

Walter Merkle
Editor

Risk Management in Medicine

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Preface

Risk Management in Hospitals – New subject or just new wine in old bottles?

Both are correct. Risk management as principle is a well-known tool, but currently not well used in hospitals.

Industrial enterprises have been developing risk management tools for decades. Motorola was the first company to start with systemic analysis as to why some procedures went wrong. It was shown that not Motorola was dealing with a problematic business, but is working with people – meaning with its staff.

Where people are working, mistakes and failures are common.

Errare humanum est – hundreds of years ago ancient Rome already knew this.

The systemic approach by Motorola and others showed that there is a baseline level of human-caused failures independent of the individual and independent of the business or procedure.

At the end of the last century, the Harvard Medical Study demonstrated that in medicine there is also a baseline level of 3 % failures in all medical procedures – what a surprise!?! Really?

Meanwhile some efforts are taken analyzing the specific details in medicine with focus on hospitals.

This book will refer the current status of the details which now firm under the title of Risk Management.

Reducing risk in patient treatment is as ethically as economically justifiable.

The cause is simple – repair of wrong treatment costs additional money and the health of the patient as well. Furthermore, problems with the law might occur if something went wrong not only by accident but by malpractice of doctors and staff. This all together will cost a large amount of money and the reputation of the hospital.

Thus, total successful risk management does cost money to install, but it definitely saves more money than it costs, and patients are healthier.

There is no better win-win situation for everybody.

How does this work?

This textbook will demonstrate in every chapter why we make some mistakes, although we do not want to do so, and how to protect everybody – patients, doctors, and hospital administration (and insurance companies) against human failures.

The German issue was published successfully in February 2014.

As editor of this textbook, I am very pleased that my authors are more than willing to write the international issue which you hold in your hands.

Main parts of the German version are also part of the international textbook, but of course important chapters are written newly under the broader sight of Europe and the USA. Especially the law chapters had to be adjusted because of country-specific medical laws.

I therefore thank my old friend Prof. Joseph Smith Jr., Chairman of Urology at Vanderbilt University, for supporting the international version and assisting in writing parts under the specific US sight. Additionally I thank Dr. Rybak spontaneously for accepting my invitation in contributing with the European law chapter.

And last but not least I am grateful to my publisher Springer in Heidelberg, New York, and London for accepting my idea to publish an international version of our risk management textbook. The professional work of this publisher is invaluable and guarantees good quality.

Wiesbaden, Germany

Walter Merkle

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Why We Do Wrong Although We Want to Do Right

1

Walter Merkle

Abstract

The question why we make mistakes although we want to do right is the main source to start risk management.

Mistakes and faults are mostly caused by principles owned by everybody. Thus it is important to find out how people act when making things wrongly. The overwhelming amount of these mistakes can happen to everybody and are not caused individually.

The principles of these processes and how to learn from these insights are discussed in this chapter. Technical aspects (e.g., zero-failure technique), psychological aspects (e.g., mobbing), solution techniques (e.g., peer reviews), and further solutions are put into a structured context.

1.1 Introduction

First of all, there is nobody who's happy to make mistakes.

And therefore nobody wants to admit to having made a mistake.

Thus, failures are covered by silence.

Consequently systemic failure will not be detected, and every single person will make the same mistake again; there's no learning process.

Everybody knows that there are systemic and principle failures independently from the person

to make the mistake. Logically it seems to be possible to prevent those failures by training and information about pitfalls, etc.

However – an individual bottom level of failures will remain because we all are human beings. And also these individual failures can be reduced to an absolute minimum by intelligent support systems.

Altogether there is only one absolutely mandatory principle to accept – we all, youngsters as well as highly trained and experienced experts, will make mistakes our whole life. We all sit in the same boat.

Thus we all have to learn the tools to reduce the imminent risks. We all can learn from each other – but we have to do it!

The ethos of doctors and all medical staff fits together with the patient's claim to work correctly.

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Both diagnostic and therapeutic procedures are focused when discussing failure management. Therefore not only surgical disciplines but also so-called conservative disciplines are involved.

In Germany we have the institution of so-called medical expert commissions regarding every single discipline to decide about correct or incorrect procedures done in case a patient might have the opinion something went wrong during his medical treatment.

This institution is a specific German way of dealing with malpractice but has many advantages – it is independent, objective, and broadly accepted by doctors, patients, lawyers, and insurance companies – and furthermore it avoids the official way to court. In case somebody does not accept the decision of this expert commission, he/she is free to go to court. However, approximately 97 % of expert decisions are confirmed by court which shows the high professionalism of the specific German way to deal with suspected malpractice. Details are presented in Chap. 2.

The most important principle of successful risk management is called “Kaizen.”

This Japanese word means: thank you for learning from you (from your mistake).

The acceptance of this principle should come first in medicine all over the world.

Other businesses are far more developed in this important tool or risk management.

Aviation business works as THE key developer.

Everything started with the announcement of all failures that have occurred during a flight – free of punishment.

Thus repeated, that means principle failures were quickly detected and could be solved. This gave the chance of fast improvement in flying safety.

Furthermore the experience of a single airline was communicated openly, thus all other airlines could learn a parallel. The overall flying risks were reduced and meanwhile flying has proved to be much safer than other forms of transportation.

The culture of blame – current status in medicine – hinders a fast improvement in avoiding failure.

Eventually there are psychological causes, too, when being of the opinion: “I’m a doctor, I do all my procedures correctly.”

This ethos is nothing more than claim, but not reality.

1.2 First Steps of Failure Theory

During the 1960, Motorola started with the systematic analysis of failures that occurred. Shortly after the PCDA cyclus was developed followed by the 6-Sigma strategy the first perception was: we ALL make mistakes.

In medicine, the Harvard Medical School showed impressively that 3 % of medical procedures were performed incorrectly (www.hms.harvard.edu). Well, this huge amount of failures does mean death cases or severe problems – most mistakes are harmless, but not to forget – also death cases are included.

Of course the main focus on strategies reducing failures is on harmful mistakes.

The first step is called Failure Analysis.

It is constructed of product quality together with structure quality and process quality.

It depends on competence in basic knowledge, methods, and social behavior.

In the field of medicine this means

- Product quality: operation successful?
- Structure quality: modern hospital with modern equipment; well-trained and educated staff working with the current knowledge in their field?
- Process quality: e.g., correct timing and following of the different steps of an OR procedure (lean management)?

Competence means

- In knowledge: Are the involved doctor and staff well educated for this specific case or is there a colleague (in another hospital) better qualified for this patient?
- In methods: do, e.g., the surgeons govern all kinds of procedures for this specific case, thus the patient has the chance to make a free

decision? For example, in hernia surgery, does the surgeon know to operate conventionally with the Shouldice procedure, Lichtenstein net, or laparoscopically, etc.

- In social behavior: reducing fear, explaining individually what is planned, accepting patient's decision, accepting partnership between patient and doctor, etc.

Important to know – lacking social competence will likely lead to court if something goes wrong whereas patients might otherwise accept a minor mistake if the doctor speaks frankly about what's going wrong and shows his/her personal concern and apologizes to the patient and family members.

On the other hand, arrogance is the “easiest” way to court and is to be blamed.

1.3 Human Factor

There are two contradictive statements:

- Humans are able to think complex, so although with a limited data basis correct decisions can be made.
- Humans are emotionally driven, so failures in their doing are imminent: praise improves correct outcome; being critical reduces success.

In summary humans are better than machines when complex processes and procedures like operations have to be performed.

Thus standardization including guidelines is helpful but should never press someone into a rigid corset as humans are principally individuals (Perabo 2012).

Meanwhile in Germany even the high court has accepted that “guidelines guide,” but they are not laws which have to be strictly followed (Chap. 15).

Consequently failure analysis, reduction by PDCA, and risk management are the way to go. To shorten learning process and avoid a long learning curve medicine should learn from parallel disciplines and adopt experience.

The most appropriate technique to install is the FMEA (Chap. 11) (Failure Mode and Effects Analysis).

Another analogue in dealing with complex procedures under limited data basis and also human driven is aviation business.

The parallels are impressive:

- Complex technique
- High stress level
- Many things to do parallelly in very short time
- Working against biorhythm (e.g., during the night)
- Limited resources
- Limited personnel

However, we all are used to safe journeys by plane, almost not even thinking about the inherent problems of going into the air.

How could this occur?

The answer is more or less simple – consequent risk management.

Risk management in medicine is lacking, as the following tables show:

Differences between medicine and airlines:

Airlines

- Strict failure management
- Consequent use of checklists
- Teamwork with flat hierarchy
- Open dealing with conflicts
- Observing soft skills
- Regular training in simulator
- Consequent support of zero-failure strategy by management (including financial support)
- SAFETY IS THE MAIN CONCERN

Medicine

- No risk management
- Culture of blame
- No support by management
- Under-refunding
- Reduction of personnel
- Disregarding soft skills
- COST REDUCTION is the main concern

Therefore the president of the German “Landesärztekammer Hessen” pointed out,

“Health policy and public insurance companies were looking more for cost reduction instead of improving curative elements” (Hess. *Ärztebl.* 8/2011, pp 468–69).

Although this is a German statement, more or less it is common all over the world.

However, in the medical business meanwhile doctors found out that it pays to learn from the flight crew (*J. Urology* 2011:185:1177–78). The reason is clear – the main risk for fatal outcome as well in airline business as in medicine is a combination of failures in communication and rigid hierarchy.

For example, “the fundamental cause of catastrophes (total loss) was not ice, snow, fog or empty fuel tanks but hierarchy” (*J. Urol.* 2011). Consequently this finding is the question: “How to turn a team of experts into an expert medical team?” (Burke et al. 2004). This is the question for CRM (Crew Resource Management).

CRM in medicine is more or less unknown although teamwork is routine but not professionally learned.

The main topics of CRM are

- Briefing before operation start – including everybody
- Explaining expected critical points of the operation
- Discussion about potential risk of the individual patient
- Freedom for everybody to show concerns
- Short briefing report in patient’s file

For details, see Chap. 14.

Additionally in case the operation reaches a critical point, TTO (Team Time-Out) is a successful tool to reduce the risk of the situation. Also here, there is no hierarchy. Everybody in the team shall contribute.

There are two further aspects to know – very human in its kind.

Night shift work is a safety risk for doctors’ own health – leading to diabetes, heart attacks, discomfort of the GI system, and (!) increased risk for accidents (e.g., when driving back home) (Straif et al. 2007).

By chronoadopted work shift this inherent problem can be reduced (Straif et al. 2007).

Furthermore – doctors who are blamed by patients show increased levels of depression and of committing suicide (Bourne et al. 2015). Therefore it is very wise to reduce any failures which can be followed by blaming and lawsuit.

Thus, the human factor problem affects not only patients but also the staff. This at least should be the most important cause accepting risk management thus reducing the very own risk of working at a hospital.

1.4 Methods

Communication first!

Yes, this is correct, more or less. While a targeted communication process improves problem solving, overboarding communication will lead to even more failures.

Why?

The OTAS study (Chap. 10) clearly pointed out that unnecessary communication risked concentration of the surgeon as well as of the team thus increasing failure level. Details will be shown in Chap. 10.

On the other hand, if communication is avoided, important information might be lacking.

In aviation business this is well known.

Therefore, “empower lower-ranking crew members to voice their concerns in a respectful but assertive manner. Teach higher-ranking members to listen to the crew and view questions as signs of honest concern for clarification but not as insubordination or doubts about the leader’s ability” (*J. Urol.* 2011).

1.5 Use of Checklists

In principle checklists are helpful tools to avoid overlooking important things to do. However, there is not one single type of checklist but as many checklists as there are hospitals.

What is appropriate for, e.g., the Vanderbilt University Hospital will definitely not fit for a