errors happen, the leadership must look at ways to improve systematic processes in order to prevent future adverse events from occurring — rather than punishing the individual that made the mistake.

6. Patient safety culture ultimately transcends the leadership. Eventually, successful implementation of a patient safety culture should come full circle. The best measure of whether an organization has achieved this is to see how well the organization’s patient safety culture continues to thrive once there is a change in leadership.

Safety culture is an aspect of organizational culture. Positive safety culture guides the many discretionary behaviors of healthcare professionals toward viewing patient safety as one of their highest priorities. The Institute of Medicine states that if there is a safety culture where adverse events can be reported without people being blamed, they have the opportunity to learn from their mistakes and it is possible to make improvements in order to prevent future
human and system errors, and thus promoting patient safety. Therefore, if hospitals want to improve patient safety, it is important to know more about the culture regarding patient safety.

2 STATUS QUO OF PATIENT SAFETY CULTURE AND DECISIONS IN HOSPITALS

The Institute Of Medicine estimates that the costs of medical errors in the United States including lost income, disability, and health care may be $17-$37.6 billion or more annually\textsuperscript{178}. Hospital management is increasingly confronted by governmental, regulatory, and consumer groups to demonstrate organizational safety culture that assures patients safely from medical error. Even after 15 years of patient safety initiatives, recent research has found that roughly 1 in 2 surgeries had a medication error and/or an adverse drug event\textsuperscript{179} and more than 12 million patients each year experience a diagnostic error in outpatient care, half of which are estimated to have the potential to cause harm\textsuperscript{180}. On the other side, there is a decrease of 1.3 million adverse events in hospital-acquired conditions (2011-2013) as a result of the federal Partnership in the US for patients initiative\textsuperscript{181}. To define patient safety, the author conducted a literature review and combined it with the results of six semi-structured expert interviews in Germany. The common result is that patient safety is not easy to define. It is a wide term and a universal definition does not exist either in literature, or as a result of expert interviews. However, there are common elements in defining patient safety which are: Reduce harm for the patient, build a culture of safety, reduce the risk for patients and report errors. Despite the growing public interest in improving patient safety, there is no universal definition in literature.

The research on decision making is substantiated and based on mature literature. Decision making as a field of organization theory gained a lot of interest in the 20th century and generated profound theories awarded with Nobel prizes. Considering this wider theoretical background and lessons learned from theoretical decision making provided a different angle and valid input for this study.

The research question and hypothesis of this research focus specifically on how the involvement of different stakeholders in hospitals influences patient safety. Furthermore, the term “patient safety” is defined as a result of semi-structured expert interviews. The overall research is devoted to a very wide and very complex topic. A decision making process with

\textsuperscript{178} Kohn, Linda; Corrigan, Janet; Donaldson, Molla: To err is human: Building a Safer Health System, 1999.
more than five stakeholders involved is complex and additionally the outcome, improved patient safety as a term is a not easy to define and measure.

Although the current evidence regarding overall improvement in patient safety in the US and internationally is mixed\textsuperscript{182}, the majority of the panel in “Free from Harm” and management felt that overall health care is safer than in the past\textsuperscript{183}.

In their 2004 article „What is driving hospitals' patient-safety efforts?” Kelly J. Devers and her co-authors argue that patient safety in hospitals is driven by professionalism, regulation and markets. The term professionalism refers to a system of self-governance wherein members of a profession set and maintain standards by way of shared values, norms, and educational activities. Regulation occurs when the government establishes a set of standards which for all parties is binding. The market impacts the safety level in hospitals thanks to the fact that purchasers and consumers reward and punish hospitals depending on their respective safety standards\textsuperscript{184}.

From these observations it follows that when endeavouring to describe the current state of affairs with regard to safety measures and decision making in hospitals the task is to offer an overview of the level of professionalism that is characteristic for the hospital work force as well as of the regulations pertaining to the level of safety in hospitals and of current market developments. This shall be done by first offering a relatively general overview of the level of professionalism, regulation and the market environment that are typical for the health care system in general and hospitals in particular before attempting in the final sub-section to draw some abstract conclusions concerning how exactly the level of professionalism, regulation and the market environment are affecting the level of safety and the decision making process in hospitals.

In most developed countries some sort of health insurance is mandatory. In the United States that is not quite the case\textsuperscript{185} which obviously creates a very different kind of market

\textsuperscript{182} Baines, Rebecca; Langelaan, Maaike; Bruijne, Martine de; Spreeuwenberg, Peter; Wagner, Cordula.: How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time, in: BMJ Quality & Safety, 24, 2015, pp. 561-571.
\textsuperscript{184} Devers, Kelly: What is driving hospitals' patient-safety efforts?, in: Health Affairs, 23 (2), 2004, pp. 103-115.
environment for all agents operating in the health sector which includes hospital staff. The following review of how the level of professionalism, the regulatory environment and the forces of the market affect the safety standards and decision making processes in hospital will be limited to the description of the status quo in the developed world. For the purpose of this review the developed world shall be represented by Germany, France, UK, Italy, Spain, United States/Canada, Australia, Japan, Taiwan and Singapore.

However, before beginning the review of these drivers of safety measures and decision making in hospitals it would be useful to acquaint the reader with some broad brush data on medical malpractice, i.e. inadequate safety in hospitals. Twenty-four years ago the first American studies on the level of safety in hospitals concluded that 3-4 % of patients hospitalized would suffer some sort of unwanted and avoidable incident during their stay in hospital. In 7 to 14 % of these incidents the problem brought about by these incidents would be lethal. Around the turn of the century somewhere between 44000 and 98000 people hospitalized in the United States would die due to medical malpractice. This means that more people die in hospitals due to medical malpractice than people die of AIDS or breast cancer. For Australia a study of 14000 medical files sourced from 28 hospitals concluded that 8.5 % of hospital patients are subjected to some sort of unwanted and avoidable incident during their hospital stay. In 13 % of these cases the patients were afflicted negatively for the long-term and in 4.9 % of the cases the unwanted, avoidable incidents caused death to occur. In Canada the analysis of a sample of 3745 patients concluded that 2.8 % of the patients in this sample were afflicted by some sort of unwanted avoidable incidents during their hospital stay. A relatively recent study for the Netherlands, a European Union member country, uncovered that approximately 6 % of 1.3 million hospital patients are harmed by unwanted and avoidable incidents that occur during their hospital stay. The methodology for all of the studies just mentioned is the methodology of the Harvard Medical Practice Study which in a two-step procedure scrutinizes patients' health files. Studies conducted on the basis of direct observations tend to uncover even higher rates of medical malpractice in the hospital environment186.

The author chooses to structure chapter two already in alignment with the dependency model in the research described later and also with figure 2.1, based on Güntert (2008), which shows that decisions in healthcare are made in a complex environment. The first part focuses on the stakeholder existing experience in decision making processes in hospitals, the second part - on development and experience in patient safety with the third part concluding on showing experience in the system and also providing evidence on implemented initiatives in hospitals. Overall the existing experience is presented on a global level with evidence from different countries.

### 2.1 Influence of professionalism to hospitals

The theory of intuitive decision-making in nursing was developed through the use of theory synthesis and empirical evidence derived from research. Intuition is universally acknowledged as an integral part of nurses’ decision making. The definition of intuition varies from author to author, however, resulting in an unclear and incoherent understanding of an important concept. Much of the nursing literature dealing with intuition relies on the subjective perception of nurses to determine if they used intuition. Nursing experience is

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defined as the sum of all exposure to domain specific nursing knowledge. This includes formal and continuing education as well as clinical exposure. Experience alone is not sufficient for the development of intuition\textsuperscript{191}. The outcomes of years of nursing experience include pattern recognition and memory development. Further, research has shown that experienced nurses make fewer errors and report the use of intuition in making clinical decisions.

With an aging population, planning for care at the end of life (EOL) is increasingly important. The greater availability of life-sustaining technologies presents health care providers, patients and caregivers with important and complicated decisions to make during the stress of acute illness\textsuperscript{192}. Addressing the gap between the care provided and that desired, and providing high-quality patient-centered EOL care will require improved communication and decision-making about goals of care. For seriously ill hospitalized patients, goals of care conversations include deliberation and decision-making about the use or non-use of life-sustaining treatments. While many previous studies of EOL communication have focused on barriers, a solution-oriented focus can also generate important insights. The study from Sharma, Heyland, You and des Ordons showed, enhancing patient and family involvement, communication between patients, families and healthcare providers, inter-professional collaboration, educational initiatives and resource availability may improve discussions and decision-making about goals of care for medical interventions among seriously ill patients in hospitals.

Another survey among more than 300 hospital managers brings the result, that the major barrier to patient safety is a lack of teamwork, negative culture and communication\textsuperscript{193}.

\begin{flushright}
\textsuperscript{191} Benner, Patricia: From novice to expert: Excellence and power in clinical nursing practice, Menlo Park 1984.  
\textsuperscript{192} Benner, Patricia: From novice to expert: Excellence and power in clinical nursing practice, Menlo Park 1984.  
\end{flushright}
As you can see in the graph from AIG above, 55% of risk managers and 42% of C-suite managers believe that lack of teamwork is the top barrier to improve patient safety. Further, lack of staff and financial issues are both rated with both groups with over 10% as barriers.

Vikram Jha et al. in an article published in 2015 state that in the literature the concept of professionalism is usually framed in Western (Anglo-Saxon) terms. This one-dimensional approach, however, according to several authors does not do the complex, multidimensional social construct that professionalism is justice. Context, geographical location and culturally important considerations ought to be taken into account in any discussion of professionalism.

In Western countries a doctor is perceived to be dealing professionally with his patients when he respects the principles of informed consent, patient rights and confidentiality. These principles are supposed to help patients safeguard their autonomy. In Asian cultures like

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Japan collective values are valued higher than in the West which to a certain extent undermines the three aforementioned principles, at least if one endows them with strictly Western connotations. It further should be noted that the reporting structure in the clinical workplace tends to be more hierarchical in countries like Japan and Singapore than in the United States or Europe\textsuperscript{195}. According to a study conducted by H. Kobayashi et al. the unacceptability of challenging seniors in Japan serves to inhibit junior staff from speaking out against unprofessional behavior when they become aware of it\textsuperscript{196}. Having touched on how cultural differences that correlate with different geographical locations impact the notion of professionalism in the medical profession we now want to take a closer look at how the practical relevancy of the Hippocratic Oath, which is one of the oldest binding oaths in history and which physicians throughout the world tend to swear upon entry into the workplace has been affected by the passage of time. In their article „The 'special obligations' of the modern Hippocratic Oath for 21st century medicine“ Eric Holmboe & Elizabeth Bernabeo\textsuperscript{197} state that in the 1960s when the modern Hippocratic Oath for the US was written Medicare and Medicaid the two most prominent public Health Care programs of today's United States had not yet been enacted. According to these authors the social changes of the 1960s and subsequent decades have led the medical profession to be guided in its professionalism less by traditional values grounded in the traditional Hippocratic Oath and more by the values of what is known as principles approach. In 2002 the American Board of Internal Medicine Foundation, the American College of Physicians and the European Federation of Internal Medicine developed a charter of professional obligations for doctors that has been endorsed by 130 organizations throughout the world. This charter focuses on three primary principles and ten commitments that doctors must make to both their patients and society at large. The charter goes as follows- three fundamental principles of professionalism in healthcare according to European Federation of Internal Medicine\textsuperscript{198}:

- **Principle of primacy of patient welfare:** The principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the


\textsuperscript{197} Bernabeo, Elithabeth; Holmboe, Eric: The «special obligations» of the modern Hippocratic Oath for the 21st century medicine, in: Medical Education 48, 2014, pp. 87–94.

physician-patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.

- **Principle of patient autonomy:** Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients’ decisions about their care must be paramount, as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care.

- **Principle of social justice:** The medical profession must promote justice in the health care system, including the fair distribution of health care resources. Physicians should work actively to eliminate discrimination in health care, whether based on race, gender, socioeconomic status, ethnicity, religion, or any other social category.

Professional responsibilities according to European Federation, Of Internal Medicine^{199}:

- Commitment to professional competence
- Commitment to honesty with patients
- Commitment to patient confidentiality
- Commitment to maintaining appropriate relations with patients
- Commitment to improving quality of care
- Commitment to improving access to care
- Commitment to a just distribution of finite resources
- Commitment to scientific knowledge
- Commitment to maintaining trust by managing conflicts of interest
- Commitment to professional responsibilities

Whereas in modern times the Hippocratic Oath has always been a central tenant of professionalism for medical doctors in the West, which is in the United States/Canada, the European Union and Australia, in Asia the situation is somewhat different. For instance in Singapore the first time those medical practitioners were required to swear a version of this oath before embarking on their medical careers was in 1995^{200}. This suggests that the professional ethos of Asian doctors is likely strongly informed by non-Western traditions like Confucianism. However, the fact that today Singaporean doctors also swear the Hippocratic

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Oath can be interpreted as evidence that within the global medical community notions of professionalism are increasingly converging. As for the content of the charter just presented to the reader it should be noted that it constitutes a specification of the following lines of the modern Hippocratic Oath:

'I will remember that I remain a member of society, with special obligations to all my fellow [human beings], those sound of mind and body, as well as the infirm.'

It is these 'special obligations' that distinguish the professionalism of the modern day physician from the professionalism of the doctors of earlier ages. For all practical purposes the most prominent of these special obligations of the clinician is that he or she work consciously to eliminate discrimination in health care. The importance of this special obligation is highlighted by the fact that due to racial, gender and socio-economic inequalities certain groups receive less care than they actually should. A special obligation that arises from societal expectations is that clinicians work to keep health care costs down. Obviously, this second special obligation carries the potential to pit the patient's individual well-being against the financial interests of society. A third special obligation of doctors’ tasks them to facilitate communication and connections between patients and health care systems. Finally, it should be noted that today's understanding of professionalism requires doctors to open themselves to continuous systematic appraisals of their level of competency and that doctors are obliged to deliberatly try to improve the quality and safety of health care provision. Consequently, for the modern physician, assessment, particularly self-directed assessment is a professional obligation and regardless of their formal training all doctors are obliged to acquire minimum competencies in improving quality and safety.

The special obligations just outlined seem to assume that the professionalism of a doctor depends merely on his personal conscientiousness with regard to these obligations. This understanding, however, stands in opposition to our earlier observation that professionalism is a complex social construct that is very much informed by contextual variables that lie outside of the individual persona.

Consequently, it makes sense to try to define special obligations for the health care systems within which medical doctors operate. Using the charter as a framework is has been argued that health care systems like hospitals make certain behavioral commitments that support particular domains of professionalism. To this end hospitals provide peer and organizational support for the uncovering of medical errors and the reporting of impaired or incompetent
clinicians. Hospitals should further enact clear policies with regard to the resolution of conflicts of interest and the maintenance of patient confidentiality. Hospitals are further encouraged to provide performance feedbacks to the care teams and to discourage the provision of services that have not been proven to bring value to the patient\textsuperscript{201}.

After the rather theoretical elaboration of the preceding paragraph we shall end this subsection with the summary of two practical studies from Australia. Since both economies, Germany and Australia are developed and both health care systems have full care and high standards\textsuperscript{202}. Therefore using Australia as an example suits perfect in this thesis focusing on Germany.

Interestingly so, in the case of Australia, academic literature frequently attributes safety and quality deficits in hospitals to a lack of professionalism. In the article in 2015 E. Davis and N. Beale\textsuperscript{203} single out bullying as a principal cause for the bad safety and quality culture in Australian hospitals. For instance, in March 2015 instances of surgeons sexually harassing surgical trainees became public knowledge and horizontal violence, i. e. the bullying of nurses by other nurses appears to be a serious problem. In fact, it is supposedly the second-most common form of bullying experienced by nurses leading to disengagement and a deterioration of productivity and patient care. As a measure to improve this negative culture the authors suggest that the WHO Patient-Safety Paper 2011 be implemented in an attempt to foster team working skills and inter-professional collaboration\textsuperscript{204}. While E. Davis and N. Beale reason in a pretty broad-brush way that the staff working at Australian hospitals is working within a poor quality and safety culture C. Kelly et al. focus on the question of what it is exactly that keeps Australian junior doctors for asking for help when needed. The following table gives an overview of the answers given by the respondents to their survey of what contributes to the non-escalation of clinical concerns:

\begin{table}
\end{table}

\begin{table}
\end{table}

\textsuperscript{201} Hin, Chew Chin: Medical Ethics and Doctor-Patient Relationship, in: SMA News 34 (3), 2002.
\textsuperscript{203} Beale, Norman; Davis, Evin: It’s time: the poor culture regarding safety and quality in Australian hospitals must be addressed!, in: Asia Pacific Journal of Health Management 10 (3), 2015, pp. 15–17.
\textsuperscript{204} Beale, Norman; Davis, Evin: It’s time: the poor culture regarding safety and quality in Australian hospitals must be addressed!, in: Asia Pacific Journal of Health Management 10 (3), 2015, pp. 15–17.
Table 2.1: Reasons for why junior physicians do not escalate when aware of medical malpractice

<table>
<thead>
<tr>
<th>THEME OF ISSUE IDENTIFIED</th>
<th>NUMBER OF RESPONSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived issue accessing more senior / specialized staff</td>
<td>52</td>
</tr>
<tr>
<td>Existence of factors that negatively impact on trainees judgement and decision making re-escalation (e.g. lack of situational awareness, competing demands)</td>
<td>35</td>
</tr>
<tr>
<td>Feel that it is not always clear who to contact / who's responsible</td>
<td>32</td>
</tr>
<tr>
<td>Concern that trainees are not always able to identify when a patient requires escalation</td>
<td>27</td>
</tr>
<tr>
<td>Have concerns about the response from seniors to escalation</td>
<td>25</td>
</tr>
<tr>
<td>Other issues</td>
<td>17</td>
</tr>
<tr>
<td>Perceived limited benefit in escalating</td>
<td>14</td>
</tr>
<tr>
<td>Not clear what the team plan is for managing deterioration or end-of-life issues</td>
<td>11</td>
</tr>
<tr>
<td>Variability in SMS expectations what should be escalated</td>
<td>9</td>
</tr>
<tr>
<td>Concerns that the system do not support optimal escalation</td>
<td>3</td>
</tr>
<tr>
<td>Feel there may be issues with the culture re-escalation</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>234</td>
</tr>
</tbody>
</table>

Source: Authors illustration according to Kelly 2014\(^{205}\)

In the table above you can see that the main factor why junior physicians do not escalate malpractice is that they perceive the issue accessing more senior or specialized staff. The second most named reason is the fear that a judgement can have some consequences for trainees.

Finally, when asked to offer up suggestions about how to improve this situation the respondents make the proposals found in the following table\(^{206}\).

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Table 2.2: Possible ways to increase the willingness or possibility to escalate situations in hospitals

<table>
<thead>
<tr>
<th>ESCALATION ENABLERS IDENTIFIED BY TRAINEES</th>
<th>NUMBER OF RESPONSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimize available workforce</td>
<td>23</td>
</tr>
<tr>
<td>Continue to have rules/policies and guidelines that support optimal escalation</td>
<td>22</td>
</tr>
<tr>
<td>Optimize training about what to escalate and consequences of non-escalation</td>
<td>20</td>
</tr>
<tr>
<td>Optimize senior staff support for and response to escalation</td>
<td>20</td>
</tr>
<tr>
<td>Optimize culture re-escalation</td>
<td>12</td>
</tr>
<tr>
<td>Optimize systems for identifying accountable senior staff</td>
<td>13</td>
</tr>
<tr>
<td>Optimize team planning for acute deterioration and end-of-life scenarios</td>
<td>10</td>
</tr>
<tr>
<td>Optimize paging, IT and telecommunications systems</td>
<td>10</td>
</tr>
<tr>
<td>Other issues</td>
<td>29</td>
</tr>
<tr>
<td>Total</td>
<td>159</td>
</tr>
</tbody>
</table>

Source: Authors illustration according to Kelly 2014

As a conclusion and summary of both tables two main issues were identified and possible solutions derived. The two main issues are availability of senior staff and hierarchy and lack of clear responsibilities in hospitals as you can see in the figure below:

Figure 2.3: Top issues and possible solutions to escalate malpractice

Source: Authors illustration, 2017

A study within the NHS (National Health Service in the UK) over eight years analysing the MSRA rates in hospitals clearly concludes, that risk management leads to reduced infection

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rates. Another example from this study is, that failure to supply such care cost the NHS £787m in clinical negligence pay-outs during 2009–10.

Improvement in patient safety is also a major aim of hospital management these days. Five years after to err is human, two authors Leape and Berwick state “The groundwork for improving safety has been laid in these past five years but progress is frustratingly low”.

Nearly 10 years later, RAND Europe estimated that in the 27 European Union member states between 8% and 12% of patients admitted to hospital suffer from adverse effects while receiving healthcare. A report from the National Patient Safety Foundation stated that 15 years after the IOM released To Err is Human the work to make care safer for patients has progressed at a rate much slower than anticipated. They further state that safety issues are far more complex and pervasive than initially appreciated.

A survey from American International Group (AIG) from 2013 states that patient safety is the highest priority for all respondents. Despite that fact, the study reveals inconsistent perceptions of who is ultimately responsible. Virtually all hospital executives agree that "every staff member in my hospital is responsible for patient safety". But half of hospital managers believe that nurses "own" it. Additionally, nine out of ten managers agree that an emphasis on safety must come from top leadership for it to be truly effective – yet only about three-fourths of executives report that their hospital have executive walk-rounds programs, and in those hospitals that do have such programs, 88% of the managers indicate that they personally participate. These data show that responsibility is beginning to flow uphill but is a difficult climb. That study shows that stakeholders do play an important role in managing patient safety and furthermore that it is not clearly defined who is responsible for patient safety. Clearly, physicians, nurses and management do play an important role.

The case study CLABSI (central line–associated bloodstream infections) from 2005 shows, that key success factor for improving patient safety is to create clinical communities in which

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210 Leape, Lucian; Berwick, Donald: Five Years After To Err is Human: What have We Learned?, 2005.
211 Conklin, Analijn; Vilamovska, Anna-Marie; de Vries, Hans; Hatziantreou, Evi.: Improving Patient Safety in the EU: Assessing the expected effects of three policy areas for future action, 2008.
peer hospitals are learning from each other\textsuperscript{214}. These communities are powerful vehicles in changing peer norms from infections are inevitable to infections are preventable and “I” can do something about it\textsuperscript{215}. The power of peer communities comes from peer learning and tapping into intrinsic motivation among professionals\textsuperscript{216}. This concept it has not reaped rewards in others\textsuperscript{217}. To achieve success, some project-based initiatives, such as the CLABSI checklist, required major changes in teamwork and culture\textsuperscript{218}. It is telling that most initiatives succeed only when they implement tactics using a broader approach. In fact, a fundamental finding from the past 15 years is that patient safety initiatives can advance only by making teamwork, culture, management and patient engagement a key focus. By taking into account systems design, human failures, human factors engineering, safety culture, and error reporting and analysis, the systems approach epitomizes a more comprehensive view. Another example from Neily\textsuperscript{219} shows, that team training in surgery has been shown to reduce mortality by 50\% compared with control sites.

**Multi-Disciplinary Meetings** (MDM) in which medical and allied health care professionals consider relevant options and collaboratively arrive at a decision regarding diagnosis, prognosis or treatment for a patient have been found to lead to better decisions than those made by sole physicians\textsuperscript{220}. Quality of care management decisions by multidisciplinary cancer teams. The multidisciplinary meeting: An indispensable aid to communication between different specialties demonstrated that treatment plans made by interacting health care professionals are more effective than those made by individual practitioners. In addition to

\textsuperscript{215} Pronovost, Peter; Cleeman, James; Wright, Donald; Srinivasan, Arjun.: Fifteen years after To Err is Human: a success story to learn from., 2015.
\textsuperscript{216} Aveling, Emma-Louise; Martin, Graham; Armstrong, Natalie; Banerjee, Jay; Dixon-Woods, Mary: Quality improvement through clinical communities: eight lessons for practice, 2012.
\textsuperscript{218} Gould, Lois J.; Wachter, Patricia a.; Aboumatar, Hanan; Blanding, Renee J.; Brotman, Daniel J.; Bullard, Janine; Gilmore, Maureen M.; Golden, Sherita H Ill; Howell, Eric; Ishii, Lisa; Lee, K. H Ken; Paul, Martin G.; Rotello, Leo C.; Satin, Andrew J.; Wick, Elizabeth C.; Winner, Laura; Zenilman, Michael E.; Pronovost, Peter J.: Clinical Communities at Johns Hopkins Medicine: An Emerging Approach to Quality Improvement, in: Joint Commission journal on quality and patient safety / Joint Commission Resources 41 (9), 2015, pp. 387–395.
\textsuperscript{219} Neily, Julia; Mills, Peter; Carney, Brian; West, Priscilla; Berger, David; Mazzia, Lisa; Paul, Douglas; Bagian, James: Association Between Implementation of a Medical Team Training Program and Surgical Morbidity, in: Archives of Surgery 146 (12), 2011, p. 1368.
\textsuperscript{220} Sharma, Vishakha; Stranieri, Andrew; Burstain, Frada; Warren, Jim; Patterson, Louise; Yearwood, John; Wolff, Alan; Sharma, Vishakha; Stranieri, Andrew; Burstain, Frada; Warren, Jim; Daly, Sharon.: Group decision making in health care : A case study of multidisciplinary meetings, in: Journal of Decision Systems 25, Taylor & Francis, 2016, pp. 476–485.
more effective treatment plans, Lamb, 2011\textsuperscript{221} found that MDMs also lead to increased communication between disciplines that are useful for training junior doctors also found that specialists from one discipline understand the possibilities and constraints of other disciplines when exposed to other disciplines through MDMs. Effects of multidisciplinary team working on breast cancer survival: Retrospective, comparative, interventional cohort study of 13722 women reports that this translated into improved breast cancer mortality rates.

According to Lamb 2011, though MDMs generate many benefits, meetings do not always lead to optimum decision-making as outcomes have been found to be highly inconsistent and largely dependent on the effective participation of the team members. Evidence, challenges, and the role of clinical decision support technology. International journal of breast cancer, established that a lack of appropriate support for participants in an MDM was an important barrier to the quality of MDMs. Another research found that many participants in an MDM setting in Australia reported a large amount of time was wasted due to disagreements between participants. However, the same survey revealed that participants were still positive about the outcome of MDMs and believed that it led to better plans for care. Although, MDMs are clearly a group decision-making process, few studies have explored MDM processes and outcomes from the perspective of group reasoning. Evidence from face to face groups for some time has revealed that participants face many barriers to sharing all of their information and effectively reaching a decision Small group decision making: Some participants dominate due to their authority or charisma, all information may not be fully shared, the groupthink phenomena described by Janis found that a lack of proper communication and interpersonal interaction can account for 70–80% of errors in health care.

MDMs are relatively recent phenomena. Some approaches to evaluate their effectiveness exemplified by Ruhstaller, Roe and Thorlimann 2006\textsuperscript{222} have followed an experimental methodology whereby decisions taken by an MDM are compared with those from single physicians. The experimental methodology is generally applicable for the evaluation of medical treatments or procedures, where the dependent variable is a measure of patient health. However, an MDM is not the same kind of intervention as a treatment or procedure. As a communication process, an MDM cannot readily be evaluated using the same approach as


\textsuperscript{222} Ruhstaller, Thomas; Roe, Heiner; Thorlimann, Bernd: The multidisciplinary meeting: An indispensable aid to communication between different specialities, in: Eur J Cancer 42 (15), 2006, P. 2459–2462.
medical interventions. This view is consistent with that held by Shaw (2002) who found that information technologies in health care were often inappropriately evaluated using randomized clinical trial methodologies.

2.2 Influence of regulatory environment to hospitals

The first piece of legislation that is going to discuss in this section is the revisions of the fee-for-service system (FFS) in Japan. More precisely we are going to review Haruko Noguchi’s 2015 article “How does the Price Regulation Policy Impact on Patient-Nurse Ratios (PNRs) and the Length of Hospital Stays (LHSs) in Japanese Hospitals?” It is widely accepted that nurses as the primary care givers in hospitals lie at the center of safety concerns which explains why this section begins with an article focused on nurses. In light of the fact that it intuitively makes sense that the risk of being subjected to some unwanted, avoidable incident is a positive function of the duration of patients' hospital stay it can be concluded that this piece of legislation while not making explicit reference to the issue of safety impacts indirectly on the level of safety that Japanese hospital patients get to experience. For the last couple of decades the number of nurses in Japan has been widely considered insufficient. As a reaction to the increase in demand for nursing care in hospitals brought about by population ageing, the diffusion of high-tech care and the disallowing of supplemental care for inpatients by family members the total quota of nursing places at universities has recently been growing at a fast pace. The following graph offers an overview of how Japan compares to other countries with regard to the number of practicing nurses per 1000 population.
Figure 2.4: Practicing nurses per 1000 population in over 10 years in different countries, 2010

Source: Authors illustration according to Hoguchi, 2015

Clearly for a developed country with arguably the best health care system in the world Japanese hospitals appear to be quite understaffed with nurses which suggests that it would be desirable that the aforementioned revisions of the fee-for-service system impact negatively on the patient-nurse ratios and the length of hospital stays in Japan. The revisions that Haruko Noguchi takes into account are the 1988 addition of a reimbursement payment, the 1992 abolition of FFS for wards that did not meet the legal standard of PNR required by the Medical Care Act, the 1994 National Health Care Reform, the bundling of three categories of

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charges for nursing care, medical supervision and management, and a hospital room into one inpatient hospital fee and finally the 2006 introduction of a new standard for inpatient hospital fees. While the preceding criterion was the number of inpatients per employed nurse this new standard was based on the number of inpatients per working nurses per working hour. Furthermore a PNR of 7:1 was introduced as a new criterion by the FFS system. Haruko Noguchi concludes that the revisions of the FFS in 2000 and 2006 definitely achieved the policy objectives of lowering PNRs and the length of a patient's hospital stay in large and medium sized hospitals though not in small hospitals. Haruko Noguchi argues that in order to bring the average LHS for acute high-tech care close to the mean of OECD countries Japan needs more intermediate facilities and clinics where subacute, long-term, and home health care are provided. A self-diagnosed weakness of his study is that it does not evaluate the impacts of the FFS on patient outcomes and the medical costs. The former means that with regard to the issue of safety his study only allows for indirect inferences. More to the point his study prompts the author of this dissertation to conclude that the revisions of the FFS in 2000 and 2006 have likely improved the level of safety in large and medium sized Japanese hospitals by significantly lowering their respective PNRs.

Anupam Jena's and Michael Frake's article “Does Medical Malpractice Law Improve Healthcare Quality“ which was published in 2015 analyzes for the United States how substantive malpractice reforms and remedy-focused liability reforms affect the behavior of physicians. Anupa Jena and his co-author begin their analysis with the observation that the clinical decisions that physicians make are shaped by a number of forces. Since these clinical decisions also pertain to decisions to perform particular treatments and to deliver certain levels of quality they obviously impact the degree of safety that hospital patients get to enjoy. One such force appears to be the fear over liability for harming a patient through actions that do not comply with the standard of care expected of physicians by law. Depending on how physicians weigh this force against other determinants of clinical practices, liability systems may compel a subset of especially risk averse physicians to uncritically follow the legally expected standards inherent in that system. Historically, the law has attempted to distill these standards from the practices of local physicians which likely is part of the reason why the standard of health care in the US varies so much. In the second half of the twentieth century, the majority of states abandoned these locality rules in favor of national standards of care which geographically harmonized clinical expectations and implicitly also safety expectations.

under the law. In their article Anupam Jena and Michael Frake test the hypothesis that prevailing rates of health care quality shift according to these modified expectations.

More precisely, he tests whether physicians respond differently to changes in malpractice standards depending on whether these modified standards expect higher or lower levels of quality. The second hypothesis that he tests is that damage cap adoptions affect the levels of treatment quality chosen by physicians. This second hypothesis is motivated by the observation that physicians may find themselves confronted with a number of uninsurable costs as a result of malpractice liability. Examples for these kinds of uninsurable costs are reputational and psychological damage. Damage caps serve to minimize the risks of these kinds of uninsurable costs.

After testing these hypotheses the authors conclude with regard to the first hypothesis that the relationship between health care quality and changes in clinical malpractice standards works only in an expansionary directions. More to the point when physicians provide a high level of quality they stick to these practices even when the law lowers expected standards at a later date. Physicians who provide a quality of care that lies below what the law expects tend to raise their practices to meet the higher expectations set by the law. It can thus be concluded that malpractice forces that change the legal clinical standard to which physicians are held therefore seem to be effective in elevating the quality floor and by consequence also the level of safety that hospital patients get to experience. With regard to the second hypothesis Anupam Jena and Michael Frake conclude that the adoption of damage caps does not seem to cause physician practices to revert back to their locality-rule-era levels. The explanation that Anupam Jena and his co-author offer for why this is the case is that physicians, particularly newer physicians, adopt beliefs over proper practices mostly through their own past experiences or through the observation of practices followed by those around them which results in malpractice-induced changes shaping more durable physician norms and customs which may survive subsequent diminishment of liability forces^225.

In the United Kingdom, the National Patient Safety Agency is an institution that is all about improving the level of safety for patients. The Agency began its work on the first of October 2001 and it is dedicated to improving patient safety by reducing medical error.

The philosophy for the establishment of this agency is the so-called systems approach which rather than blame individuals for medical malpractice asks the three following questions:

1) Reason why it is needed

2) Improvements in processes to make it less error prone

3) Identify barriers to errors

According to James Reason, a British academic psychologist focused on the systems approach, the Swiss Cheese Model as exemplified by the following illustration offers a good representation of how hazards ultimately lead to losses in the context of an organization.

![Figure 2.5: Schematic view of hazards leading to losses in organizations](image.png)

*Source: Authors illustration, adapted from Shaw, 2002*

The idea is that organizations have defensive barriers that are designed to and that usually do prevent accidents. The imperfections in these barriers are represented by holes and an accident happens when through force of circumstances all holes are aligned. Reason argues that system barriers fail in two ways. On the one hand side there are active failures – slips, lapses, fumbles, mistakes and procedural violations and on the other hand there are so called latent conditions that convert into error-provoking conditions. The following graph highlights the relationship between culture, decisions and incidents.

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Figure 2.6: Relationship between corporate culture, decisions and incidents

Source: Authors illustration, adapted from Shaw, 2002

This graph motivates the following three questions about an occurred adverse event in an hospital:

1) Explanation what happened – narration about the event

2) The predisposing conditions – explore reason why accident / incident happened

3) The failures in the defense mechanism – explore why accident / incident occurred

The National Patient Safety Agency is built on Reason's analysis and its objectives go as follows:

- Collect and analyze information on adverse events from local NHS organizations, NHS Staff and patients and careers;
- Assimilate other safety-related information from a variety of existing reporting systems and other sources in this country and abroad;
- Learn lessons and ensure that they are fed back into practice, service organization and delivery;
- Where risks are identified, produce solutions to prevent harm, specify national goals and establish mechanisms to track progress.

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Since improved patient safety calls for the collaboration of other agencies and organizations both within and outside government the National Patient Safety Agency finds itself situated at the center of communications network.

![Communications network and participants in United Kingdom](image)

**Figure 2.7:** Communications network and participants in United Kingdom

*Source: Authors illustration according to Shaw, 2002*

The quality of communication flows is what ultimately determines how well the National Patient Safety Agency succeeds in meeting its objects. It can thus be concluded that in the United Kingdom ever since 2001 hospital safety concerns are being dealt with in a centralized way.

### 2.3 Influence of economic environment to hospitals

When discussing the role of the market in the context of health care and the developed world it is advisable to distinguish between Europe, Canada, Japan and Australia on the one hand side and the United States and Singapore on the other hand. The member countries of the EU,

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Canada, Japan and Australia follow for the most part what is known as the European government payer model. Progressives in the United States who are discontent with the performance of their own healthcare system regularly argue that the United States ought to emulate the health care systems of these countries and abandon its own mainly market driven health care system. In his article „The Singapore Model“ Rowan Callick argues that instead the United States ought to consider emulating Singapore since Singapore has proven that it is possible to develop an efficient and equitable health care system based on the market that truly serves the people. To buttress this argument he points to the fact that in 2008 life expectancy at birth in the United States was 78 years and in Singapore 82 years, that the US infant mortality rate was 6.4 deaths per 1000 live births whereas in Singapore it only was 2.3 deaths per 1000 live births. All of this even though the United States has far more caregivers per 1000 people than Singapore. More precisely, in 2008 in the United States there existed 2.6 physicians per 1000 people and in Singapore only 1.4. The situation in the nursing profession was not much different with 9.4 nurses covering 1000 people in the United States and 4.2 nurses covering 1000 people in Singapore. Furthermore the United States had six times as many dentists as Singapore and three times as many pharmacists. This implies that compared to the United States Singapore is better at extracting value for consumers from the supply on offer. In Singapore, the state funds merely one-fourth of total health costs. The rest is paid for by individuals and their employers. Clearly, Singapore requires individuals to be responsible for their own health and to be responsible for much of their own spending on medical care with the state merely providing a safety net for the few people that are unable to save enough to pay their own way.

A welcome consequence of all of this is that decisions are put in the hands of patients and doctors rather than of insurers and government bureaucrats. The state further subsidizes public hospitals and funds preventative health campaigns. The institutions that carry Singapore's health care system are Medisave, Medishield and Medifund. About 85 % of Singaporeans are covered by Medisave. The program functions such that employees pay 20 % of their wages into the Central Provident Fund (CPF) while employers pay 13 %. Hospital expenses can be paid for directly by resorting to the savings of Medisave accounts. However, there exists thresholds for the Medisave funds that can be used for daily hospital charges, physicians fees and surgical fees. The principle goal of this arrangement is to cover fully the bills of most patients in state-subsidized wards of public hospitals.

The second central institution of Singapore's health care system Medishield is a national insurance plan that covers the higher cost of catastrophic illness. Singaporeans get to choose
between Medishield and several private alternatives. In Singapore's health care system the principal role of the government is to require people to save so that they will be able to meet medical expenses that they do not expect. According to Rowan Callick the Singaporean government also regulates prices and services though nowhere near as heavily as the governments with extensive nationalized health care like the governments of the United Kingdom or Germany. Since 2002 public health care facilities in Singapore have been clustered into two integrated networks that are each government owned and managed by two integrated networks as nonprofits. According to the Health Ministry these clusters “Provide cooperation amongst the institutions within the cluster, foster vertical integration of services, and enhance synergy and economies of scale. The friendly competition between the clusters spurs them to innovate and improve the quality of care while ensuring that medical costs remain affordable. “ Both networks benchmark against international standards and publish performance figures. According to Rowan Callick private general practitioners meet 80 percent of primary healthcare needs and 20 % of these needs are met by public outpatient “polyclinics“. Phua Kain Hong, associate professor of health policy and management at the Lee Kuan Yew School of Public Policy at the National University of Singapore lists five prerequisites for countries that may want to emulate Singapore's health care system230:

Status 2018:

1) A willingness and ability to save
2) High participation in formal employment
3) Effective payroll collection with efficient fund management and claims processing
4) A well-developed information system with strong security and accounting controls
5) Effective public education in the proper use of medical accounts.

With regard to the private-public mix he states that most people lean toward the private system for primary care and the public system for hospital care. In 2008 there existed 13 public-sector specialty centers and hospitals in Singapore and 16 private-sector hospitals. 74 % of the beds, however were within the public sector. From this last observation it follows that the safety of hospital patients in Singapore is a problem that for the most part must be addressed by those responsible for the management of public hospitals.

The market for hospitals in Germany is especially interesting because Germany is an ageing society. According to a study by Roland Berger Strategy Consultants more than 70 % of German hospital managers expect their financial prospects to deteriorate in the next couple of years. In 2015 about 30 % of German hospitals were not able to generate a profit. The most important negative trends that German hospitals find themselves subjected to are the insufficient supply of expert professionals and the pressure on profit margins. Most hospitals seem to be focused on investing in divisions of their hospitals that cater to a high percentage of elderly patients. Since elderly patients are more vulnerable than young patients this likely means that the risk of accidents occurring in the future is somewhat elevated by this investment policy. More than 60 % of the managers interviewed for the Roland Berger Strategy Consultant study indicated that their hospitals were currently being restructured and more than 75 % of these managers characterized the restructuring efforts as being quite intense. 40 % of the managers interviewed admitted that their hospital was not investing enough. As for the process of digitization, remarkably so, German hospital managers do not seem to be prioritizing it, which implies that their hospitals are likely not leveraging these technologies to their potential when it comes to designing safer treatment procedures for customers and more efficient communication channels for decision makers.

Given the fact that German hospitals have been underfunded since the 1990s it can be concluded that the staff working at German hospitals is working in a stressful environment in which people likely do not have the luxury to be particularly innovative when it comes to designing safety measures.

The last article that we want to review in this sub-section is Rhay-Hung Weng's et al. article “The impact of market orientation on patient safety climate among hospital nurses”. The authors conceptualize market orientation as a combination of customer orientation, competitor orientation, and interfunctional coordination. According to the authors market orientation is the principal adaptive strategy for hospitals in the Taiwanese health care market. Nurses that are strongly customer oriented prioritize patient benefits and safety, which prompts them to proactively search for methods to minimize risks thereby decreasing the chance of adverse effects occurring. Hospital managers that are oriented towards the competition are well positioned to elucidate the strengths, abilities, and actions of their competitors to improve health care quality and patient value. Employees that perceive customer satisfaction as a form of duty are more likely to communicate effectively improving frontline staff communication

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and ensuring that the information flow between different departments is adequate. The authors point out that nurses are the key to improving patient safety since they are the primary providers of inpatient care in hospitals. Consequently, their perceptions of the work environment affect patient safety.

The patient safety climate is conceptualized as depending on four key dimensions which correspond to employee perceptions regarding four variables: safety procedures, managerial safety practices, safety information flow, and safety priority. Safety procedures are about the shared perceptions of employees regarding the level of detail in the safety procedures of a given organization. Managerial safety practice denotes employee perceptions regarding the safety-related activities and methods of supervisors. Safety information flow refers to the amount of information that employees receive through circulation of routine information and training. Safety priority, finally, is the level of concern assigned to safety within an organizational unit. Based on the concepts that were just introduced the authors go on to test the following three hypotheses:

1) Customer orientation is positively associated with the patient safety climate.

2) Competitor orientation is positively associated with the patient safety climate.

3) Inter-functional coordination is positively associated with the patient safety climate.

The sample for the testing of these hypotheses comprised 77 nurses from various project teams and 266 nurses from a variety of departments. These nurses were asked to answer questions that led to the following responses:

The authors conclude that the data only supports hypothesis one and that the results of their study warrant making the following suggestions:

1. Hospital managers ought to formulate appealing goals and appropriate reward systems that reward employees for behaving in a way that promotes market orientation.

2. Hospital managers should develop training systems to collect, disseminate, and respond to market intelligence.

3. Hospital managers should establish a formal mechanism for collecting, disseminating, and responding to market intelligence in hospitals so that health care professionals get to benefit from clear implementation procedures and sufficient administrative support.

4. Health care professionals should share competitor information throughout the organization thereby strengthening competitor orientation and ensuring that information regarding patient demands and competitor intelligence is voluntarily collected.

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The conclusions drawn at this stage should be viewed as tentative since the author is very much aware of the fact that this overview does not cover every aspect that is relevant for the level of safety that hospital patients get to experience in the developed world. Nonetheless, we shall now attempt to draw some general conclusions.

With regard to the level of professionalism of hospital staff it seems to be the case that the standard for professional behavior is becoming increasingly global and that in today's world professional behavior requires physicians to also be well aware of socio-economic and business related issues. It further is important to note that in Asia's developed societies collectivist values dominate individualist values which has serious repercussions for the flow of information which implies that the loopholes in safety barriers will likely differ systematically between the East and the West at least in so far as these loop holes are caused by inefficient communication. Finally it is worth noting that in Australia there seems to exist a consensus that the team work of hospital staff must be improved if patients are to benefit from better safety standards.

With regard to the issue of regulation it is noteworthy that in the United Kingdom there exists a centralized institution that is dedicated specifically to improving the level of patient safety and that in the United States a country known for its aggressive litigation culture liability caps do not appear to have a major impact on the way physicians go about administering care to patients and thus they should not have a major impact on the level of safety patients get to enjoy. In light of the fact that America's litigation culture is likely the most aggressive of all countries surveyed it can be concluded that liability caps in other developed countries probably also do not have a major impact on the way physicians go about their business. It further is noteworthy that in the United States, a country where from state to state the quality of care and thus the level of safety sometimes differs drastically efforts are being undertaken to get rid of these inequities.

Finally turning to the effect that market forces have on the level of safety in hospitals it is important to note that a strong patient orientation among hospital nurses has proven to be the most effective way to improve the level of safety and that ageing societies like Germany find their hospital staff increasingly having to take care of the elderly which likely increases the risk of accidents occurring. In fact, the author of this dissertation thinks that in ageing societies like Germany hospitals should perhaps deliberately undertake an effort to develop safety guidelines that deal specifically with the safety issues of elderly patients. As for the dissatisfaction of American progressives with the state of their health care system it is worth
noting that the United States does not really meet the criteria to import a health care system that basically is a copy of the one of Singapore, mostly because unlike Singaporean citizens American citizens are not known for saving instead American citizens are known to be enthusiastic about making use of their credit cards. Given this fact and the problems that America's health care system has it does not seem likely that in the US the level of safety for patients can be improved merely by attempting to leverage market forces, particularly when one takes into consideration that even in market driven Singapore most patients frequent public hospitals turning the safety of hospital patients very much into a public issue.

In closing the author of this dissertation would like to suggest that the main conclusion to be drawn probably is that the safety of hospital patients ultimately appears to be a public issue and that and that market forces are best employed when the goal is to ensure that hospital nurses consistently give the safety of their patients a high priority.

The U.S. Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 earmarked more than $20 billion to foster electronic health records (EHRs) at U.S. hospitals and other medical facilities, and facilities have spent billions of their own to digitize patient records and clinical workflows. What benefits have accrued? Have EHRs lowered the cost and improved the quality of healthcare? In particular, what has been the effect of EHRs on patient safety? There is some evidence that EHRs reduce costs over the long term and under the right conditions. But evidence is scant on the effect of EHRs on patient safety.\textsuperscript{234} An Institute of Medicine (IOM) 2012 study, Health IT and Patient Safety, concluded, “current literature is inconclusive about the overall impact of health IT on patient safety.”\textsuperscript{235} This lack of evidence prompted an econometric study of patient safety at Pennsylvania (PA) hospitals. Patient safety improved for Pennsylvania hospitals that adopted EHRs: a 27% decline in overall patient safety events and a 30% decline in medication errors. Electronic health records were already recommended in the review of 5 years after to err is human as a next step,\textsuperscript{236} however so far not very widely spread. The example of EHR shows, that even if a safer system (like EHR) was implemented it must not be successful. Without having a safe culture and commitment from management the whole new system will not be successful. In general,

\textsuperscript{234} Dranove, David; Forman, Chris; Goldfarb, Avi; Greenstein, Shane: The trillion dollar conundrum: Complementarities and health information technology, in: American Economic Journal 1, 2014.
\textsuperscript{235} Institute of Medicine (IOM): Health IT and Patient Safety: Building Better Systems for Better Care, 2011.
\textsuperscript{236} Institute of Medicine (IOM): Health IT and Patient Safety: Building Better Systems for Better Care, 2011.
electronic support in health care will lead to safer care, e.g. barcoding has been shown to reduce medication administration errors.\textsuperscript{237}

Another topic is the conflict of interest between Patient Safety and Financial Performance in HealthCare.

A telephone survey conducted by Edelman among 250 hospital C-Suite executives and 100 Risk Managers in hospitals in 2012 across the US\textsuperscript{238}. One major finding of that study is the competing goals: patient safety and financial sustainability challenge hospital and risk managers for their time and attention. Two third of hospital leaders surveyed report, that maximizing patient safety is their top priority. Nearly two-thirds also say that failing to maximize financial sustainability is the biggest threat to their hospitals this year. Only 2\% of hospital managers considered maximizing financial sustainability as their highest priority, but 16\% of their time was devoted to this goal. In contrast, 64\% of hospital managers ranked maximizing patient safety as the highest priority, while 33\% of the time was devoted to this goal. The need to address each goal is high\textsuperscript{239} and the resources to do so are limited\textsuperscript{240}. Figure 10 below shows the conflicting goals including time spent.

\textsuperscript{237} Leape; Berwick: Five Years After To Err is Human: What have We Learned?, 2005.
\textsuperscript{240} Kohn; Corrigan; Donaldson: To err is human: Building a SaferHealth System, 1999.
Figure 2.9: Relationship of priority and perceived threats of activities from C-Suite and risk managers


Some outcomes and finding of this study including 350 healthcare professionals are\textsuperscript{241}:

1) Patient safety and financial sustainability should be complementary goals, not competing objectives. Given that nearly half of every dollar spent on health care costs is related to a medical mistake, improvements in patient safety will have a quick return on investment and ease financial burdens.

2) Strategies to relieve the “safety vs finance” tension should be explored at the executive level to set a deliberate focus and course.

3) Hospitals should seek to define and establish clear responsibility for patient safety. To have positive outcomes, patient safety must be a multi-disciplinary goal.

4) Executives need to walk the talk and set the tone for a consistent culture of patient safety where open communication is not only valued but expected. Everyone needs to

\textsuperscript{241} American International Group (AIG), Patient safety, hospital risk: Perspectives of hospital c-suite and risk managers, (2013).
be able to influence the culture as well as the deployment of safe patient care. Everyone who touches a patient is equally responsible for patient safety. Anyone who identifies an issue with patient safety must feel free to discuss that issue for the benefit of patient safety without fear of retribution.

5) All stakeholders/disciplines need to engage in a thoughtful, collaborative and strategic approach to creating effective tools and processes for improving patient safety and reducing the potential for adverse outcomes.

6) Insurance carriers can play a larger role in patient safety. For example, they can provide services to assess a hospital’s patient safety culture and program components.

The overall outcome is clearly competing goals together with rising cost pressure in hospitals. The next case study from Germany also addresses this conflicting issue.

2.4 Patient safety culture in hospitals

Increasingly, healthcare organizations are becoming aware of the importance of transforming organizational culture in order to improve patient safety. Growing interest in safety culture has been accompanied by the need for assessment tools focused on the cultural aspects of patient safety improvement efforts.²⁴² Hospital leaders are increasingly pressured by federal, state, regulatory, and consumer groups to demonstrate an organizational safety culture that assures patients are safe from medical error.²⁴³ Seven subcultures are identified as teamwork, evidence-based, leadership, communication, learning, justice²⁴⁴ and patient-centered care as showed in the graph below.

²⁴⁴ A culture that recognizes errors as system failures rather than individual failures and, at the same time, does not shrink from holding individuals accountable for their actions.
In 2018, a review about the Bulgarian patient safety culture was conducted. This review shows the need to develop and maintain a positive patient safety culture in the healthcare settings in Bulgaria. It requires amendments to the existing regulations, the introduction of uniform taxonomy, universal measuring instruments of patient safety culture and registration of medical errors in healthcare settings. Summarizing the result, we would like to mention a number of initiatives that should be encouraged in the Bulgarian healthcare system:

- Creating of work environment, where patient safety culture is the main priority and among the most important organizational objectives;

- Introduction of information and communication system (ICT) for registration of and assessment of adverse events and medical errors (PSRS) at a national level;

- Introduction of patient safety programs;

- Introduction of instruments to measure patient safety culture.

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Patient safety culture was measured using a validated Belgian adaptation of the Hospital Survey on Patient Safety Culture (HSOPSC) questionnaire. Studies before autumn 2005 and after spring 2007 on how the improvement approach was implemented were carried out. Using HSOPSC, safety culture was measured using twelve dimensions\(^{247}\). In 2004, the Agency for Healthcare Research and Quality (AHRQ), based in the USA, released the Hospital Survey on Patient Safety Culture for providers and other staff to assess the patient safety culture in their hospitals\(^{248}\). Since then, hundreds of hospitals across the United States and internationally have implemented the survey. In this study in Belgian Hospital after an 18 to 26-month period, significant improvement was observed for the “hospital management support for patient safety” dimension - all main effects were found to be significant. Regression analysis suggests there is a significant difference between professional subgroups. In one hospital the “supervisor expectations and actions promoting safety” improved. The dimension “teamwork within hospital units” received the highest scores in both surveys. There was no improvement and sometimes declining scores in the lowest scoring dimensions: “hospital transfers and transitions”, “non-punitive response to error”, and “staffing”. Although much needs to be done on the road towards better hospital patient safety, this study presents lessons from various perspectives. It illustrates that hospital staff is highly motivated to participate in measuring patient safety culture. Safety domains that urgently need improvement in these hospitals are identified: hospital transfers and transitions; non-punitive response to error; and staffing. It confirms that realizing progress in patient safety culture, demonstrating at the same time that it is possible to improve management support, is complex.

In 2010, an estimated 8 – 12% of patients admitted to hospital in the EU suffer from adverse events whilst receiving healthcare.\(^{249}\) These are the latest statistics available in 2018.

The conclusion from Dr. Jonitz\(^{250}\) is that there is already some progress made in Germany, however joint action there is needed. Improvement of culture is absolutely essential to further improve the safety of patients and therefore also to make hospitals more successful and sustainable.


A case study on need for improvement in patient safety culture in Germany says that the change of culture needs the promotion of action and acceptance.\textsuperscript{251} This study states the following “win-win-goals”:

- Better confidence in health care
- Higher quality
- Less harm, pain and grief (patients, families and „second victims”)  
- Lower costs
- Better cooperation based on common sense and trust
- Evidence based health care
- Understanding of a better organization
- End of „passing the buck“
- More job satisfaction
- Promote action and acceptance

Further this report about Germany states the following key success factors for implementing a patient safety culture:

- Leadership by professionals and leading institutions!
- Bad issue but „good news“!! (Positive framing)
- Taking action! (No more suffering as a victim – help yourself AND your patients)
- Participation, honesty, appreciation, support, friendliness, cooperation, confidence, common responsibility!
- Free access and share ware of know how and products/ materials (recommendations, scientific results, reports, information…)
- Involvement of leading stakeholders up to the minister! (Top-down-revolution)

The conclusion from Dr. Jonitz\textsuperscript{252} is that there is already some progress made in Germany, however there is a joint action needed. Improvement of culture is absolutely essential to further improve the safety of patients and therefore also to make hospitals more successful and sustainable.


Another study on German safety culture in hospitals was conducted in 2017 and highlighted the need for training to improve patient safety.\textsuperscript{253} Related factors regarding the subject areas were derived: teamwork (team-building exercises, interprofessional teamwork, and interprofessional communication), safety culture (dealing with criticism, appraisals, open handling of errors/proactive error reporting), and patient involvement (inclusion of patients and/or relatives, question types). The combination of e-learning and interprofessional in-person training was emphasized as a conducive learning format. The desire for practical tips, Continuing Medical Education credits, and intuitive review of theories was expressed. This study initially presents the current situation regarding patient safety, existing training, teamwork, safety culture, and patient involvement in southern German hospitals and provides recommendations for related content and learning format. Based on the results, it is recommended to develop a combination of e-learning and interprofessional in-person training. This training should systematically link all three subject areas and address the derived content from the focus groups to improve patient safety.

2.5 Case study in German hospitals to improve patient safety

Hospitals do have several drugs which are prepared in the hospital. Preparation of drugs is one of the major sources of medication errors and therefore relevant for patient safety. These drugs are either prepared in the hospital pharmacy or directly before administering into the patient on the different wards. In both cases, the drug is not in the original packaging anymore, not primary nor is secondary packaging still the original. Therefore, the information with regards to the drug, e.g. dosing, concentration is not with the drug anymore. In the case study that this research is concerned with, the original drug comes in a vial and has to be wound into a syringe which is customized for a specific patient. There is the error potential and the question is: how does the nurse on the ward know which syringe is for which patient if there is not information on the syringe.

The case study on that question was conducted by the author of this doctoral thesis in 2009. This case study was part of the Master thesis during the authors studies at Imperial College London. During that case study, the author interviewed fifteen relevant stakeholders of fifteen different hospitals in Germany. The aim was to analyze the process of preparing drugs in the hospital with regard to patient safety and to analyze the potential of a new labeling system which could increase patient safety and reduce medication errors. By doing that it is clear what can be done to improve patient safety.

If you look at the process how it is recorded in 2009, without a labelling system it is very clear, that there are potential risks of error.

**Status quo – process without label**

<table>
<thead>
<tr>
<th>Order in pharmacy</th>
<th>Open or newly develop recipe</th>
<th>Develop the label</th>
<th>Automated design and printing of label</th>
<th>First and check the label</th>
<th>Label the drug</th>
<th>Check the label</th>
<th>Transport to general ward</th>
<th>If needed, include patient label</th>
<th>Administer drug</th>
<th>Documentation with pass-off possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated</td>
<td>In program</td>
<td>Not integrated</td>
<td>Opening of word document</td>
<td>First and check the label</td>
<td>Label the drug</td>
<td>Check the label</td>
<td>Transport to general ward</td>
<td>If connected to patient database, my patient label needed</td>
<td>Administer drug</td>
<td>Documentation with pass-off possible</td>
</tr>
</tbody>
</table>

**Figure 2.11: Preparation of drugs in hospital pharmacy in hospitals, without labelling solution**

*Source: Authors illustration, 2009*

By comparing the two processes, one as it is now and the other one as it would be with the labeling solution is it clear that the added label with reduce the risks of medication errors and therefore increase patient safety.

**Process including label**

<table>
<thead>
<tr>
<th>Order in pharmacy</th>
<th>Open or newly develop recipe</th>
<th>Develop the label</th>
<th>Automated design of label and adding of warnings (if needed)</th>
<th>First and check the label</th>
<th>Label the drug</th>
<th>Check the label</th>
<th>Transport to general ward</th>
<th>If connected to patient database, my patient label needed</th>
<th>Administer drug</th>
<th>Documentation with pass-off possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated</td>
<td>In program</td>
<td></td>
<td>Automated design of label and adding of warnings (if needed)</td>
<td>First and check the label</td>
<td>Label the drug</td>
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<td>If connected to patient database, my patient label needed</td>
<td>Administer drug</td>
<td>Documentation with pass-off possible</td>
</tr>
</tbody>
</table>

**Figure 2.12: Preparation of drugs in hospital pharmacy in hospitals, including label solution**

*Source: Authors illustration, 2009*

As a result of comparing the processes with and without the label there are clear advantages of using a label: 1) Producing the label: More information at point of administration; saving of time and reduction of risk for the patient 2) Administration of drug: saving of time and reduction of risk for the patient 3) After administration: better cost effectiveness. To sum it up, the usage of labels would increase safety, reduce time and reduce costs.

In all 15 interviews, the interviewees confirmed the added value of the presented labeling solution. Further, they all confirmed that the labels would decrease the risk of medication errors and increase the level of patient safety. However, they mentioned critical barriers of implementation. The most critical barrier is cost. All interviewed persons stated that costs are
the major driver. Even if they see a clear reduction of patient risk, the hospitals are only willing to pay little money. The second major hurdle is the change in processes in the hospital. All hospitals involved are quite hesitating to change established processes in hospitals.

The result of the case study is clear: added value and increased patient safety is noticed however high adoption barriers due to cost sensitivity and internal switching barriers such as change of processes. 7 years later, the concept is still not implemented in hospitals due to cost issues.

2.6 Professional Healthcare Associations view on Patient Safety

The European Board of Anaesthesiology (EBA) recommendations for safe medication practice replace the first edition of the EBA recommendations published in 2011. They were updated because evidence from critical incident reporting systems continues to show that medication errors remain a major safety issue in anaesthesia, intensive care, emergency medicine and pain medicine, and there is an ongoing need for relevant up-to-date clinical guidance for practising anaesthesiologists. The recommendations are based on evidence wherever possible, with a focus on patient safety, and are primarily aimed at anaesthesiologists practising in Europe, although many will be applicable elsewhere. They emphasise the importance of correct labelling practice and the value of incident reporting so that lessons can be learned, risks reduced and a safety culture developed\textsuperscript{254}.

The European Board of Anesthesiology recommendations for safe medication Practice

\textit{Drug syringe preparation and labelling.}

All medications prepared for routine use in anaesthesia, intensive care, emergency medicine and pain medicine should be clearly labelled. The EBA recommends that pre-filled syringes should be used wherever possible. Hospital pharmacies and manufacturers should be encouraged to supply them particularly in the first instance for high-risk medicines and those administered as infusions because of the risks of dilution errors and infection. The EBA recommends the International Organisation for Standardisation (ISO) anaesthetic and respiratory equipment.

\textsuperscript{254} Whitaker, David; Brattebo, Guttorm; Trenkler, Stefan; Vanags, Indulis; Petrini, Flavia; Aykac, Zuhal; Longrois, Dan; Loer, Stephan Alexander; Gaszynski, Tomasz; Sipylaite, Jurate; Copaciu, Elena; Černy, Vladimir; Akeson, Jonas; Mellin-olsen, Jannicke; Abela, Carmel; Stecher, Adela; Kozek-langenecker, Sibylle; Ra, Indrek.: The European Board of Anaesthesiology recommendations for safe medication practice First update, in, 2017, pp. 4–7.
Drug packaging and labelling
The labelling and packaging of all drugs should facilitate their easy identification. When a drug is available from more than one manufacturer, the clarity of the labelling and the avoidance of look-alike packaging or labelling should be considered when making purchasing decisions. Labelling should conform to applicable national or international standards as these are adopted.

Drug contamination and transmission of infections
Contamination of any drug must be avoided. To minimize the risk of cross-infection between patients, the contents of any one ampoule should be administered to only one patient. The use of multi-dose ampoules is not recommended.
To prevent the transmission of nosocomial infections such as hepatitis C and malaria between patients, the use of saline bags with reusable administration ports to provide fluid for drug dilution and syringes for flushing i.v. lines for more than one patient should no longer take place. Single ampoules of saline or preferably single pre-filled syringes of saline should be used instead.

Drug cupboards, anaesthetic trays and storage systems
Drugs should be stored in ways designed to facilitate their easy identification and minimise the risk of error or misidentification. Arranging medicines in drug cupboards in their pharmacological medication class groups can reduce the risk of between-class errors, which are generally likely to be more dangerous than within-class errors.
Consideration should be given to storing drug ampoules in their original packaging until just before they are drawn up. Special care should be taken with ampoules that look similar, have similar names or have labels that are difficult to read. Local anaesthetic agents should be stored separately from anaesthetic drugs and high-risk medicines such as i.v. potassium should be stored securely. Gallipots, bowls or other open containers for drugs, antiseptics or saline should no longer be used on the sterile field to prevent possible contamination and drug errors, some of which have been fatal.
Adequate, uncluttered surface space and appropriate trays, clean for each patient, should be provided for drawing up, arranging and holding the syringes and drugs used in each anaesthetic. Wherever possible, this should be standardised. Cannulae should be flushed after administration of drugs to reduce the risk of inadvertent administration of anaesthetic drugs in the recovery room or on the ward.

Distractions
Distractions are a significant cause of medication errors. All members of the anaesthesia team should avoid distractions or interrupting others during the preparation and administration of patients’ medications. Similarly, working under pressure of time and in unfamiliar circumstances should be avoided. Double-checking at any stage, particularly with high-risk medications, is recommended.

**Reliability and resilience of medication supply**

All drugs supplied should meet current national standards and regulations. When there are supply problems, like-for-like replacements should always be sought and end-users promptly made aware of any changes to packaging or concentrations. For high-risk medicines, for example heparin/protamine, hospitals should invest in sufficiently large buffer stocks to be able maintain continuity of supply to clinicians throughout periods of external shortages.

**Incident reporting**

All anaesthetists should report any medication incidents to their local and/or national incident reporting systems and these should be regularly reviewed in departmental meetings so that lessons can be learned and passed on. The focus should be on having a safety culture, the prevention of the recurrence of adverse events and managing such events when they occur.

**Checklist**

To assist departments that may wish to implement these guidelines and monitor their introduction locally, an implementation assessment/checklist has been developed.

The Canadian Institute on Health Information (CIHI) and the Canadian Institutes of Health Research (CIHR) have collaborated to study the prevalence of adverse events within Canada’s health care facilities.

Similar studies done in other countries have suggested that adverse events occur in 5 – 10% of hospital admissions, many of which are preventable. There is no reason to expect that the findings in the current Canadian study will be significantly different. There is great propensity for adverse event and failure within our health care systems, as increasingly ill patients are being cared for through complex processes in an environment stressed by limited resources. Health care professionals are obligated to continually improve systems and processes to ensure that where possible, adverse events are prevented.
An adverse event is defined as “an unintended injury or complication which results in disability, death or prolonged hospital stay and is caused by health care management”\(^\text{255}\).

Medication errors or incidents represent a significant category of preventable adverse events. Within healthcare facilities, pharmacists play a pivotal role in the prevention and review of medication-related adverse events. They work proactively to address medication system issues so that the potential for medication-related adverse events is reduced. Through progressive services and initiatives, hospital pharmacists promote best practices which strive to improve medication use systems. Examples of pharmacy services and programs that positively impact patient safety include:

- Direct patient care activities
- Use of Formulary systems
- Standardized medication policies and guidelines
- Drug order review
- Implementation of safe drug distribution systems
- Application of computer technology
- Provision of drug information/education to patients and health care workers
- Medication incident reporting and review systems

While pharmacists and other health care professionals have done much to reduce the risk of medication-related adverse events, the CIHI/CIHR report (Canadian Institute for Health Information / Canadian Institute for Health Research) is expected to demonstrate that there is still a need for considerable improvements to our medication use system. Persistent efforts and continued system improvements are required to ensure patients are as safe as possible within our facilities. To that end, CSHP (Canadian Society of Hospital Pharmacists) recommends that all stakeholders and decision-makers work together to accomplish the following:

1. Address staff shortages within our health care facilities
2. Increase involvement of pharmacists in direct patient care activities
3. Improve drug distribution systems
4. Expand use of technology and automation
5. Increase use of computerized prescriber order entry (CPOE) systems

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6. Improve medication-related adverse event reporting and analysis
7. Foster a collaborative approach to adverse event prevention

With their considerable expertise and experience in drug use management, hospital pharmacists can continue to provide significant leadership in this area.

Hospital Pharmacists are key stakeholders in medication management in hospitals and should be fully engaged by hospital administrators in ensuring the judicious, safe, efficacious, appropriate, and cost-effective use of medicines. A key part of this role is ensuring that for patients receiving care in either a hospital setting or in specialized ambulatories, the 7 “rights” are respected i.e. right patient, right dose, right route, right time, right drug with the right information and the right documentation.

Some of the ways hospital pharmacists can improve patient safety and ensure that the seven rights are applied in practice include:

- Providing the right advice to patients, physicians and nurses on the safe use of medicine and contributing to improved patient outcomes through collaborative therapeutic monitoring and decision-making.
- Acquiring the additional expertise needed to meet the specific needs of particularly vulnerable patient groups such as haemato-oncology, intensive care, infectious diseases, and pediatrics
- Reducing medication errors by implementing evidence-based systems or technologies, such as automated prescription-filling, unit dose distribution, and bar coding systems.
- Improving standard operating procedures and patient safety protocols by reporting medication errors or adverse reactions to non-punitive national and European clinical incident systems.
- Procuring the right drugs and related medical devices on the basis of strong safety and quality assurance principles and putting in place strategies to cope with drug shortages.

European Association of Hospital Pharmacists believes that all patients must have equal access to safe high quality pharmaceutical care and that in a complex hospital setting this is underpinned by the specialized knowledge, skills and experience of the hospital pharmacist.

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There are a number of policies and legislative initiatives on the European agenda which represent opportunities for hospital pharmacists to use their expertise to advocate for patient safety. This includes the review of EU rules on professional mobility, public procurement and clinical trials as well as the implementation of EU rules at national level in areas such as pharmacovigilance and tackling counterfeit drugs.

The following section summaries the barriers identified in alerts from National Patient Safety Agency (NPSA) that NHS organizations still need to routinely consider as part of clinical governance and ensure are embedded in clinical practice to prevent Never Events in United Kingdom258:

2002, updated 2003: Potassium chloride concentrate solutions: This alert recommends that potassium chloride concentrate solutions should be restricted to pharmacy departments and to those critical care areas where they are needed for urgent use. All supplies should come directly from the pharmacy department and be stored in a separate locked cupboard away from common diluting solutions such as sodium chloride (normal saline) solution.

The following timeline is from the NHS Recommendation from National Patient Safety Agency from 2018:

2005: Wristbands for hospital inpatients improves safety - all hospital inpatients in acute settings should wear wristbands (also known as identity bands) with accurate details that correctly identify them and match them to their car.

2006: Improving compliance with oral methotrexate guidelines: two actions in this alert still require monitoring:

• All electronic prescribing and dispensing software programs in primary and secondary care locations must include oral methotrexate alerts and prompts.

• Patients taking oral methotrexate should be given a patient information leaflet and monitoring document.

2007: Standardizing wristbands improves safety - This alert identifies the requirement that all NHS organizations in England that use wristbands should only include the following core patient identifiers:

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last name, first name, date of birth, NHS number (if the NHS number is not immediately available, a temporary number should be used until it is).

If any additional identifiers are thought to be necessary, these should be formally risk assessed. Only white wristbands with black text should be used. If you wish to have a system for identifying a known risk (eg an allergy or where a patient does not want to receive blood or blood products), the wristband should be red with patient identifiers in black text on a white panel on the wristband.

2007: Promoting safer measurement and administration of liquid medicines via oral and other enteral routes: An ISO standard has now been developed for enteral equipment (EnFit). This alert is the key source for the recommendation that intravenous syringes are not used to measure and administer oral liquid medication; only approved oral/enteral (EnFit) syringes that cannot be connected to intravenous catheters or ports should be used. Patients or carers who need to administer oral liquid medicines with a syringe must be supplied with approved oral or enteral (EnFit) syringes.

2007: Safer practice with epidural injections and infusions: This alert identifies the requirements to clearly label infusion bags and syringes for epidural therapy (whether purchased commercially, manufactured by the hospital pharmacy or prepared in clinical areas) 'For Epidural Use Only' in a large font. Judicious use of colour and design should differentiate these products from those for intravenous and other routes of administration. Risk of the wrong medicine being selected should be reduced by storing epidural infusions in different cupboards or refrigerators from those holding intravenous and other types of infusions.

2008: Reducing risk of overdose with midazolam injection in adults: This Rapid Response Report recommends that the storage and use of high strength midazolam (5 mg/mL in 2 mL and 10 mL ampoules or 2 mg/mL in 5 mL ampoules) is restricted to general anesthesia, intensive care, palliative medicine and clinical areas/situations where its use has been formally risk assessed – for example, where syringe drivers are used. It also recommends that other clinical areas store and use low strength midazolam (1 mg/mL in 2 mL and 5 mL ampoules), not high strength.

2009: WHO surgical safety checklist: national safety standards for invasive procedures (NatSSIPs) now incorporate the contents of the WHO surgical safety checklist. This alert requires the checklist to be completed for every patient undergoing a surgical procedure (including local anesthesia). This alert also determines that the overall responsibility for the site marking for regional blocks lies with the operating surgeon. The anesthetist should only proceed with a regional block after confirming that the site for surgery has been marked.

2009: Reducing the risk of retained throat packs after surgery: The principles of ensuring that throat packs are included in swab counts are now included in the NatSSIPs. This Safer Practice Notice identifies the additional requirement that a visually based procedure is followed whenever a throat pack is deemed necessary. Recommended visual procedures are to:

• label or mark the patient either on their head or, exceptionally, on another visible part of their body with an adherent sticker or marker

• label the artificial airway (eg tracheal tube or supraglottic mask airway)

• attach the pack securely to the artificial airway

• leave part of the pack protruding.

2010: Reducing the risk of retained swabs after vaginal birth and perineal suturing\textsuperscript{260}: Normal vaginal deliveries do not involve any invasive procedures and so are not covered by NatSSIPs. This Rapid Response Report highlights the requirement for swabs to be counted when used in a vaginal delivery (including for perineal suturing) and the need to ensure that lead professionals (midwives and obstetricians) are aware of their responsibility for documenting the completed swab count in the woman’s health record.

2010: Safer administration of insulin: This Rapid Response Report introduced the requirement for all regular and single insulin (bolus) doses to be measured and administered using an insulin syringe or commercial insulin pen device. It also determined that the term ‘units’ is written out in full in all contexts and not abbreviated. An insulin syringe must always be used to measure and prepare insulin for an intravenous infusion. Insulin infusions are administered in 50 mL intravenous syringes or larger infusion bags.

\textsuperscript{260} Burnett, Susan: Surgical Never Report Learning from 38 cases occurring in English hospitals between April 2016 and March 2017. September 2018.
Summary of literature review and status quo

Overall the literature states clear need to analyze and to improve patient safety. Since Kohn in 1999 started the patient safety initiative more and more authors and papers are focusing on this important topic. Four key elements were identified in order to improve patient safety: transparency\textsuperscript{261,262,263}, peer learning\textsuperscript{264}, measurement of patient safety\textsuperscript{265} and regulatory framework\textsuperscript{266}. Even though the levers to improve patient safety are well known as stated above, the definition of patient safety in literature lacks of clarity. For further research it should be a clear priority to further develop a clear definition of patient safety.

Besides the factors professionalism, regulations and markets the existing evidence is talking a lot about barriers why patient safety is not improved. This shows that there are efforts to improve the safety level of patients with moderate success. As a next step the identified barriers should be analyzed more carefully in order to fully understand and to be competent to develop strategies to overcome these barriers. The following research will help to get a clearer picture on who is influencing patient safety at the moment and which stakeholders should be involved when taking decisions in hospitals with regards to patient safety. The identified problems or barriers are:

1) Lack of staff
2) Communication issues
3) Financial issues
4) Lack of access to more senior staff
5) Lack of staff
6) Lack of responsibilities.

\textsuperscript{261} (NHS), National Health Service: Recommendations from National Patient Safety Agency, 2018.
\textsuperscript{263} Ball, Debra; Kaminski, Brian; Webb, Kevin: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve Safety, 2016.
\textsuperscript{264} Neily, Julia; Mills, Peter; Carney, Brian; West, Priscilla; Berger, David; Mazzia, Lisa; Paull, Douglas; Bagian, James.: Association Between Implementation of a Medical Team Training Program and Surgical Morbidity, in: Archives of Surgery 146 (12), 2011, p. 1368.
\textsuperscript{265} Pronovost, Peter; Ravitz, Alan; Stoll, Robert; Kennedy, Susan.: Transforming Patient Safety: A Sector-Wide Systems Approach, 2015.
\textsuperscript{266} Leape; Berwick: Five Years After To Err is Human: What have We Learned?, 2005.
3 PRIMARY RESEARCH ON HOW STAKEHOLDERS INFLUENCE DECISIONS WITH REGARDS TO PATIENT SAFETY CULTURE

This chapter introduces the primary research conducted in order to evaluate the impact of stakeholders in decision making processes on patient safety culture in German hospitals. Primary research, with both qualitative and quantitative research methods, has been conducted between February 2016 and February 2017.

3.1 Development of Dependency Model between Stakeholders and Patient Safety Culture

Aims and tasks of the research

This dissertation target is to investigate the dependency of involved stakeholders in decision making process for investment goods in hospitals in Germany with patient safety culture. The extensive growing awareness of patient safety in German hospitals has attracted particular interest in how to improve the safety of the patients. This recent development is caused by an increasing cost pressure and increasing need for reputation and image because of direct competition between hospitals in Germany. Furthermore, the interest in patient safety culture is not only driven by hospitals but also from health insurance, government, medical device industry and of course patient initiatives. To develop a dependency model, the first step is to identify one area in the hospitals, which has influence on patient safety and therefore patient safety culture. This dissertation focuses on decision making processes and more specifically to whether the involved stakeholders have an influence on patient safety culture. For this thesis research, the example of a buying decision for an investment good (e.g. infusion pump) is used. The study gives more insights on self-awareness and awareness of others in importance in the decision making process and contribution to patient safety culture.

The main aim of this thesis is to show how stakeholders influence the decision making processes with regard to patient safety culture by differentiating self-awareness and awareness of others.

Consequently, this research aims to answer the question whether there is a relation between involving different stakeholders in the decision making process in hospitals and improving patient safety culture. And is there a difference between self-awareness and awareness of others? In doing so, it addresses various elements that can help hospital managers to adjust their decision making processes and to improve patient safety culture and therefore increase their economic performance.
Figure 3.1 shows the underlying basic dependency model: \( f(x) = y \); (\( x \): stakeholders in decision making process; \( y \): patient safety); this is the simplified version of the final dependency model. Both variables are defined to make them measurable. Stakeholders in decision process are defined as physicians, nurses, biomedical engineers, hospital buyers and hospital management (the last three are grouped as administrative staff in hospitals). Patient safety culture is operationalized as a result of quantitative questionnaires with reduce pain/pain free patient, reduce medication errors, reduce risk. Both variables are measured in quantitative questionnaires on a 5-point Likert scale.

![Diagram: Dependency model between stakeholders in decision making process and patient safety culture](image)

**Figure 3.1: Dependency model between stakeholders in decision making process and patient safety culture**

*Source: Author’s illustration*

The key research question for this research is as follows: does there exist a relation between involving different stakeholders in the decision making process in hospitals and improving patient safety culture? And is there a difference between self-awareness and awareness of others? These research questions lead to the main hypothesis driving the overall research:

Involving different stakeholders in decision making processes in hospitals influences patient safety culture by differentiating self-awareness and awareness of others.

Thesis for defense:

- There is a difference between self-awareness and awareness of others regarding the role and consideration of patient safety culture in decision making processes.
- Self-awareness shows a higher influence on patient safety culture in decision making process than awareness of others.
- Physicians and nurses consider themselves to be more important than Management, Buyer and Biomedical staff.

The better the role of different stakeholders in decision making process in hospital is understood and defined the better this research can help to improve patient safety culture. Furthermore, by involving the right people in the decision making process in healthcare
setting, the better patient safety culture can be achieved. And even more, the more the costs are reduced and the more efficient the system can be.

3.2 Mixed Methods Research Approach

The underlying framework of the primary research is illustrated in table below. This dissertation follows the pragmatic research paradigm for mixed methods research and applies both qualitative and quantitative research methods. The mixed method research design compensates the weaknesses of one research method with the strengths of the other one and eventually elevates research credibility and the validity of findings.

<table>
<thead>
<tr>
<th>1. Quantitative Research</th>
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<tr>
<td>Purpose:</td>
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<tr>
<td>Participants:</td>
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<tr>
<td>Instrument:</td>
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<td>Data collection:</td>
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<td>Data analysis:</td>
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<th>2. Develop Dependency Model</th>
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<td>Combine literature research and results of expert interviews to develop dependency model</td>
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| 4. Research Results |

Figure 3.2: Framework of empirical research

Source: Author’s illustration, 2017

Multi-method or mixed method approaches are a recurrent topic of debate in academia. Scholars from different disciplines recommend the use of multiple methods to study complex social phenomena\textsuperscript{267,268,269}. In information systems, Mingers\textsuperscript{270,271} presents several reasons for using a combination of research methods. However, the methodology for this research must be explained on the basis of its research subjects. While natural sciences often deal with

\textsuperscript{267} Leape; Berwick: Five Years After To Err is Human: What have We Learned?, 2005.
\textsuperscript{268} Creswell: Research design: Qualitative, quantitative, and mixed methods approaches, 2013.
\textsuperscript{269} Creswell: Research design: Qualitative, quantitative, and mixed methods approaches, 2013.
\textsuperscript{270} Newman; Benz: Qualitative-quantitative Research Methodology: Exploring the Interactive Continuum, 1998.
phenomena that can be measured and expressed in numbers and formulas, the subjects of social sciences must be treated differently. In economics, the same applies when the behaviour of groups or individuals need to be enclosed in the research.

ONTOLOGY: As explained above, this thesis shall gain insights into the roles of different stakeholders in decision processes at hospitals. More specifically, the research shall establish whether the involved stakeholders do have an influence on patient safety. Apart from the necessity of defining a complex term such as patient safety, the whole research is concerned with the actions and perceptions of social actors. The ontological framework of the thesis is therefore subjectivist, not objectivist, as it is not concerned with rational explanations offer solutions to rational problems\(^\text{272}\).

EPISTEMOLOGY: The thesis addresses the research question in a pragmatic way. Since the subject of stakeholder involvement in decisions at hospitals is a very complex social phenomenon, the thesis cannot be positivist, since this would imply the belief that only phenomena that can be observed will lead to credible data. (Saunders) Nor can it be interpretivist, since the social actors and the outcome of their actions will be observed, but this will not happen from the research subjects’ point of view. Therefore, the research will be carried out by methods that "bring about positive consequences within the value system."\(^\text{273}\)

APPROACH: One aim of the research is to figure out various elements that can be useful in adjusting the decision processes and in improving patient safety while increasing the economic performance of the hospital at the same time. This problem is new and complex and cannot be approached with a prefabricated theory in mind. Hence, the focus is on theory development. After the first set of data has been collected through various means that will be described in the next paragraph. The approach is inductive in nature rather than deductive, where the theoretical position is developed prior to the collection of data. The concept of the thesis is illustrated in the graph below.

This graph shows the schematic overview of the qualitative and quantitative research. The author did start with qualitative questionnaires of six in order to further develop the dependency model. As a second step, the questionnaire and survey of quantitative research was developed and conducted.

\(^{272}\) Saunders, CF. Mark; Lewis, Philip; Thornhill, Adrian: Research Methods for Business Students, Harlow 2009.

\(^{273}\) Saunders, CF. Mark; Lewis, Philip; Thornhill, Adrian: Research Methods for Business Students, Harlow 2009.
Figure 3.3: Research design of quantitative and qualitative research

Source: Author's illustration, 2017

The research design can also serve as an illustration of a statement by Mingers. "The first argument is that the real world is ontologically stratified and differentiated [...], consisting of a plurality of structures that generate the events that occur (and do not occur). [...] Multimethod research is necessary to deal effectively with the full richness of the real world. The second argument is that a research study is not usually a single, discrete event but a process that typically proceeds through a number of phases. These phases pose different tasks and problems for the researcher."

Table 3.1: Advantages of multi-method approaches

| A more comprehensive approach to the phenomenon | Multi-method approaches help to obtain full answers and increase the robustness of our understanding. |
| | Using multiple methods has the potential of gaining knowledge about different aspects of a phenomenon under study and therefore, an overall better and more complete explanation. |
| | Mingers argues that “different research methods (especially from different paradigms) focus on different aspects of reality |


and therefore a richer understanding of a research topic will be gained by combining several methods together in a single piece of research or research program.” (p. 241).

| Triangulate results | • Validating interpretations of what is happening in a particular environment is considered a key advantage of multi-method studies.  
• Triangulation of results can be useful not only for the single study level but also at the meta-analysis or review level. |
| A broader set of questions can be asked (e.g., what, how, why) | • Researchers can expand their scope of study and take into consideration other aspects of the phenomenon.  
• They can enrich their understanding of specific situations by having the analytical power of quantitative and qualitative research methods. |
| Enable discovery | • Discovering new or paradoxical factors that could foster future research might be considered the capstone advantage.  
• The opportunity to discover paradoxes, to discover and confirm unexpected outcomes may be the tipping point that drives teams to undertake the cost and complexity of multi-method approaches. |


As stated, a mixed method approach is applied to the thesis. This indicates that both, qualitative and quantitative data was collected and respectively analyzed. In this context, qualitative and quantitative data was collected simultaneously through the applied research methods. These research methods were semi-structured expert interview and structured

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Sammons, Pam; Siraj-Blatchford, Iram; Sylva, Kathy, Melhuish, Edward; Taggart, Brenda; Elliot, Karen.: Investigating the Effects of Pre-school Provision: Using Mixed Methods in the EPPE Research, 2005.
questionnaires. “Semi-structured” indicated both, open- and closed-ended questions. Extensive expert interviews are considered the best research method in order to gain as much insight into the research subject as possible. Within a semi-structured expert-interview, in addition to the questions prepared the interviewer is able to add additional questions in order to obtain more detailed information about a particular answer or to explore additional issues that arise from a particular answer. For this present research, this interview strategy seems most applicable as a standardized fill-in questionnaire would not be suitable in order to take the individual specifics and methods applied throughout the hospital into account in detail.

The goal of mixed methods research is not to replace either of these (quantitative or qualitative) approaches but rather to draw from the strengths and minimize the weaknesses of both. Throughout the last decade, the mixed methods approach has been included more and more into the discussion about research paradigms. An increasing number of authors recognize it as a third paradigm along with qualitative and quantitative research. It may be seen as an advancement of the existing paradigms – a synthesis which includes ideas from qualitative and quantitative research.

For the underlying research exactly, these mixed method approach is used. As outlined the field of patient safety culture is complex and not easy to analyze. Therefore, a mixed approach with qualitative and quantitative approaches is the best way to get as much insights as possible.

Strategy: The research strategy shall help to determine which stakeholders have to be involved to increase success in decision processes. This means collecting a huge array of data by the means of a survey and expert interviews. This will allow to study the roles of the stakeholders in depth and thoroughly. While this is no ethnography, the research strategy pursued in this thesis is close to archival research and ethnography, as it is hardly feasible to use experiments or case studies in lieu of a theory.

Method: The research will not employ one single method, as implied earlier. It will rather apply mixed methods, i.e. the quantitative analysis of data that will lead to a theory that will be evaluated using qualitative research criteria. The advantage of this open approach is that the mixed research design will compensate the weaknesses of one research method by making use of the strengths of the other one method, thus reaching a higher validity of the findings and higher credibility of the research.

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Following the suggestion by Saunders, Lewis and Thornhill (2008:108), the entire research project can be described similar to an onion. The following graph shows the concept of this thesis based on the idea by Saunders, Lewis and Thornhill.

**Figure 3.4: Research concept from data collection to ontology**

*Source: Author’s illustration, based on Saunders, Lewis and Thornhill.*

### 3.3 Expert Interviews on Definition of Patient Safety Culture and Advanced Dependency Model

Expert interviews are a research method to conduct qualitative research. The group of interviewed persons is selected carefully based on their qualifications, which support their expertise. According to Sußner, this method is a trichotomy in executing the interviews using the explorative knowledge and the content knowledge or the company knowledge of an expert.

In the pragmatic perspective – focusing on the local context of knowledge production, the status of an expert could be understood as ascribed by the researcher: a person is attributed as expert by virtue of his/her role as informant. Who is identified as expert and who not depends on the researcher’s judgment; in literature there are basically three approaches to defining of an expert, namely, voluntaristic, constructivist and according to the sociology of knowledge. According to the latter, experts have special knowledge which is related to their professions;

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281 Saunders; Lewis; Thornhill: Research Methods for Business Students, 2009, p. 108.
focus on conscious knowledge (not implicit or tacit knowledge), this method is used for the present research.

The author chose to conduct semi-structured expert interviews to explore the definition of patient safety. The expert interview is a method of qualitative empirical research, designed to explore expert knowledge, and has been developed considerably since the early 1990s\(^{284}\).

Table 3.1 shows the list of interviewed experts face-to-face of over phone from July 2016 to November 2016.

**Table 3.2: Experts who participated in deep interviews from July to November 2016**

<table>
<thead>
<tr>
<th>Expert No</th>
<th>Profession</th>
<th>Working experience</th>
<th>Date of interview</th>
<th>Location (area code)</th>
<th>Hospital / institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Head physician</td>
<td>31 yrs</td>
<td>19/07/2016</td>
<td>93047</td>
<td>Caritas Krankenhaus St. Josef</td>
</tr>
<tr>
<td>2</td>
<td>Head physician</td>
<td>23 yrs</td>
<td>21/07/2016</td>
<td>93086</td>
<td>Kreisklinik Wörth an der Donau</td>
</tr>
<tr>
<td>3</td>
<td>General manager</td>
<td>35 yrs</td>
<td>27/07/2016</td>
<td>10115</td>
<td>Aktionsbündnis Patientensicherheit</td>
</tr>
<tr>
<td>4</td>
<td>Head physician</td>
<td>10 yrs</td>
<td>17/08/2016</td>
<td>64839</td>
<td>University Hospital of Muenster</td>
</tr>
<tr>
<td>5</td>
<td>Head physician &amp; general manager</td>
<td>21 yrs</td>
<td>22/09/2016</td>
<td>14193</td>
<td>Berlin Heart</td>
</tr>
<tr>
<td>6</td>
<td>General Managing Physician</td>
<td>16 yrs</td>
<td>21/11/2016</td>
<td>52074</td>
<td>University Hospital of Aachen</td>
</tr>
</tbody>
</table>

*Source: Authors illustration, 2016*

“Semi-structured” indicates both, open- and closed-ended questions. In order to determine the status quo of patient safety as well as defining patient safety, semi-structured expert interviews (within hospitals in Germany) were conducted. In this context, an expert is defined by the existence of all the following five criteria:

- To be an expert, the interviewee must have substantial knowledge (at least “Oberarzt”\(^{285}\)) of the processes in hospitals, in particular about risk management systems
- To be an expert, the interviewee must have decision making power within his/her role;

\(^{284}\) Nagel, Ulrike; Meuser, Michael: Das Experteninterview in der Bildungsforschung, Marburg 2005.

\(^{285}\) “Oberarzt” means a certain hierarchical level including responsibility for direct reports and a whole department
• To be considered as an expert, the relevant work experience must be more than 10 years;
• To be considered as an expert, patient safety has to be part of the wider working context of the daily business of the interviewee;
• Need to have an valid approbation as physician.

The semi-structured expert interviews are all conducted in face-to-face meetings with duration of 90-120 minutes. Three experts are head physicians, the other three general managers which is showing the high level of responsibility of experts. Their work experience is from 10 to 35 years. Four are actively working as physicians, one is general manager for patient safety association and one is general manager for a medical device company developing artificial hearts. From a distribution in Germany their working location is widely spread to make sure local differences are covered as well.

Patient safety and patient safety culture has a growing importance and therefore this term is more and more defined due to widely use. Especially when it comes to improving patient safety the definition is key to measure if and how it has improved. If it is not known, what to improve, it cannot be measured. Explicitly in the expert interviews, it was mentioned, when it comes to investments in patient safety the measurement of success is crucial. Given this is definition would not be clear, the return on investment would also not be measurable. Therefore, the clear recommendation is, even if it is not the universal definition, every hospital should define patient safety, using the listed key elements and try to make it as public as possible.

Patient safety itself is not easy to define. It is a wide term and a universal definition does not exist in literature; it also has not been obtained during the expert interviews either. However, there are common elements in defining patient safety which are:

1. Reduction of harm/pain. Harm/pain for the patient should be reduced: everything that can be done to prevent patient from additional harm has to be done. This is quite a universal statement but is clearly part of patient safety definition.

2. Building the culture of safety / reducing and reporting of errors: the higher the general attitude is towards patient safety in the hospital the more people support it, the more it is implemented. That starts with management and senior leadership and has to be a top-down approach. Reporting means firstly to have a system, which encompasses the errors and then have a process to derive actions from the errors,
when they occur, and secondly to create an atmosphere where clinicians/nurses etc. are not hesitant to report errors.

3. Reducing risk for the patient: that means all systems/products, which help to reduce the risk for the patient, are part of safety. For example, marking all epidural accesses/lines yellow to reduce or even eliminate confusions.

Table 3.3: Similar definitions of patient safety culture / quotes of expert interviews and literature

<table>
<thead>
<tr>
<th>Expert Interviews</th>
<th>Literature review</th>
<th>Factors of patient safety culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Patient leaves the hospital <strong>without damage</strong> or almost without damage”</td>
<td>The <strong>prevention of harm</strong> to patients(^{286})</td>
<td>Reduction of harm /</td>
</tr>
<tr>
<td></td>
<td>Prevention of adverse outcomes from medical errors(^{287})</td>
<td>Reduction of pain</td>
</tr>
<tr>
<td>“Absence of mistakes, making <strong>environment safer</strong>”</td>
<td>Is built on a <strong>culture of safety</strong> that involves health care professionals(^{288})</td>
<td>Culture of safety / reduction and reporting of errors</td>
</tr>
<tr>
<td>“If everyone follows the <strong>process/protocols</strong> and if there is no damage to patient”</td>
<td>Errors have to be <strong>reported</strong>(^{289})</td>
<td></td>
</tr>
<tr>
<td>“Patient safety is not 0 errors, patient safety is knowing your limits”</td>
<td><strong>Reduction of risk</strong> of unnecessary harm(^{290})</td>
<td>Reduction of risk</td>
</tr>
<tr>
<td>“Patient safety means also <strong>talking about errors</strong>”</td>
<td><strong>Reduction of the occurrence of</strong> preventable adverse events(^{291})</td>
<td></td>
</tr>
<tr>
<td>“<strong>Minimizing of negative</strong> impact of a planned procedure”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{287}\) Aspden; Corrigan; Wolcott: Patient safety: achieving a new standard for care., 2004.  
\(^{289}\) Ball; Kaminski; Webb: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve Safety, 2016.  
\(^{290}\) Ball; Kaminski; Webb: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve Safety, 2016.  
\(^{291}\) Ball; Kaminski; Webb: First; Do less harm: A Health Care Cultural Operating System Case Study to Improve Safety, 2016.
This joint result from literature review and expert interviews is used by the author as the definition of patient safety and patient safety culture for further research.

As a result of the expert interviews, the dependency model is further developed and the dependent variable Y (patient safety culture) is further defined. The combined results of theoretical research and expert interviews allowed to define patient safety in the form of three main variables: pain-free patient / the reduction of pain, the reduction of medication errors and the reduction of risk.

**Figure 3.5: Advanced dependency model - Stakeholders in decision making process to patient safety culture**

Stakeholders in decision making process are the independent variable. This variable is measured with two questions in the questionnaire about importance and contribution in decision processes. These two questions are asked about every stakeholder, which means per questions 5 sub-questions and make it therefore possible to differentiate between self-awareness and awareness of others. Both questions are measured on a 5-point Likert scale from strongly agree to strongly disagree.

Patient safety culture is the dependent variable; this variable is measured in quantitative questionnaires with the three question blocks on pain-free, reduction of medication errors and reduction of risk. Every question has 5 sub-questions regarding each stakeholder. The questions are measured on a 5-point Likert scale from strongly agree to strongly disagree. The measurement is done in respect to what the stakeholders think about themselves (self-awareness) and what other stakeholders think about them (awareness of others). The five sub-questions are e.g. Nurses/physicians/biomedical engineers/buyers/management do consider reducing risk when taking decisions. In the demographics in the questionnaire the question

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which stakeholder are you is stated, therefore it can be differentiated what they think about themselves and what they think about other stakeholders.

The core of dependency model is dependent and independent variable. The independent variable is the stakeholders in the decision making process in hospitals. The dependent variable is patient safety culture. As explained in paragraph above, they are measured through the quantitative questionnaire on a 5-point Likert scale.

Stakeholders in decision making process are grouped into users and administrative staff. The stakeholders working in administrative positions in this thesis are people who are responsible for buying hospital investment goods as well as hospital management. Users are doctors, nurses and technicians / biomedical staff in hospitals. The group of users is actively using medical devices, machines and is closer to the patient with regards to daily care than the group administrative workers like the mentioned buyers in hospitals and hospital management.

3.4 Quantitative Research Questionnaires of Stakeholders

Because the survey was carried out in Germany, the survey was formulated in the German language. Besides the fact that context is easier to understand in the first language, it also needs to be mentioned that English as business language is not so common in hospital

is, especially at a nurse level. To avoid any misunderstandings or misinterpretations, the English translation was also provided for every item.

To avoid any misunderstandings or misinterpretations, an English translation was also provided for every item. Double questions, addressing two or more issues in a question, ought to be avoided. In addition, statement should not have complicated grammatical constructions.
The targeted population of research is the relevant population with 656,650 people. To get access to hospital workers is not easy. Hospitals do not allow external people to enter the hospitals and further the different stakeholders. Therefore, this research was conducted on several exhibitions for healthcare professionals. The accessible population therefore were the people attending these professional exhibitions and symposia. The selection of surveyed people was following the willingness to participate. The split between nurses, physicians and Biomed/Mngmt/Buyer was chosen with the closeness to the patient. Nurses are closest to the patient, physicians second and Biomeds/Mngmt/Buyer least close to patient.

The sample size in total is 114 completed questionnaires of which 30 physicians, 67 nurses and 17 biomedical engineers/ hospital buyers. In German hospitals are 14,000 executive physicians of which 0,2% participated in the survey, 146,000 medical nurses of which 0,04% participated and 117,000 non-medical staff of which 0,02% completed the questionnaire. The total population is 277,000 people. These include also staff without any knowledge of patient safety and with no or limited work experience. Assuming that 25% are experienced the population is 69,000 in total in Germany. In order to achieve 95% confidence level and 5% margin of error a sample size of 380 is required. Considering the expert-interviews which selected already the three determined factors for patient safety and that the target group is very specialized and difficult to access the size of 114 is significant for this research.

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The developed questionnaire is structured in a general section with personal questions and questions about the hospital first and followed by the five main questions and concluding with two general questions. The main five questions are all structured into five sub-questions which are referring to the different stakeholders: physician, nurse, biomed, buyer, and management. This indicates automatically that every stakeholder is filling out self-awareness and awareness of others. Question one and five are of importance and relevance in decision making process whereas question two, three and four are about the operationalized patient safety culture (pain-free patient, reduce medication errors, reduce risk) and how stakeholders do influence these factors while taking decisions.

Both language version, German and English, of the questionnaire are in the appendix 1 – quantitative questionnaire.

![Figure 3.7: Structure of quantitative questionnaire](source: Author's illustration, 2017)

To explore the role of various groups of hospital staff in the decision-making process, it was necessary to put questions to wide sample of people employed in the health sector. It would not have served the purpose to rely on information from one group of employees alone. Therefore, a survey was developed that targeted physicians, nurses, biomedical staff and technicians, management staff and buyers alike.

Practicalities determined the way the survey was conducted. While the quality and amount of the information to be gathered was important, time restrictions demanded to consider how much information could be analysed and what resources were available. Thus, a self-completed questionnaire presented itself as the most viable alternative. A survey of this kind is most commonly presented as list of written questions on paper which are to be filled in by
the participants, usually without any assistance from the people who designed the questionnaire. It is also the least time consuming one for the participants, a fact that will increase the likelihood that they will be returned. The printed form also guarantees that the respondents are all asked exactly the same questions.

Even though self-completed questionnaires provide no opportunity for any clarification of the questions, misunderstanding may happen; this problem does not pose a risk in this case, as the survey addresses highly-educated, well-trained professionals.

As this thesis focuses on Germany, the survey was conceived in German. In contrast to other sectors of the industry, English is not a common language in the health sector, especially on the employment level of nurses and technicians. To avoid any misunderstandings or misinterpretations, an English translation was also provided for every item. It is this translation that is being used in the printed version of the thesis.

At the top of the page, the respondents are informed that the questionnaire will take about 10-15 minutes to fill in. They are also told that all their answers will be kept anonymous and will be treated confidentially. The respondents learn that the questionnaire is about decision making processes in hospital work.

Some basic data about the respondents are also collected, such as the country where they are working and the kind of hospital they are working at, i.e. whether it is a public hospital, a privately run clinic or a hospital owned by an NGO, such as the Evangelical Christian of Germany or the Catholic Church. The respondents are also asked how long they have been working.

The main part of the questionnaire focuses on five issues that are accompanied by five statements each. The following example is taken from the English translation of the questionnaire in the section pain level:

• Doctors do consider pain level of patients when taking decisions.
• Nurses do consider pain level of patients when taking decisions.
• Biomed/Technicians do consider pain level of patients when taking decisions.
• Hospital management do consider pain level of patients when taking decisions.
• Hospital buyers do consider pain level of patients when taking decisions.
The respondents are asked to react to each statement individually. They can specify their level of agreement or disagreements on a symmetric agree/disagree Likert scale with five possible responses: strongly agree, agree, undecided, disagree and strongly disagree.

Even though Likert scales with an odd number of responses invite the respondent to mark the middle item on the scale (undecided) to avoid any pressure to make a decision. In this case, however, it is surmised that the respondents will feel strongly about the subject matter and that will revert to the 'undecided'-option only if they are truly undecided.

The items were phrased as statements, not as questions to avoid any negative bias when answering the questions. This is also the reason why the rhetorically affirmative "do" is included here. It is meant to encourage the respondents to think twice about their answers.

Figure 3-7 above shows that three items focus on patient safety, while two items focus on the role of the decision makers in the decision-making. All of the items need to be considered from five different points of view. This is of course crucial in testing the self-awareness and the awareness of others of the respondents.

The criteria for selection of taking part in the quantitative research are combination of following three criteria: 1) profession has to be nurse, physician, biomed, management or buyer 2) in a hospital (public, private, church or others), and 3) more than fifty percentage of interviewees have to have more than 15 years work experience. The selection of participants was done accordingly. The split between stakeholders should reflect the ratio in reality. This was also considered while selecting interviewees.

![Figure 3.8: Surveyed stakeholders regarding type of hospital (n=114)](image-url)
Reality is 1956 hospitals in Germany, with 577 public, 679 church and 700 private hospitals. The underlying research in this thesis is 51% public, 20% private and 27% church hospital participants.

Figure 3.9: Role of surveyed stakeholders (n=114)

In German hospitals are 14,000 executive physicians of which 0.2% participated in the survey, 146,000 medical nurses of which 0.04% participated and 117,000 non-medical staff of which 0.02% completed the questionnaire. The total population is 277,000 people.

Figure 3.10: Work experience of surveyed stakeholders (n=114)

As you can see in the table above, the majority of interviewees are very experienced with over 15 years work experience in hospitals. That means the participants understanding the context and therefore has the ability to give realistic and valuable answers.

Correlation analysis is used as a first step to show and quantify the association between independent and dependent variable. Dependent variable: Patient safety (pain level, reduction

294 Statistisches Bundesamt: Daten der Krankenhäuser, in: Fachserie 12 Reihe 6.1.1 1 (0), 2012, pp. 1–137.
of medication errors and reduction of risk); Independent variable: Stakeholders (Physician, Nurse, Technician, Buyer, and Management) – this is operationalized with the variables: Contribution in decision making processes, Importance in decision making processes and the mean value of these two. As explained in chapter 3.3 with developing the dependency model. The dependent variable patient safety culture is tested in the model by using these three components: \( Y_1 \) is pain free patient in the regression model, \( y_2 \) is reduction of medication errors and \( y_3 \) is reduction of risk. These three components were tested in the quantitative questionnaire and measured on a 5-point-Likert scale. The influential variable is the importance or relevant input in the decision making process of the stakeholders. This is measured with two questions on a 5-point Likert scale in the questionnaire and also differentiated between self-awareness and awareness of others. This means the answers from e.g. physicians are looked at what they say about themselves (self-awareness) and at the same time the answers of all other stakeholders are aggregated what they say about physicians (awareness of others).

All statistical tests were conducted two ways: self-awareness and awareness of others. That means that for example the results in respect to nurses were considered only in terms of their self-evaluation and then what all other stakeholders said about nurses is considered as awareness of others.

All correlation coefficients are rather weak, none exceeds the value of +0.3. A correlation is significant when coefficients smaller than 0.05. This means that the connection between considerations of patients' safety and decision making is also weak. The weakest connection exists between considerations of the patients’ pain level and decision-making. The value of \( r^2 \) for the influence of “Pain Level” on “Input Decision Process” is 0.036 and it is 0.076 for “Medication Errors”. The differences of “Pain Level” and of “Medication Errors” can be explained by the influence of the independent variable “Input in Decision Process” with 3.6 % and 7.6 %, respectively. If respondents, who estimate that their importance is high and that their input is appreciated, paid a lot attention to any of these items, the values would be much higher. However, if they did not consider patients’ safety at all and if they thought that these issues were detrimental to their decision-making, the values would be negative. This was not to be expected here.

Practicalities determined the way the survey was conducted. While the quality and amount of the information to be gathered was important, time restrictions demanded to consider how much information could be analysed and what resources were available. Thus, a self-
completed questionnaire presented itself as the most viable alternative. A survey of this kind is most commonly presented as list of written questions on paper which are to be filled in by the participants, usually without any assistance from the people who designed the questionnaire. Even though the return rate depends on the conscientiousness of the respondents and can be low, self-completed questionnaires are commonly the least expensive kind of survey. It is also the least time consuming one for the participants, a fact that will increase the likelihood that they will be returned. The printed form also guarantees that the respondents are all asked exactly the same questions.

After showing that there are significant correlations between independent and dependent variables, the next statistical test is to do a regression analysis. Regression analysis is used to understand which among the independent variables are related to the dependent variable, and to explore the forms of these relationships. This has been explained above, showing that $r^2$ displays how much of the occurring differences in the dependent variable are explained by the influence of the independent variable.

![Figure 3.11: Underlying Model based on the dependency model between stakeholders and patient safety culture (x), showing components of patient safety culture which are reduction of pain (y1), reduction of medication errors (y2) and reduction of risks (y3)](image)

Source: Author’s illustration

The model includes the operationalized factors of patient safety culture. As analyzed in the semi-structured expert interviews, patient safety culture has to be operationalized in order to make it measurable. The experts defined patient safety culture during semi-structured expert interviews as reduction of pain, reduction of medication errors and reduction of risks. The answers from experts were analyzed and clustered regarding the same content. The result are three operational components of patient safety culture (y1,y2,y3). The dependent variable patient safety culture is tested in the model by using these three components: $Y_1$ is pain free patient in the regression model, $y_2$ is reduction of medication errors and $y_3$ is reduction of risk. These three components were tested in the quantitative questionnaire and measured on a 5-point-Likert scale. The influential variable is the importance or relevant input in the decision
making process of the stakeholders. This is measured with two questions on a 5-point Likert scale in the questionnaire and also differentiated between self-awareness and awareness of others. This means the answers from e.g. physicians are looked at what they say about themselves (self-awareness) and at the same time the answers of all other stakeholders are aggregated what they say about physicians (awareness of others).

Table 3.4: Coefficient of determination - regression analysis of self-awareness

<table>
<thead>
<tr>
<th>a) dependent variable</th>
<th>Pain level (self awareness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) all variables included</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R-square</th>
<th>Corrected R-square</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.196²</td>
<td>0.039</td>
<td>0.03</td>
<td>1.03</td>
</tr>
</tbody>
</table>

a) Variable: Importance and input (self awareness)

<table>
<thead>
<tr>
<th>a) dependent variable</th>
<th>Medication error (self awareness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) all variables included</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R-square</th>
<th>Corrected R-square</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.291²</td>
<td>0.085</td>
<td>0.077</td>
<td>0.824</td>
</tr>
</tbody>
</table>

a) Variable: Importance and input (self awareness)

<table>
<thead>
<tr>
<th>a) dependent variable</th>
<th>Reduction of risk (self awareness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) all variables included</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R-square</th>
<th>Corrected R-square</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.264²</td>
<td>0.07</td>
<td>0.061</td>
<td>0.754</td>
</tr>
</tbody>
</table>

a) Variable: Importance and input (self awareness)

Source: Authors Illustration, based on SPSS analysis

Regression analysis is used to understand which among the independent variables are related to the dependent variable, and to explore the forms of these relationships. This has been explained, showing that $r^2$ displays how much of the occurring differences in the dependent variable are explained by the influence of the independent variable. To prove the fit of the model, the statistical $r^2$ will be used. This test shows how much percentage the Y (patient safety) is determined by the $x_1$, $x_2$, $x_3$… (Stakeholders in decision processes). Since $r$ is positive, there is a positive relation between dependent and independent variable.

The regression analysis from self-awareness shows

- that 3.9% of variance of pain level of patients can be explained by the stakeholders in the decision-making process.
that 8.5% of variance of medication errors can be explained by the stakeholders in the decision-making process.

that 7.0% of variance of risk level of patients can be explained by the stakeholders in the decision-making process.

For the decision making in hospitals it means that from a standpoint of self-awareness of stakeholders the pain level can nearly not be influenced at all and risk level with only 7%. The medication errors are the most to influence with stakeholders with 8.5%.

### Coefficient of determination - regression analysis of awareness of others

**Table 3.5: Coefficient of determination - regression analysis of awareness of others**

<table>
<thead>
<tr>
<th>Table 3.5: Coefficient of determination - regression analysis of awareness of others</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) dependent variable</td>
</tr>
<tr>
<td>b) all variables included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R-square</th>
<th>Corrected R-square</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>.275a</td>
<td>.075</td>
<td>.067</td>
<td>.59171</td>
</tr>
</tbody>
</table>

a) Variable: Importance and input (self awareness)

<table>
<thead>
<tr>
<th>Table 3.5: Coefficient of determination - regression analysis of awareness of others</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) dependent variable</td>
</tr>
<tr>
<td>b) all variables included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R-square</th>
<th>Corrected R-square</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>.278a</td>
<td>.077</td>
<td>.069</td>
<td>.73474</td>
</tr>
</tbody>
</table>

a) Variable: Importance and input (self awareness)

<table>
<thead>
<tr>
<th>Table 3.5: Coefficient of determination - regression analysis of awareness of others</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) dependent variable</td>
</tr>
<tr>
<td>b) all variables included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R-square</th>
<th>Corrected R-square</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>.434a</td>
<td>.188</td>
<td>.181</td>
<td>.57659</td>
</tr>
</tbody>
</table>

a) Variable: Importance and input (self awareness)

*Source: Authors Illustration*

The regression analysis from awareness of others shows

- that 7.5% of variance of pain level of patients can be explained by the stakeholders in the decision-making process.
- that 7.7% of variance of medication errors can be explained by the stakeholders in the decision-making process.
- that 18.8% of variance of risk level of patients can be explained by the stakeholders in the decision-making process.
Pain level and medication errors do not have major differences between self-awareness and awareness of others, however risk level does. Nearly 19% of risk level can be influenced when stakeholders think about others compared to 7% when they talk about themselves.

A t-test with all variables (importance in decision process, contribution in decision process, reduction of pain, reduction of errors, reduction of risk) each tested self-awareness against awareness of others shows, that there is a significant difference in answers between the stakeholder groups, 2-sided significance is <0.005 (Input for decisions, contribution/importance, pain, medication and risk). Except for importance, this is with 0.079 nearly significant. The answers of stakeholders are measured on a 5-point-Likert scale on the quantitative questionnaire from strongly agree to strongly disagree.

**Table 3.6: T-Test, group statistic; self-awareness and awareness of others**

<table>
<thead>
<tr>
<th>Wahrnehmung</th>
<th>n</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Standard error of mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>INPUT DECISION</td>
<td>.00</td>
<td>114</td>
<td>2.24</td>
<td>.779</td>
</tr>
<tr>
<td>PROCESS</td>
<td>1.00</td>
<td>114</td>
<td>2.66</td>
<td>.792</td>
</tr>
<tr>
<td>Importance</td>
<td>.00</td>
<td>114</td>
<td>2.33</td>
<td>1.086</td>
</tr>
<tr>
<td></td>
<td>1.00</td>
<td>114</td>
<td>2.55</td>
<td>.716</td>
</tr>
<tr>
<td>Input_Importance</td>
<td>.00</td>
<td>114</td>
<td>2.285</td>
<td>.7842</td>
</tr>
<tr>
<td></td>
<td>1.00</td>
<td>114</td>
<td>2.603</td>
<td>.6022</td>
</tr>
<tr>
<td>Pain</td>
<td>.00</td>
<td>114</td>
<td>1.95</td>
<td>1.046</td>
</tr>
<tr>
<td></td>
<td>1.00</td>
<td>114</td>
<td>3.27</td>
<td>.613</td>
</tr>
<tr>
<td>Medication</td>
<td>.00</td>
<td>114</td>
<td>2.09</td>
<td>.858</td>
</tr>
<tr>
<td></td>
<td>1.00</td>
<td>114</td>
<td>3.02</td>
<td>.761</td>
</tr>
<tr>
<td>Risk</td>
<td>.00</td>
<td>114</td>
<td>1.82</td>
<td>.779</td>
</tr>
<tr>
<td></td>
<td>1.00</td>
<td>114</td>
<td>2.84</td>
<td>.637</td>
</tr>
</tbody>
</table>

Source: Authors Illustration, based on SPSS analysis

Table 3.9 shows that there is barely discernible difference between the analysis "Self-Awareness" (0) and "Awareness of Others" (1) concerning "Importance" and "Input", respectively. However, concerning such items as "Pain Level," "Medication Error," and
"Reduction of Risk", the values for "Awareness of Others" are consistently and significantly higher than the values for "Self-Awareness."

The following table shows the results of an analysis of Variance (ANOVA) for the different items. The results are as follows:

**Table 3.7: Variance analysis – one-way descriptive statistics**

| Source: Authors Illustration, based on SPSS analysis |

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>mean</th>
<th>standard deviation</th>
<th>standard error</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Input</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physician</td>
<td>114</td>
<td>2,17</td>
<td>0,775</td>
<td>0,073</td>
<td>2,02</td>
</tr>
<tr>
<td>nurse</td>
<td>114</td>
<td>2,35</td>
<td>0,831</td>
<td>0,078</td>
<td>2,2</td>
</tr>
<tr>
<td>biomed</td>
<td>114</td>
<td>2,68</td>
<td>0,857</td>
<td>0,08</td>
<td>2,52</td>
</tr>
<tr>
<td>management</td>
<td>114</td>
<td>2,94</td>
<td>2,117</td>
<td>0,198</td>
<td>2,55</td>
</tr>
<tr>
<td>buyer</td>
<td>114</td>
<td>2,74</td>
<td>1,073</td>
<td>0,1</td>
<td>2,54</td>
</tr>
<tr>
<td><strong>Importance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physician</td>
<td>114</td>
<td>1,91</td>
<td>0,771</td>
<td>0,072</td>
<td>1,77</td>
</tr>
<tr>
<td>nurse</td>
<td>114</td>
<td>2,54</td>
<td>1,049</td>
<td>0,098</td>
<td>2,34</td>
</tr>
<tr>
<td>biomed</td>
<td>114</td>
<td>2,9</td>
<td>0,931</td>
<td>0,087</td>
<td>2,73</td>
</tr>
<tr>
<td>management</td>
<td>114</td>
<td>2,54</td>
<td>1,27</td>
<td>0,119</td>
<td>2,3</td>
</tr>
<tr>
<td>buyer</td>
<td>114</td>
<td>2,64</td>
<td>1,22</td>
<td>0,114</td>
<td>2,41</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physician</td>
<td>114</td>
<td>2,06</td>
<td>0,855</td>
<td>0,08</td>
<td>1,9</td>
</tr>
<tr>
<td>nurse</td>
<td>114</td>
<td>1,8</td>
<td>0,778</td>
<td>0,073</td>
<td>1,65</td>
</tr>
<tr>
<td>biomed</td>
<td>114</td>
<td>3,51</td>
<td>0,905</td>
<td>0,085</td>
<td>3,34</td>
</tr>
<tr>
<td>management</td>
<td>114</td>
<td>3,79</td>
<td>0,846</td>
<td>0,079</td>
<td>3,63</td>
</tr>
<tr>
<td>buyer</td>
<td>114</td>
<td>3,85</td>
<td>0,833</td>
<td>0,078</td>
<td>3,7</td>
</tr>
<tr>
<td><strong>Medication errors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physician</td>
<td>114</td>
<td>2,13</td>
<td>0,804</td>
<td>0,075</td>
<td>1,98</td>
</tr>
<tr>
<td>nurse</td>
<td>114</td>
<td>2,02</td>
<td>0,741</td>
<td>0,069</td>
<td>1,88</td>
</tr>
<tr>
<td>biomed</td>
<td>114</td>
<td>3,14</td>
<td>1,063</td>
<td>0,1</td>
<td>2,94</td>
</tr>
<tr>
<td>management</td>
<td>114</td>
<td>3,4</td>
<td>1,054</td>
<td>0,099</td>
<td>3,21</td>
</tr>
<tr>
<td>buyer</td>
<td>114</td>
<td>3,47</td>
<td>0,989</td>
<td>0,093</td>
<td>3,29</td>
</tr>
<tr>
<td><strong>Risk</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physician</td>
<td>114</td>
<td>1,95</td>
<td>0,762</td>
<td>0,071</td>
<td>1,81</td>
</tr>
<tr>
<td>nurse</td>
<td>114</td>
<td>1,75</td>
<td>0,649</td>
<td>0,061</td>
<td>1,63</td>
</tr>
<tr>
<td>biomed</td>
<td>114</td>
<td>2,82</td>
<td>0,998</td>
<td>0,093</td>
<td>2,64</td>
</tr>
<tr>
<td>management</td>
<td>114</td>
<td>3,16</td>
<td>0,927</td>
<td>0,087</td>
<td>2,99</td>
</tr>
<tr>
<td>buyer</td>
<td>114</td>
<td>3,5</td>
<td>0,924</td>
<td>0,087</td>
<td>3,33</td>
</tr>
</tbody>
</table>

In this table, the mean describes the average of all responses to the statements in the quantitative questionnaire. The standard error indicates, how far apart the actual answers are. If, for example, the mean is 2.5 and the standard deviation is 0.5, answer range between 2 and 3. The following illustration shows that the results are quite telling and crucial for managerial considerations of the decision-making at hospitals.
The values for physicians are quite consistent. On average, they are the lowest of all values.

The values for nurses show an extreme concerning "Importance" and two low values for "Pain Level" and "Risk Reduction." This means that the nurses consider themselves important (more so than the physicians) and that they pay most attention to one of their key responsibilities, i.e. dispensing and administering medication.

The graphs are rather similar for the staff who are not directly involved in caring for the patients. Technicians, managers and buyers alike consider themselves more important than doctors and nurses, or their role is perceived as being so. All three sections show high values for the statement that they take the patients' Pain Level into consideration. Doctors and nurses show much lower values in this respect. It can be surmised that they are aware that pain cannot always be avoided. Those who are familiar with pain but not with its treatment will certainly say that they have the patients' pain levels in mind when making decisions.

Whether the input by hospital managers is well-perceived or not seems to be contentious. The responses range from values below 1 to values above 5.

**Figure 3.12: Graphical analysis of variance analysis per stakeholder**

*Source: Authors Illustration, based on SPSS analysis*
This aspect deserves more scrutiny. Therefore, the graph below shows the correlation coefficients of "Input" and "Importance" for two stakeholders, physicians and managers.

Figure 3.13: Graphical analysis of ANOVA management and physicians—details about importance and input

The graph above depicts a flawed relationship between physicians and management. For both aspects shown, the evaluation of the role of the managers scored means that are by about 35% higher than the values of the physicians. Since more physicians and nurses filled in the questionnaire, the estimates cannot be dominated or manipulated by the managers. As low values indicate strong support for the positive statements, doctors and nurses alike see that their own input to and their own importance for the decision-making process is considerably higher than that of technicians, managers and buyers. Whether this is just a realistic estimate or a misrepresentation of their own roles in the decision-making cannot be deduced from these numbers. This is not the crucial point, though.

The fact that the role of the management seems to be highly contentious indicates that changes in procedures or communication processes are required. If some staff very strongly agree that the input of the managers is well-perceived (0.82) and some do not agree at all with this statement (≥ 5), something is awry. This is crucial because this research has found that involving different stakeholders in the decision-making at hospitals can influence patient safety. Figure 3-10 has shown that management staff is less concerned with issues of patient safety than doctors and nurses. No conclusive evidence for the influence of self-awareness or awareness of others could be found, though.
The table below is showing ANOVA analysis for self-awareness and awareness of others.

### Table 3.8: ANOVA analysis of self-awareness

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of squares</th>
<th>df</th>
<th>Means of squares</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>4,773</td>
<td>1</td>
<td>4,773</td>
<td>4,495</td>
<td>.036*</td>
</tr>
<tr>
<td>Non-standardized residuals</td>
<td>118,912</td>
<td>112</td>
<td>1,062</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>123,684</td>
<td>113</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Dependent variable: Pain_Self  
b. Influential variable: (Constant), Input_Importance_Self

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of squares</th>
<th>df</th>
<th>Means of squares</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>7,060</td>
<td>1</td>
<td>7,060</td>
<td>10,396</td>
<td>.002*</td>
</tr>
<tr>
<td>Non-standardized residuals</td>
<td>76,062</td>
<td>112</td>
<td>679</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>83,123</td>
<td>113</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Dependent variable: Medication_Self  
b. Influential variable: (Constant), Input_Importance_Self

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of squares</th>
<th>df</th>
<th>Means of squares</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
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<td>1</td>
<td>4,768</td>
<td>8,380</td>
<td>.005*</td>
</tr>
<tr>
<td>Non-standardized residuals</td>
<td>63,723</td>
<td>112</td>
<td>569</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>68,491</td>
<td>113</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Dependent variable: Risk_Self  
b. Influential variable: (Constant), Input_Importance_Self

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of squares</th>
<th>df</th>
<th>Means of squares</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>3,196</td>
<td>1</td>
<td>3,196</td>
<td>9,129</td>
<td>.003*</td>
</tr>
<tr>
<td>Non-standardized residuals</td>
<td>39,214</td>
<td>112</td>
<td>350</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum</td>
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<td>113</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Dependent variable: Pain_Others  
b. Influential variable: (Constant), Input_Importance_Others

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of squares</th>
<th>df</th>
<th>Means of squares</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>5,056</td>
<td>1</td>
<td>5,056</td>
<td>9,365</td>
<td>.003*</td>
</tr>
<tr>
<td>Non-standardized residuals</td>
<td>60,462</td>
<td>112</td>
<td>540</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>65,518</td>
<td>113</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Dependent variable: Medication_Others  
b. Influential variable: (Constant), Input_Importance_Others

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of squares</th>
<th>df</th>
<th>Means of squares</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
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<td>8,637</td>
<td>25,980</td>
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<tr>
<td>Non-standardized residuals</td>
<td>37,235</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>45,873</td>
<td>113</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Dependent variable: Risk_Others  
b. Influential variable: (Constant), Input_Importance_Others

Source: Authors Illustration, based on SPSS analysis of data from quantitative questionnaire
The ANOVA analysis was conducted in regression analysis and analyzed in self-awareness and awareness of others. Within self-awareness, three analysis were made, one with y1 reduction of pain, one with y2 reduction of medication errors and y3 reduction of risk all with the influential variable importance in decision process of stakeholders (physicians, nurses, biomedical engineers, hospital management and hospital buyers). The same three test were made for awareness of others.

Significance is assigned if p<0.05. In all ANOVA tests focusing on awareness of others the results are significant. For self-awareness, one test is significant: reduction of medication errors. The other two tests (reduction of risk and reduction of pain) are not showing significant level what means that the self-awareness importance in decision processes cannot predict reduction of risk and reduction of pain.

### 3.5 Support and Rejection of the Hypothesis and Propositions

The key research question for this research is:

Is there a relation between involving different stakeholders in the decision making process in hospitals and improving patient safety culture? Yes, there is a relation which was analyzed in the correlation analysis.

How to define patient safety culture? Patient safety culture can be operationalized and defined by three factors: reduction of risk, reduction of harm/pain, reduction and reporting of errors. This is the result of joint analysis of semi-structured expert interviews and literature review.

Is there a difference between self-awareness and awareness of others? Yes, there is a difference between self-awareness and awareness of others which is shown in the regression analysis.

Main hypothesis:

- Involving different stakeholders in decision making processes in hospitals influences patient safety culture by differentiating self-awareness and awareness of others. That there is an influence of stakeholders in decision making processes has been shown in the statistical analysis above. There is a difference between self-awareness and awareness of others regarding the role and consideration of patient safety culture in decision making processes.
  - Regarding the role, there is no difference between self-awareness and awareness of others however regarding consideration of patient safety culture
(reduction of pain, reduction of medication errors, reduction of risk) there is a difference in regression analysis.

- Self-awareness shows a higher influence on patient safety culture in decision making process than awareness of others.
  - No, on the contrary: awareness of others displays higher influence. Meaning, physicians, biomedical engineers and buyers of investment goods in hospitals consider nurses as having a higher influence on patient safety culture than nurses themselves.

- Physicians and nurses consider themselves more important than Management, Buyers of investment goods in hospitals and Biomedical engineers.
  - No, on the contrary, nurses and physicians consider themselves to be influencing patient safety less. This was shown in variance analysis self-awareness. That means that care-givers close to the patient (nurses and physicians) do think that they do not have a big impact in improving patient safety.

3.6 Conceptual Framework to Improve Patient Safety Culture and set up Decision Making Processes in Hospitals

After having analyzed the research of 114 quantitative questionnaires from different stakeholders it is clear that stakeholders influence the decision making processes with regards to patient safety. Despite the fact that stakeholders influence the whole process of decision making, the influence on patient safety is far more complex in hospitals than only building the right decision making team.

As stated in chapter 2 there are many barriers and hurdles in hospitals in order to improve patient safety. The highest barrier identified is the lack of team work and negative culture and communications. By implementing the proposed conceptual framework, hospital managers can overcome this barrier and therefore improve patient safety culture. Therefore, the author chooses to develop a framework for decision making, including the hospital environment and systems. The best decision making process is not valuable if the people / organization are not enabled to improve patient safety.

The author is proposing the framework called “The House of Patient Safety” and is built with three pillars and a roof. The three pillars are availability of staff, multi-disciplinary-teams and tools & systems. The “roof” of the House of Patient Safety is full commitment on the part of the hospital leadership with regards to improving patient safety.
The House of Patient Safety has three “pillars” which will lead to creation of a culture of patient safety. The culture of safety means a culture that recognizes the possibility of errors, permits discussing them and most importantly permits developing tools and systems to prevent them in the future. This is reflected in the analysis in chapter 2 and the expert interviews also confirm the mentioned requirements.

![Conceptual Framework: the House of Patient Safety](image)

**Figure 3.14: Conceptual Framework: the House of Patient Safety**

*Source: Author’s illustration, based on research results*

In order to illustrate how to create the culture of patient safety, the author developed three categories, which are called pillars in the model. These categories will be explained below.

**Availability of staff:**

It is essential to have enough staff on all levels to improve patient safety. If there is lack of staff that means lack of time and therefore increased time pressure and increased risk of failure. This is a general requirement which will need to be addressed from the health insurance and government side, when discussing the payments of hospitals. Besides having enough staff is valuable only, provided the staff is accessible. In order to ensure this, it is essential to establish an open communication across hierarchies. Further it helps a lot to establish regular meetings to help make staff accessible.

**Multi-Disciplinary-Teams:**

- Involve all stakeholders
- No hierarchy in those teams
- Enable and empower nurses

**Tools & Systems**

- Training
- Anonymous reporting
- Follow up; derive actions
- Regular meetings
In order to take decisions in hospitals the recommendation is clearly to form multi-disciplinary-teams, which will then prepare and drive the decisions. When building those teams, the key to success is to involve all stakeholders, such as, nurses, physicians, hospital management and biomedical department. Within these teams the importance is that there is no hierarchy, every opinion is as important as the others. In order to still be able to make decisions there is always one group president, who is changing from year to year. This “president” has the chair and is not necessarily the person whose position in the hierarchy is the highest. The research in chapter 3 showed that the score of awareness of others is significantly higher than the score from self-awareness when it comes to how a stakeholder can influence patient safety. That means it is important to enable and empower nurses to provide input in order to really improve patient safety. How can nurses be empowered? It is really necessary to convince the nurses that their opinions are as important as those of the physicians. No hierarchy in these teams means that the normal hierarchy like doctor is higher than nurse does not count in those teams. In those teams, every voice is equal and there is no higher decision power due to hierarchy level.

A case study is the “wound group”295 from a hospital in Germany. They have a team of 7 people including physicians, nurses and administrative staff. They are meeting 3-4 times a year and analyzing and deciding on new products, systems or changes in the treatment of wounds in their hospital. No one has the autonomy to change something by themselves but always needs to get approval from this multi-disciplinary working group. This is a great example how productive those groups can be.

**Tools & Systems:**

Firstly and essentially, the staff needs to be trained. Every relevant person needs to be aware of patient safety culture and what it means to their daily work life. Training and awareness in respect to patient safety culture for all levels needs to be provided. Every hospital needs to make sure that they have reporting systems, where incidents with regards to patient safety are registered. Depending on how developed the patient safety culture already is, in the beginning it makes sense to have an anonymous system. Certainly the system alone is not a solution. At the same time it is essential to implement follow-up actions after an incident is registered. First, the people who register errors need to see that an improvement is taking place and secondly for the hospital a system only makes sense, if the result is improved patient safety.

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295 Interview in hospital Murnau, conducted by the author on 11th December 2017
Then the identified changes and actions can be developed and implemented through the multi-disciplinary-teams. It is necessary to ensure that all stakeholders are involved and that the solution is comprehensive and working.
CONCLUSIONS AND SUGGESTIONS FOR ADJUSTING DECISION MAKING PROCESSES IN ORDER TO IMPROVE PATIENT SAFETY CULTURE

Conclusions

1) In literature, there is no clear definition of patient safety. Patient safety itself is discussed in literature, but not in a structured and comprehensive way. Further, there exists no clear definition of patient safety in reality. The result of the expert interviews was that patient safety is not easy to define. Also, in hospitals it is a wide term and a universal definition does not exist. Main elements of the definition are defined as: reduction of harm/pain, reduction of errors, minimizing of risk.

2) Patient safety and financial sustainability of a hospital should be complementary and not competing goals. However, these are competing goals together with raising cost pressure in hospitals.

3) The healthcare environment is with economic, legal, historical and cultural structures of society is very complex. In the decision making process in the complex system of a hospital various stakeholders are involved: physicians, nurses, biomedical staff, buyers and management. These stakeholders are not equally involved and the influence level also varies among hospitals. All these stakeholders significantly influence patient safety.

4) Hospital structures in Germany are still very hierarchical. This means there is a clear top down management approach in most hospitals. Consequently, the cascade is from management through physicians and then to nurses. Therefore, nurses often do not perceive themselves as important and, even more essentially, hesitate discuss errors or mistakes.

5) The hospitals examined in Germany do not have proper patient safety awareness or even risk management systems. Some departments in hospitals, which are perceived as higher risk areas, e.g. intensive care, sometimes have a risk management system, however in most cases the said systems are not hospital wide.

6) Besides systems, there are several barriers to improve patient safety in hospitals, such as lack of teamwork, resistance in culture, lack of staff, financial issues, time, training
to name a few. These identified barriers can be seen as key success factors to improve patient safety.

7) Stakeholders (nurses, physicians, biomedical staff, buyers and management) influence patient safety and there is a difference between self-perception and perception of others. Influence on patient safety is perceived higher in the perception of others than in self-perception.

8) Fear to take too much risk: management (buyers, biomedical staff, and management) perceive themselves as more important in improving patient safety than nurses and physicians.

9) As patient safety is important for the image of hospitals, the decision from economic and managerial point of view should be clear: hospital managers have to focus on the decision making processes in hospitals in order to make the right decisions regarding patient safety in order to make their hospitals successful.
Suggestions

For hospital management

1) The hospital management needs to create awareness for patient safety in hospitals and should ensure that patient safety is one of the top aims in the hospital. Further it has to be ensured that this message is cascaded to different departments and within them to all people. Important is that the awareness is also created among nurses and not only among physicians.

2) Hospital managers should seek to define and establish clear responsibility for patient safety. To have positive outcomes, patient safety must be a multi-disciplinary goal.

3) Hospital management needs to ensure that effective tools and processes for improving patient safety and reducing the potential for adverse outcomes are selected and implemented.

4) Hospital management has to ensure that there is no negative impact for employees, when they speak up to talk about a problem or the source of the problem.

5) Hospital management should ensure that every suggestion / identified problem will receive a solution or reaction and make sure that the person, who raised it, is informed in respect to the outcome. This can be done in meetings or with the help of the implemented tools.

For physicians

6) Physicians need to walk the talk and set the tone for a consistent culture of patient safety, where open communication is not only valued but expected. Everyone needs to be able to influence the culture as well as the deployment of safe patient care.

For health insurance providers/ government and health care professional associations

7) Government and health insurances need to create a reimbursement system for hospitals where it is ensured that they have enough financial capabilities to recruit enough staff, but on the other hand still ensure a cost-effective health system.
8) Health insurance providers should make budget or reimbursement available not only for pure treatment of patients but also for identifying and implementing systems to prevent and identify risks with regards to patient safety.

9) Professional health care associations can help to improve patient safety to actively communicating and educating the interested parties on the importance of making the right decisions and consequences of wrong decisions.
Implications for further research

The underlying empirical research with its items revealed in this thesis provides a basis for further research of decision making processes in hospitals and the relevance of different stakeholders. The practical implication from the findings concerning the decision making processes and respectively improvement of patient safety can be seen as management handbook for hospital managers. As a consequence, it might be useful to develop a new questionnaire, which will be focusing on the outcomes in order to provide clear guidelines *inter alia* to physicians and nurses. A survey needs to be developed which will help physicians and nurses to understand better how to improve patient safety. The present research has demonstrated the importance of involving all stakeholders in the decision making processes and in the development of safety culture, therefore it might be useful to include the other identified interested parties in the further research.

One specific limitation which seems advisable to be neutralized in the potential future research is the limitation to “healthcare professionals”. It seems promising to widen the research to also include the patients’ views, as by doing so a multiple focus might be reached.

The present research is purely operationally focused. In the eventual next step, the financial aspect may be added in terms of how a hospital can save money by doing the right decisions and therefore addressing the financial pressure. By doing so, the managerial relevance of applying the right decision model might even be enhanced.
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APPENDIX

1. Sample quantitative Questionnaires (English & German)
2. Questions/Guideline Expert Interviews
3. List of Experts
4. SPSS Tables
Sample quantitative Questionnaires - English

Questionnaire
This questionnaire takes about 10-15 minutes. All your answers will be anonymous and be treated confidential. Thank you very much for filling out that questionnaire. The questionnaire is about decision process in hospital. Different stakeholders are considered. The stakeholders are doctors, nurses, biomed or technicians, hospital management and hospital buyers.

In which country are you working? _______________________

What kind of hospital are you working in?

☐ public  ☐ private  ☐ “Church” (relevant for specific countries)

How long are you already working?

☐ 1-5 years  ☐ 6-10 years  ☐ 11-15 years  ☐ >15 years

PAIN LEVEL

Doctors do consider pain level of patients when taking decisions

☐ strongly agree  ☐ agree  ☐ undecided  ☐ disagree  ☐ strongly disagree

Nurses do consider pain level of patients when taking decisions

☐ strongly agree  ☐ agree  ☐ undecided  ☐ disagree  ☐ strongly disagree

Biomed/Technician do consider pain level of patients when taking decisions

☐ strongly agree  ☐ agree  ☐ undecided  ☐ disagree  ☐ strongly disagree

Hospital management do consider pain level of patients when taking decisions

☐ strongly agree  ☐ agree  ☐ undecided  ☐ disagree  ☐ strongly disagree

Hospital buyer do consider pain level of patients when taking decisions

☐ strongly agree  ☐ agree  ☐ undecided  ☐ disagree  ☐ strongly disagree

REDUCTION OF MEDICATION ERRORS

Doctors do consider the reduction of medication errors when taking decisions

☐ strongly agree  ☐ agree  ☐ undecided  ☐ disagree  ☐ strongly disagree
strongly agree   agree   undecided   disagree   strongly disagree

**Nurses** do consider the **reduction of medication errors** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Biomed/Technician** do consider the **reduction of medication errors** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Hospital management** do consider the **reduction of medication errors** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Hospital buyers** do consider the **reduction of medication errors** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

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**REDSUCING PATIENTS RISK**

**Doctors** do consider **reducing patients risk** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Nurses** do consider **reducing patients risk** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Biomed/Technician** do consider **reducing patients risk** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Hospital management** do consider **reducing patients risk** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree

**Hospital buyers** do consider **reducing patients risk** when taking decisions

strongly agree   agree   undecided   disagree   strongly disagree
**Role**

**Doctors** do play an important role in decision process

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**Nurses** do play an important role in decision process

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**Biomed/Technician** do play an important role in decision process

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**Hospital management** do play an important role in decision process

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Hospital buyers do play an important role in decision process

strongly agree    agree    undecided    disagree    strongly disagree

OTHERS

When I have to decide, I have all information to decide well (always/mostly/often/rarely/never)

Always    mostly    often    rarely    never

I would like to invest our hospital more for patient safety

strongly agree    agree    undecided    disagree    strongly disagree

Thank you very much for your participation!

If you have any questions please contact ma at:
barbara.ehrnsperger@gmail.com
Sample quantitative Questionnaires – German

Fragebogen


Ihr Antworten tragen essentiell zum Erfolg der Dissertation bei und helfen zu verstehen, ob und wie man Patientensicherheit verbessern kann.

Das Ausfüllen des Fragebogens dauert circa 10-15 Minuten. Alle Antworten werden anonym behandelt und nicht an Dritte weiter gegeben. Herzlichen Dank für Ihre Hilfe!

In welchem Bundesland arbeiten Sie? ______________________

In welcher Art von Krankenhaus arbeiten Sie (Träger des Hauses)?
☐ ☐ ☐
öffentlich privat kirchlich

Was ist Ihre momentane Rolle im Krankenhaus?
☐ ☐ ☐ ☐ ☐
Arzt Pflegepersonal Medizintechnik Mngmt./Verwaltung Einkauf

Wie viele Jahre arbeiten Sie bereits in dieser Rolle (nicht zwangsläufig in diesem KH)?
☐ ☐ ☐ ☐
1-5 Jahre 6-10 Jahre 11-15 Jahre >15 Jahre

Input im Entscheidungsprozess

Der Input von Ärzten im Entscheidungsprozess wird als wertvoll wahrgenommen
☐ ☐ ☐ ☐ ☐ ☐
stark zustimmend zustimmend unentschlossen ablehnend stark ablehnend

Der Input von Pflegepersonal im Entscheidungsprozess wird als wertvoll wahrgenommen
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Der Input von Medizintechnikern im Entscheidungsprozess wird als wertvoll wahrgenommen
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Der Input von Mngmt./Verwaltung im Entscheidungsprozess wird als wertvoll wahrgenommen

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Der Input vom Einkauf im Entscheidungsprozess wird als wertvoll wahrgenommen

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Painlevel

Ärzte berücksichtigen das Painlevel des Patienten wenn Sie Entscheidungen treffen

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Pflegepersonal berücksichtigt das Painlevel des Patienten wenn Sie Entscheidungen treffen

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Medizintechnik berücksichtigt das Painlevel des Patienten wenn Sie Entscheidungen treffen

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Mngmt./Verwaltung berücksichtigt das Painlevel des Patienten bei Entscheidungen

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Einkauf berücksichtigt das Painlevel des Patienten wenn Sie Entscheidungen treffen

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Reduzierung von Medicationsfehlern

Ärzte berücksichtigen bei Entscheidungen die Reduzierung von Medicationsfehlern

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Pflegepersonal berücksichtigt bei Entscheidungen die Reduzierung von Medicationsfehlern

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Medizintechniker berücksichtigen bei Entscheidungen die Reduzierung von Medicationsfehlern

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Reduzierung von Risk für den Patienten

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Ärzte berücksichtigen die Reduktion des Risks für den Patienten bei Entscheidungen

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**Einkauf** berücksichtigt die **Reduktion des Risks** für den Patienten bei Entscheidungen

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**Rolle / Importance**

**Arzte** werden als **Importance Entschieder** im Entscheidungsprozess wahrgenommen

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**Sonstiges**

Wenn **ich** entscheiden muss habe ich alle **Informationen**, um gut und richtig zu entscheiden

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163
Ich würde gerne mehr **Initiativen** für **Patientensicherheit** in unserem Krankenhaus vorantreiben.

☐ stark zustimmend  ☐ zustimmend  ☐ unentschlossen  ☐ ablehnend  ☐ stark ablehnend

Herzlichen Dank für Ihre Teilnahme.

Falls Sie Fragen haben, können Sie mich gerne unter folgender Email kontaktieren:  
barbara.ehrnsperger@gmail.com
### SPSS Tables

#### Correlations

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**Correlation Matrix** AWARENESS OF OTHERS

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**. Correlation at a level of 0.01 (2-sided) significant.
*. Correlation at a level of 0.05 (2-sided) significant.

**Regression**

**Modellzusammenfassung**

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a. Einflußvariablen: (Konstante), Input_Importance_Self

**ANOVA**

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a. Abhängige Variable: Pain_Self
b. Einflußvariablen: (Konstante), Input_Importance_Self

**Koeffizienten**
Modell Zusammenfassung

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a. Einflußvariablen: (Konstante), Input_Importance_Self

ANOVA

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a. Abhängige Variable: Medication_Self
b. Einflußvariablen: (Konstante), Input_Importance_Self

t. Koeffizienten

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#### a. Abhängige Variable: Medication_Self

### Regression

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#### a. Einflußvariablen: (Konstante), Input_Importance_Self

### ANOVA

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#### a. Abhängige Variable: Risk_Self

#### b. Einflußvariablen: (Konstante), Input_Importance_Self
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a. Abhängige Variable: Risk_Self

### Regression

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a. Einflußvariablen: (Konstante), Input_Importance_Others

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a. Abhängige Variable: Pain_Others

b. Einflußvariablen: (Konstante), Input_Importance_Others
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a. Abhängige Variable: Pain_Others

### Regression

**Modellzusammenfassung**

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a. Einflußvariablen: (Konstante), Input_Importance_Others

### ANOVA

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a. Abhängige Variable: Medication_Others

b. Einflußvariablen: (Konstante), Input_Importance_Others
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*a. Abhängige Variable: Medication_Others*

### Regression

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*a. Einflußvariablen: (Konstante), Input_Importance_Others*

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*a. Abhängige Variable: Risk_Others*
b. Einflußvariablen: (Konstante), Input_Importance_Others

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a. Abhängige Variable: Risk_Others

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## Test bei unabhängigen Stichproben

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Varianzen sind nicht gleich | .000 | -1,013 | .094

**Test bei unabhängigen Stichproben**

T-Test für die Mittelwertgleichheit

95% Konfidenzintervall der Differenz

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**Univariat**

**ONEWAY deskriptive Statistiken**

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**ONEWAY deskriptive Statistiken**

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**Einfaktorielle ANOVA**

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WORDS OF GRATITUDE

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First of all, I would like to particularly thank Prof. Dr. oec. Baiba Šavriņa and Prof. Dr. Josef Neuert for coordinating the doctoral studies program in management. They were strongly supported by Markus Spriestersbach, Kristine Blumfelde-Rutka, and Eva Kazaka. The structure of the program is more than valuable by offering constant communication within the cohort as well as with professors of different departments. This enables a constant progression of the research subject.

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