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PRIMUM NON NOCERE

– Medicine's Culture of Dealing with and Denial of the Occurrence of Medical Harm

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Content

"One hopes that everything goes well – but: what if it does *not*?" **Anonymous patient**

Abstract

The hippocratic principle "primum non nocere" (above all do no harm) has always been and still is the strong foundation of medical conduct. For a long time healthcare professionals created the image of infallibility of medicine (Youngberg, 2013, pp. 159/160). Even within the "closed" hierarchies mistakes and malpractice were never openly discussed. This paper first investigates reasons for medical mistakes and introduces the legislation when malpractice occurs. Secondly ethical questions concerning medical mistakes are discussed through the lens of Beauchamp and Childress´ principles of biomedical ethics (nonmaleficence, beneficence, respect for autonomy, justice). Thirdly, an ethically defensible strategy to deal with failure and malpractice is proposed. This proposal stresses how to improve the patient-physician communication by involving patients´ experiences in order to increase patient safety and lower costs in the healthcare system. In regard to tackling medical harm there is the strong recommendation to follow four directives: open disclosure and explanation, adequate restorative and/or compensatory actions, fair and square apologies and information about strategies to avoid recurrence.

Key Words

failure, malpractice, nonmaleficence, patient safety, risk management, patient involvement, reconciliation, cost reduction

Introduction

The aim of this Master thesis is already stated in the title "PRIMUM NON NOCERE – Medicine´s Culture of Dealing with and Denial of the Occurrence of Medical Harm". Thus the thesis deals with two major, interconnected issues. The professional principle in medicine is "primum non nocere" – above all do no harm. Therefore the overall directive of medical acting is nonmaleficence. However it is human to make mistakes and regrettably medical harm occurs. Thus the question arises of how healthcare professionals deal with failure. The very volatile problem of denial of medical harm illuminates the dark side of the sensitive issue since it asks for an answer to the questions of how denial can be avoided and how medicine´s culture of dealing with mistakes can be improved. This is of high interest in the first instance for the harmed patient and also for the healthcare professionals.

Four ethical problems can be identified within this issue:

Can the principle of nonmaleficence, with its main aim to avoid harm, be credible if medical harm occurs?

If the principle of beneficence of medical conduct is presupposed, why is the helping aspect and communication with the patient not played for keeps more, if medical harm occurs?
Is the respect for autonomy and informed consent credible if the denial of medical harm instead of telling the truth is the daily practice and: should a patient have an obligation to contribute to nonmaleficent and beneficent treatment before medical harm happens as well as after medical harm has occurred?
Is the occurrence and the denial of medical harm ethically justified in times where the effective distribution of resources is a main goal of the principle of justice?

The tripartite structure of the Master thesis is as following:
Firstly the medical and legal background of medical harm is unfolded in order to give an insight into factors that influence or create medical harm. This background describes the situation in Germany.
Secondly ethical problems concerning nonmaleficence, beneficence, autonomy and justice are presented. All arguments and statements are illustrated and applied to constructed cases which build on real cases. In order to protect the patients´ privacy they are anonymised and therefore no source is provided.
Thirdly, I present a proposal in form of a conclusion regarding how medical harm can be dealt with and how satisfying and adequate solutions for both sides, the patient and the professional, can be found.

The literature used for the arguments and statements in this Master thesis are the following:
Euteneier´s "Handbuch Klinisches Risikomanagement (handbook clinical risk management) is seen as the standard reference in Germany when strategies for risk management and patient safety are implemented in German hospitals. I used it to investigate medical and legal aspects. The ethical lens to discuss ethical concerns builds on the four principles of nonmaleficence, beneficence, autonomy and justice which are presented in Beauchamp and Childress´ book "Principles of Biomedical Ethics". The proposal and conclusion were basically inspired by Gottschlich´s "Medizin und Mitgefühl" (medicine and compassion) which was edited again after twenty years. This can be seen as proof that is has not lost anything of its actuality. Some more recent publications which consider the improvement of the physician-patient communication and emphasize the patient involvement are also referred to.

Surprisingly, research in the area of risk management and patient safety is quite new even though the problematic nature of the issue has a long history. The literature on this topic can be divided into two factions: Some authors emphasize patient safety by implementing a standardized risk management through implementing procedures and guidelines and other authors give weight to the improvement of social skills of healthcare professionals. As well, I point out the importance and obligation of the

patient role as well as the involvement of patient´s experiences. The latter is becoming more important as patient autonomy was strengthened in the last few years. However, this aspect is not considered enough in daily practice. I emphasize this niche as I am convinced that successful treatment as well as the dealing with failure in medicine hinges on the question of mutual respect and communication. In addition to this I argue that a positive change in the paradigm of dealing with medical harm can be advanced decisively by shared decision-making and when playing for keeps for the patient´s experience is put into practice.

The proceeding of the above described structure follows one of the approaches applied biomedical ethics pursues: The theory/ies or principles are described, balanced and weighed and then finally presented as a reflective equilibrium, supported by examples. This approach seems promising with this topic where scientific theory and the practice of cases can be ideally combined: the practice is illuminated by the theory. This is compliant with Friedrich Schleiermacher´s educational theory approach of the 19th century which I borrow for this Master thesis as it could throw a new light on the old perspective that reality and knowledge are congruent (Kenklies, 2012, p. 266). The underlying leading postulate for this master thesis is Schleiermacher´s conviction about education which can be equally applied to medicine and ethics: "Still, it is nevertheless a fact that in every domain that goes under the name of art, in a narrower sense, practice is much older than theory, so that it can simply not be said that practice gets its own definite character only with theory. The dignity of practice is independent of theory, practice only becomes more conscious with theory."[1] (Schleiermacher as cited in Uljens, 1997, pp. 9/10)

Very often physicians have not experienced failure personally when they were in school. However, even if they follow the principle to "primum non nocere" in their specific professional capacity, they still experience failure and malpractice. Only through life-long-learning-experience they can become more confident, on one hand, and more humble, on the other hand, since they discover how vulnerable their directive is as well as how unpredictable the situation may be.

The background for this Master thesis is provided by two German congresses of physicians and surgeons, somewhat more than ten years ago. After those congresses, the debate on the issue and topic of patient safety became known to a broader public and heralded changes in the German healthcare system (Bauer, 2015, p. 73). The basis for the discussions during these congresses had been international studies that showed the importance of dealing openly with mistakes and failure and breaking the code of silence in order to profoundly improve patient safety.

[1] Ist doch überhaupt auf jedem Gebiete, das Kunst heißt im engeren Sinne, die Praxis viel älter als die Theorie, so daß man nicht einmal sagen kann, die Praxis bekomme ihren bestimmten Charakter erst mit der Theorie. Die Dignität der Praxis ist unabhängig von der Theorie, die Praxis wird nur mit der Theorie eine bewusstere.

As the main aim of this Master thesis is the dealing with and denial of medical harm, it is essential to take in the setting, decisions and treatment situation *before* an incident happens. This is because the deficits in communication and the neglect to take in the patient´s experience seriously from the beginning on is continued when it comes to medical harm.

Medical and legal aspects

In this part I give an overview of reasons and sources that contribute to or are the origin of mistakes in healthcare. This part has two aims. Firstly, I want to show the complexity of the issue when so many diverse aspects are held up to be the way to avoid failure and malpractice. Many of these aspects are "system inherent". Secondly, I want to stress the relevance of the human factor. I am convinced that the human factor can most influence the dealing and the denying of medical harm.

Basic aspects of medical mistakes

What high risk organisations (HRO) like airlines, fire brigades or hospitals have in common is that they have a very low tolerance of mistakes. In order to avoid mistakes they have rules for critical processes in order to deliver the intended product. A comparison of healthcare with other HROs is yet only of restricted value as within healthcare it is not mainly process- or product-oriented standard procedures that should determine treatment. The treatment is oriented towards the individual suffering of patients (Euteneier, 2015, pp. 63/4).

Iatrogenic illness or medical harm mean that illness is caused or induced by a doctor or by being exposed to healthcare (Sharpe and Faden, 1998, p. 117). At first sight it seems absurd that a physician is the source of an illness as the patient reckons that a doctor cures or relieves illness instead of impairing it. However studies in the US dating back to the time between 1956-1991 (Sharpe and Faden, 1998, p. 241) show that on an average 30% of the treated patients in hospitals experienced medical harm. Yet German statistics from the last few years differ enormously and are controversial because of the inconsistencies that result from who commissions a study or which numbers count in a statistic (Le Ker, 2014; Fricke, 2016; Bundesärztekammer, 2016). Even though numbers and statistics show diverse results it is undeniable that medical harm is a significant issue in healthcare. When the sources for medical harm are found, strategies can be developed to improve the situation.

The code of silence is common when one approaches the eventuality of mistakes in medicine. Mostly doctors claim, when questioned, that it is only the tabloids which report on these issues and therefore they are exaggerated or do not exist or they refer to big scandals like the Macchiarini case in Sweden. They are advanced whereas the possibility of personal failure is never discussed publically. However the US surgeon Marty Makary inferred from it, that those colleagues who denied medical harm are those committing it – which then means that the above presented numbers are correct as they correlate with these findings (Makary, 2012, p. 3). The fact that physicians deny the occurrence of mistakes

seems as it should serve in the following way as far as I can see: Firstly, the occurrence of mistakes could be interpreted as if a doctor could not be trusted anymore and secondly, the occurrence of mistakes would have reverse consequences for their career.

Mostly medical failure is the sum of several factors. Mistakes occur as a combination of lack of sufficient care, deficient communication with patients and high pressure of work. The risk of making mistakes are underestimated as many decisions have to be taken too quick and too spontaneous (Bauer, 2015, p. 68).

Medical mistakes have the following typology due to Bauer:

- Incidents (unintended or non-essential / unnecessary harm)
- Adverse Events (unintended incidence under the treatment which does not necessary result in harm)
- Mistakes (act or omission because of not following a plan, without a plan or a wrong plan which results in not achieving the aim or goal)
- Medical Malpractice (diagnostic or therapeutic intervention which was not indicated or required or carelessly performed)
- Complications (planned and or unexpected clinical course which exacerbates, impairs, thwarts healing)

  (Bauer, 2015, p. 68)

Mistakes of an individual physician or adverse incidents are the result of deficiencies and problems of organisations or a whole system. Two different models (SHELL/SEIPS)[2] exist to describe the elements that contribute to the human factor. These are for example active mistakes (wrong decisions), situative factors (context: patient, task, individual), local working conditions or organisation factors (responsibilities, guidelines, workload, sleep deprivation) or external factors (political, economic). (Hörmann, 2015, p. 134)

Beyond that patient safety is under threat from diverse circumstances, like primary and secondary illnesses, a physician´s attitude or competence, patterns of team relationships or cost pressure. Euteneier states therefore that mistakes arise partly because of inefficient dealing with potential danger either because of a miscarriage of planned actions or the choice of a wrong plan (Kohn et al. as cited in Hörmann, 2015, p. 142).

This is aggravated by the continuing complexity of using more technology, and its sophisticated handling which requires a lot more time than in the past. It is therefore an indispensable necessity to provide physicians more time for their core tasks, namely time with their patients and time with their

[2] SHELL (software, hardware, environment, liveware) and SEIPS (Systems Engineering Initiative for Patient Safety)

colleagues to work against inadequate communication (Bauer as cited in Bauer, 2015, pp. 72/73). The colleague and his team become more important, especially when multimorbid patients need treatment and several specialists in different shifts have to arrange treatment. However, a team is embedded in a hierarchical organised healthcare system. The implications that arise from this fact are described next.

Hierarchy and health management

High quality in hospital settings is not achievable in teams of low quality (Euteneier, R., 2015, p. 102). However, how can high quality in a team be defined and how can it be reached? Euteneier presents communication theories that started to develop as early as 1949 (Shannon-Weaver-Model) as well as other standard works of communication (human communication – Paul Watzlavick) complemented by authors who refined verbal and nonverbal communication. The success of a team hinges on the question of successful communication. Communication plays a key role in healthcare as all other competencies build on communicative skills and it is seen as a sign of good medical care (Makary, 2012, p. 23). In general communication is successful when the sender of a message releases the reaction or action intended, when nonverbal communication (body language, countenance etc.), factual level and relationship level are considered adequately (Euteneier, R., 2015, pp. 105/6).

A team however has to be seen in connection to leadership in hospitals in Germany. Hierarchies are much more distinct than in English-speaking countries where already several consultants within a department form a team and decision-making is a shared process. A head physician in Germany is increasingly becoming the manager of his department with different roles. He is a medical specialist, a team player, an advocate for health, manager, representative and lifelong learner (Euteneier, A., 2015, p. 117) which shows the comprehensiveness of his tasks beyond the core task of healing.

However one should bring up the fact that in various areas of care and treatment evidence-based rules compete with eminence-based rules where a head physician´s or a ward nurse´s experience-based directive is followed rather than rules or guidelines (Euteneier, A., 2015, p. 148). This practice cannot be taken as a basis for improvement of patient safety. Yet most changes in patient care – even though the knowledge is already available – are only performed with a new head physician. This shows that patient safety is still dependent on the hierarchy in Germany (Euteneier, A., 2015, p. 304).

Therefore rules and the compliance to them need to be more focussed on in the future to improve patient safety.

Rules and compliance

Checklists are proposed to improve the reliability of routine processes and compliance to rules, however they cannot replace the judgement of a physician or a nurse. They can help in situations of tiredness or physical overload in order to react rule-conform (Euteneier, A., 2015, p.158).

Involuntary and unintentional mistakes (inattention and lapses of memory) have their origin in cognitive flawed processes and remain a threat to the patient.

Intentional rule violations however are rooted in bias and attitude and the social values of physicians and these have far-reaching consequences for an organisation as they may lead to a deleterious safety culture. Rule-breaking in emergency cases seem to exist more often than thought, as well as the flexible interpretation of indications of operations (Euteneier, A., 2015, p. 151).

If a laissez-faire attitude of a head physician or other responsible physicians on the one hand predominates in the detection of rule-breaking, it may have fatal effects for the patient´s safety.

However on the other hand, the healthcare professionals´ illusion of control, illusion of invulnerability and illusion of superiority are expressions of non-compliance to rules and add to this risk (Reason as cited in Euteneier, A., 2015, p. 156) as well as not talking openly about incidents because of fear to endanger the career.

As I have now focussed on the professionals´ side of healthcare to tackle medical harm one may ask what role the patient who experiences medical harm, plays.

The patient

A patient who is readmitted within a short time (90 days) to the same or another hospital may suffer from complications from the treatment he was given before. Therefore the patient outcome is seen as a metric for transparency and in order to lower readmission rates patients get more information at their discharge (Makary, 2012, p. 85).

Yet international surveys show that a considerable number of patients assume that they experienced medical malpractice show that patients´ reports are correct (Schwappach, 2015, p. 553).

Standardised questionnaires or safety walk rounds where patients are asked about their personal observations could help improve risk management. It seems to be highly important to encourage patients to report any procedures they find questionable. The reason for not telling is that patients want to have a good relationship with their doctors.

Patient-advocacy groups like the *Aktionsbündnis Patientensicherheit* support patients and provide well-designed information material to increase patient safety and transparency (Aktionsbündnis Patientensicherheit e.V.), however they cannot change the system (Makary, 2012, p. 213). Therefore legislation was needed to strengthen patients´ rights. Legislation plays an important role when medical harm is dealt with and therefore I investigate this issue in particular.

Legal aspects of medical mistakes

The legislative basis in Germany builds on two grounds. First it is subject of civil law and second it concerns prosecution. These two subjects are presented in this part.

Civil law

The civil proceedings deal with reconciliation through indemnity. This is mainly monetary compensation for the infringement of life quality which is covered by indemnity insurances.

The costs of medical harm are increasing due to rising amounts of loss and therefore it becomes a threat to the profitability of a hospital (Bock, 2015, p. 219). The conclusion from the perspective of a hospital´s risk managment is, that medical harm is an unforeseeable parameter of cost and therefore it has to be eliminated. This is due to the fact that indemnity insurers like the Ecclesia Group in Germany are not willing to pay the actual high sums for medical damages and therefore abrogate insurance contracts, which puts hospitals into a difficult situation: on the one hand it is mandatory by law that hospitals have indemnity insurance; on the other hand the available insurers do not pay in the event of damage due to the extraorbitantly increased costs during the last 30 years (Petry and Grabow, 2013, p. 601). However it is argued by insurers that a change of the legal situation is needed as well so that escalating costs in the event of damage are capped by co-payment obligations of hospitals (Petry and Grabow, 2013, p. 604).

Criminal prosecution

The patients´ rights law *(Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten vom 20. Februar 2013)* which is part of the Civil Law Code *(Bürgerliches Gesetzbuch (BGB))* of Germany, stresses the importance of informed consent and liability and asks for particular diligence when informed consent is obtained. The content, the way of communicating and timeliness are important parameters (§§ 630a-h, BGB). All relevant data concerning the patient´s treatment have to be put down in writing in a comprehensive way and the patient´s right of inspection and duplication of records is guaranteed (§§ 630f-g, BGB). Finally, the burden or reversal of burden of proof in the case of medical malpractice is established by law (§ 630h, BGB).

This law regulates all patients´ rights even though in consequence it affects the physician personally in the case of prosecution. Albeit the physician is insured and (the) acruing costs are covered, one can imagine that the loss of reputation is a result of making mistakes, further consequences of the code of medical conduct *(Berufsordnung für Ärzte)* or labour-law related may follow.

This section of the thesis showed the sources of medical reasons which contribute to medical mistakes as well as the legal aspects which play a role when medical harm occurs. Even though the aspects can occur solitary the complexity of reality can become more intricate if these aspects are related to ethical principles of medical care.

In the following part I investigate these aspects further through the lens of biomedical ethics principles and apply them to constructed and anonymised cases based on reality.

Ethical problems

Nonmaleficence

Introduction

The issue of not harming and preventing harm means basically to act in the person´s best interest. However it is worth looking at a "concept of harm" (Beauchamp and Childress, 2013, p. 153) which specifies the principle of nonmaleficence as this helps to understand what harm means, why harm may not be seen negatively in toto or in general. Secondly, examining this concept helps us understand what it means for nonmaleficent acting.

A questionable definition of harm and its justification is the following.

> "[Medical] harm is a thwarting, defeating, or setting back of some party´s interests, but a harmful action is not always a wrong or unjustified. Harmful actions that involve justifiable setbacks to another´s interests are not wrong – for example, justified amputation of a patient´s leg, justified punishment of physicians for incompetence or negligence […]. Nevertheless, the principle of nonmaleficence is a prima facie principle that requires the justification of harmful actions. This justification may come from showing that the harmful actions do not infringe specific obligations of nonmaleficence or that the infringements are outweighed by other ethical principles and rules. Some definitions of harm are so broad that they include setbacks to interests in reputation, property, privacy, and liberty or, in some writings, discomfort, humiliation, offense, and annoyance. […] Although harm is a contested concept, significant bodily harms and setbacks to other significant interests are paradigm instances of harm." (Beauchamp and Childress, 2013, p. 153-154).

This definition may be misleading if moral rules do not specify the superior principle of nonmaleficence. The moral rules of not to cause suffering, not to incapacitate, not to cause offense or not to deprive someone of goods of life (Beauchamp and Childress, 2013, p. 154) are basic rules that have to be accepted and followed by healthcare professionals. Still a physician could mistreat a patient without a malevolent aim or due to ignorance and this leads to the question of an acknowledged standard of due care.

Due care determines the criteria of whether the agent who provoked the risk is either morally or legally accountable. In general it would help to define the case of negligence of due care: if a health professional either intentioned or unintentioned yet careless exposes a patient to risks of unreasonable occurring harm, it should both valued as ethically vicious. Sharpe and Faden state that a physician is guilty of malpractice if it includes the non-observance of professional standards of care (Sharpe and Faden as cited in Beauchamp and Childress, 2013, p. 155). Yet it is one of the unresolved big questions in international and national medicine: what should "due care" include, how or whether can

it be guaranteed, and which parameters have to be taken in to frame a quality standard? (Jennings, 2017, p.1; personal communication with Prof. Dr. J. Graf, Frankfurt). Professional standards of care in Germany are defined on different levels. There are directives *(Richtlinien)* by the Federal Chamber of Medicine *(Bundesärztekammer)* which are based on national laws and express the actual state of the art of medical research. Further there are the guidelines for all medical specialities which are published by medical associations *(AWMF-Leitlinien)* with varying evidence-based levels. These regulations are complemented by recommendations and statements. All of them work as orienting standards based on the latest state of the art for the diagnostics, treatment and care of specified diagnosis, yet they have no enforcing character (Bundesärztekammer). However the physician´s action is subjected to the code of medical ethics of the federal state *(Berufsordnung der Landesärztekammer)*. They are of a more general nature as they do not specify actions in detail except for diverse areas of genetic research, though they are legally binding. The question still remains as to what extent physicians are in charge of reducing risks (Beauchamp and Childress, 2013, p. 156).

Discussion

The above mentioned *AWMF-Leitlinien* often define the requisition of nonmaleficence as well as ruling treatment or nontreatment in a court case of medical harm. Beauchamp and Childress´s argument that medical decisions have to be a question of morality or evaluation and not only of medical indication (Beauchamp and Childress, 2013, pp. 168/172) should be taken into consideration as well. This is because for none of the above named *specified* guidelines there is enforcement for a physician to follow them. This creates different moral deficiencies when it comes to medical harm.

In general a physician´s assessment can be described as wide as the duties appeal to the physician´s conscience, medical ethics and benevolence (Landesärztekammer, 2016, p. 4). This can mean in practice that what one physician accepts as an adverse effect of a medical treatment is evaluated as being untenable by another physician. It can also mean that the chosen follow-up treatment to limit or reduce adverse effects depends on the physician´s decision regarding which symptoms will be treated and which have to be tolerated. If a physician has good reasons for his decisions or actions they can be justified. The following case illuminates this.

The patient is prescribed an anti-hormonal injection (gnrh-analogue) which should serve the following surgery to reduce the size of a benign tumor. The family practitioner gives the injection recommended by the hospital, however it is the first time he administers the drug. The patient develops severe insomnia symptoms, severe constipation, nausea, heavy pain in limbs, tendons, muscles and bones as well as a heavy fatigue syndrome within four days after the first injection. This is followed by racking headache. The physician decides upon the description of the patient to prescribe sleeping pills and asks the patient to take over-the-counter painkillers to relieve the insomnia and pain. He assumes that the rest of the adverse effects are the result of the insomnia and

pain. Neither the pain-killers nor the sleeping pills show any effect. Therefore the physician decides to prescribe stronger pain-killers and stronger sleeping pills. Both add even more side-effects however show no abatement of the treated symptoms. The physician decides to change the medication again which again does not show any effect. Finally the patient decides to accept the persisting adverse effects than trying new medication even though suffering a lot. Though the patient relies on the statement of the physician that after the duration of effectiveness of the gnrh-analogue the symptoms stop. The *AWMF-Leitlinie* however commanded an add-back therapy with part of the hormones if adverse effects occur to relieve the effect (Arbeitsgruppe „Leitlinie [...]“, 2013, p. 16). The physicians answer why he did not follow this guideline was, that the report of the prescribing hospital did not mention this. Further he explained that for the described symptoms of insomnia and pain the standard prescription is sleeping pills and pain killers. The patient later told the physician about an impression of not tolerating any kind of medicine anymore after a round of antibiotics (prescribed because of an infection) with severe side effects which were confirmed by the physician as a very rare condition that occurs only with less than 1:10.000 patients, however he prescribed stronger medication to treat the uncontrollable pain which was accompanied by qualm and severe weakness of muscles. The patient in sequence had to quit the job because of enduring fatigue, dramatic weight loss and finally the patient needed assistance for personal hygiene and household for years. The patient searched information to find an answer to the deteriorating health condition and found out that there was genetic testing available where the pharmacokinetics (metabolisation rate) of the liver can be tested in order to adjust dosage and choice of drugs in order to prevent toxic overdosage due to the fact that there is genetic defects which slow down the CYP 450 cytochromes of the liver. The testing was positive with many CYP 450 enzymes which showed that many of the already prescribed drugs as well as the dosage were not only not well tolerated by the patient however led to the severe health condition and the lab´s recommendation was that all medication had to be dramatically reduced or if possible to be avoided.

This case can question the physician´s attitude towards nonmaleficence and the call for due care:

I first argue that due care should be based on the standard of the state of the art. Therefore treatment should be evidence-based instead of eminence-based where experience or “standard prescription” is defended. Therefore the legislation could be changed in the following way: the *AWMF-Leitlinien* should no longer be of consultative nature however legally binding. This could be a step to guarantee a better standard of due care within Germany for many diseases. Therefore *AWMF-Leitli*nien should always be updated to the highest evidence-level in order to guarantee state-of-the-art treatment as they still exist on different levels in different medical subjects. Otherwise the present situation enhances the risk of a treatment which follows a physician´s personal convictions rather than good practice. It is therefore more likely that a treatment does not meet the principle of nonmaleficence.

Yet one has to have in mind that there are chronic diseases where the range of symptoms and the range of treatment can vary extremely which can still make it difficult to define standardized due care.

Second I make the point that specific medication as in the case described above should only be allowed to be given and supervised by medical specialists who would not just treat occurring symptoms however know their source and treat the patient adequately instead of adding further adverse effects. However one can imagine that there are situations where a specialist is not always available. In this case I state that according to the principle of nonmaleficence and the concept of harm a physician should be obligated to report the adverse effects to specialists and ask for advice *before* continuing treatment. This would help to find out what symptom has be tolerated if the overarching goal justifies this. Nonmaleficent harm could then be justified as well. All this starts with good communication: communication between family physician and hospital.

Third a physician should have in mind the moral rules of nonmaleficence: If suffering, general incapacitation, offense and/or deprivation of a patient´s goods of life is caused, the treatment can hardly be valued as nonmaleficent (Beauchamp and Childress, 2009, p. 154).

Fourth I propose that due care based on the *AWMF-Leitlinien* should not in all cases replace a physician´s radius of operation when he has generated good evidence-based reasons because of his experience in his subject. This can be evaluated as a counterargument to my first argument however I state that not all results of good patient outcomes are reported in a timely manner and therefore these results are not yet accepted by a medical society still they might be useful for a selection of patients. In addition to this one has to be aware of the fact that medical science is as other sciences continuously progressing. This includes the fact that conventional wisdom is maybe not the ideal however the persisting practice and teaching asserts the claim to be evidence-based. Stephen Genuis states that 50% of the medical knowledge is dogma and will be seen as dogmatically wrong after four years (Genuis, 2006, p. 24) even though it is evidence-based. One has to accept that new knowledge is maybe unearthing a physician´s ignorance and arrogance. I agree with Stephen Genuis and therefore argue that it is crucial for physicians to be critically thinking as well as studiously learning, and not taking the stand that the status quo is the religion to be abided to (Genuis, 2006, p. 30). This was not only the case in Ignaz Semmelweis´ times where a traditional practice caused the death of innumerable delivering women and only a simple hand-washing protocol saved the lives of innumerable delivering women however it is nowadays the case with hormone-replacement therapies and others (Genuis, 2006, p. 27) where latest research shows the adverse effects of these therapies and add to the suffering patients already experience, even though it has for years been a *standard therapy*.

The above described case can be adducted again to support this argument.

After the gnrh-analogue medication the surgery followed. It proved that the surgery could be performed organ-obtaining and therefore the medication seemed to have the prospected effect. Some weeks later the patient reported to the surgeon that the pain of the same benign tumor was back however the patient was not believed at first, further MRI imaging showed suspect growth and a second-look surgery was performed, still they could not find it. The patient turned to another hospital as he did not believe that his pain was of psychosomatic nature. An ultrasound confirmed the patient´s assumption. The head of department there said that he never uses this gnrh-analogue due to severe side effects even though they as physicians were put under enormous pressure by the pharmacy company to use it, however he could show that a surgeon has to be skilled in detecting the growths via ultrasound as well as to operate well and then the medication is not necessary at all. A few years later this view was shared by many specialists and further studies showed that the medication does not show long term positive effects and therefore more and more hospitals follow the new findings, yet the *AWMF-Leitlinien* are still not updated in this area.

I conclude that even if the decision of the first physician was defended by other colleagues in that he had good reasons for prescribing painkillers and sleeping pills, his "good reasons" remain highly questionable towards nonmaleficent acting as the discomfort the patient was put in, cannot be justified if one looks at the proceeding of the case. It will always remain difficult to define what counts as "good reasons" and what does not. This question can as well be put to the first surgeons who, during the operation, could not find what had already been confirmed by the MRI diagnostics. It would have been their job to find the tumor, but they, however, turned the physical disease into a psychosomatic diagnosis. I therefore argue that a four or six eyes principle should be supported or guaranteed in order to foster the nonmaleficence principle. This means that two or three physicians approve a medical action before it is realized. It is likely that two healthcare professionals see more than one. This confirms Euteneiers statement about the necessity of a team. Moreover it is necessary to have good teams who are highly qualified and who would for example have the conviction not to complete a surgery until they found what imaging had already confirmed instead of shifting on the problem to the patient´s personality. The "good team" however is characterised by good social and communicative skills as hierarchy problems or other individual factors could become a risk for the patient.

The threat of missing training, the rule-breaking because of freedom of conscience and the human factor issue described in the first part of the master thesis play an important role with nonmaleficence in the described case. Nonmaleficent treatment and "due care" can be better guaranteed if operation skills training is advanced, and freedom of conscience decisions are viewed critically when non-specialists like family practitioners or inexperienced surgeons provide treatment where they do not

have experience or expertise. Intentionally nor unintentionally acting against nonmaleficence is not an excuse for the fact that humans make mistakes, and thus nonmaleficence is a question of responsibility.

The discussion about nonmaleficence can be summarized as following: Nonmaleficence is jeopardised by three variables: They are jeopardised firstly by the physician as the treatment the physician offers depends on his experience, his attitude towards risk, freedom of conscience and his personal sense of diligence. The second risk occurs by the level and viability of evidence-based studies which standardize due care. Thirdly there is the jeopardy occasioned by the patient himself as the kind of disease and the patient´s constitution include high variability. These three variables require a high demand of vigilance in order to find a nonmaleficent treatment.
If one attributed do "[rather] something doubtful than nothing" to nonmaleficence, the clear mandate of beneficence is do "better nothing than something doubtful" (Ackerknecht as cited in Sharpe and Faden, 1998, p. 40) a concept which I will discuss next.

Beneficence

Introduction

The core of the principle of beneficence is the idea of preventing harm, removing harm and the obligation of helping.

The learning healthcare system can be seen as the reciprocity-based justification of the obligation of beneficence. A workshop of the Institute of Medicine of the National Academies in 2007 defines it as "one in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care." (Olsen, 2007, p. 6). This means in other words that professionals have the obligation of learning to improve helping their patients whereas the patients have the obligation to foster learning within the healthcare system by adherence and following a treatment plan in order to enhance care for *all* patients as Beauchamp and Childress describe it (Beauchamp and Childress, 2013, p. 213).

Discussion

I argue that a beneficent acting physician would be called a "good physician" whose supreme principle is to seek the most beneficence possible for the patient. This means that beneficence can be valued higher than nonmaleficence even the background idea is equal: do no harm. Yet beneficence includes an even higher claim: prevent harm. Beneficence includes the idea of a physician seeing the patient as a sick person and not only as a laboratory identity. Therefore one could go further and ask whether there is a prototype of the "good physician" or what the characteristics of medical acting of

a good *beneficent* physician are? I doubt that such one exists, but I maintain that it is ordinary people who perform extraordinary achievement by showing extraordinary diligence.

The following case can be valued as a best practice example to support this argument.

Before an operation the patient meets a young anaesthetist for the pre-operation discussion. The patient tells her (as he did with seven anaesthetists before her) the history of what he experienced as severe adverse effects of previous anaesthesia (being already awake for hours after the surgery, however unable to communicate, unable to open the eyelids, being conscious but not feeling the rest of the body, unable to empty the bladder, unable to speak even though he could hear and understand everything that was going on around him and what the staff in the ICU decided to lower the tachycardia). He mentioned that the symptoms described were always ascribed to his personal constitution. The anaesthetist admits that these have been serious adverse effects and she is not willing to take over the responsibility for this case. She takes the decision to inform the senior physician to take over even though she admits that it is not welcomed by her superior if she passes on a case, yet beneficence for the patient is more important than a directive. In the following pre-op discussion with the senior physician who had read through the previous anaesthetic protocols very carefully, the patient was explained why and how the adverse effects occurred and that they use a different medication which the patient will profit from. They use a kind of anaesthesia which had been successfully established for many years instead of "the latest state of the art" medication. It sounded like a promise and the result of the anaesthesia proved right. There was not a single complication or adverse effect. In addition to that, on the morning of this surgery the anaesthetist in charge came for a medical round and told what had been reported to her by the senior anaesthetist. She expressed her deepest regret for what the patient had experienced before. She comforted the patient and showed empathy towards the patient. She came for another medical round after the surgery and wanted to know how everything had gone. She then copied the protocol instantly so the patient would have a working medication which he could hand over to possible future anaesthetists.

This example can satisfy the principle of beneficence in three ways par excellence.

First it shows how important it is, which conclusion a physician draws out of the information he gets from the patient. Seven previous anaesthetists took the history as well however they did not name the occurred medical harm as adverse effects and complications but rather an individual constitution which has to be accepted and the patient suffered needlessly. A patient is shown respect when he is believed and his symptoms are taken serious. Therefore I propose the active listening of the physician as the basis for every beneficent decision following.

Second it shows how physicians (the young and the senior anaesthetist) show responsibility towards the principle of "primum non nocere" as the anaesthetists realized that the previous anaesthesia had

not been beneficent for the patient. The young physician put beneficence for the patient higher than the beneficence for her career and passed on the case. As described in the first part, hierarchies can mean a threat to the patient, however this example shows that (young) physicians need the courage to challenge a decision if patient beneficence is at risk. The senior physician shows diligence by reading through previous anaesthetic protocols and listening to the patient´s experience. This is a piece of information the anaesthetist cannot read in protocols. She then combines her knowledge and the patient´s experience and by this act of reflective listening she can deliver two beneficent things: firstly she discloses information about medical harm. Secondly it shows as well that these anaesthetists are part of the learning healthcare system described above: they learn from previous occurrences and improve treatment. Beyond that beneficence needs the openness and honesty of a physician who names a failure a failure even though he is not loyal towards his colleagues. However beneficence is *the* basic medical principle per se.

Third it shows the characteristic of beneficence of "the good physician" when the anaesthetist in charge talks to the patient. The encounter between physician and patient is more than a formal procedure which is ticked off. The decisive point which makes a significant difference to previous anaesthetics is not only the individual anaesthetic-specific decisions that were made (dosage and choice of drugs) which proved to be beneficent for the patient. As well the helping aspect of beneficence through the physician´s personal reactions and emotions touch the patient in his suffering as a person and not only as a laboratory identity. This is the result of a personalized communication between physician and patient and it shows that beneficence is facilitated by mindful and empathic communication.

I am convinced that benificence can be described as, apart from the characteristics of a beneficent acting good physician, a *listening relationship* between physician humbleness, physician–patient communication, and patient health. Therefore I claim that it is more effective to foster beneficence by education in communication skills and further training of social skills rather than by increasing technology and knowledge and many other proposals in risk management. I argue for the precedency of improved communication that starts with listening. This is because to a very high percentage it is people who deal with people in a hospital first, before technology or knowledge are challenged. However technology or knowledge can only be used properly if they are communicated.

The stethoscope may support the idea of beneficence, too: it has two earpieces for the physician and one chest-piece for the patient. The physician connects his ears with the patient, he listens to the patient which is only possible if the physician bows to the patients. This is a humble act. After he had listened to the patient he talks to the patient. Listening comes first, as the physician needs to hear the patient first before he tells him what he thinks is beneficent for him. Listening is the prerequisite of beneficence.

Bernard Lown, a cardiologist and bearer of the Nobel Peace Prize, expresses this concern as well: „In order to be able to heal successfully, a physician has to be educated to listen first and foremost. Attentive listening belongs to a treatment […].“[3] (Lown, 2008, p. 7).

The remaining concept of my view of beneficence states that the task of medicine of the present should be to take more seriously the tradition of medicine where the physician´s senses were his only diagnostic tools. Therefore primum non nocere starts with “listen first”.

A study showed that patients disclose significantly more disclosed information if a physicians´ nonverbal attunement makes him to pause at moments where the patient is more anxious, frightened or gets emotional, as Jodi Halpern describes (Halpern, 2003, p. 671). It often helps to repeat the patient´s words as they contain meanings that may not exist on an accomplished checklist. Empathy instead of detached concern is what a patient waits for. The empathy with the patient is what counts. The patient feels if a physician is emotionally attuned. Attunement increases trust in the patient-physician relationship and empathetic attunement helps the physician to lead the conversation with the patient and last but not least it prevents physician burnout (Halpern, 2003, p. 673).

Even in times of time constraint and pressure where brochures for patients explain a treatment or diagnostic measures, where electronic devices to take the patient´s history may support the communication between physicians and patients are becoming increasingly important, none of them replaces eye-to-eye contact and empathy.

The word beneficence is a very traditional expression for “doing someone good”. I therefore make the point that a physician who is acting beneficently, is doing a patient good.

Aesculap is the professional symbol of medicine. The snake symbolizes the polarity of life´s reality since her realm is the earth whereas the erected snake symbolises the professional´s task: to set upright the patient who is laid low. The snake´s poison can kill and it can heal. Aesculapian doctors in ancient times were physicians and priests in one. Therefore healing as well as dealing with medical harm is more than a profane job: it is a healing art which embraces the patient´s physical and emotional suffering from his disease as well as from medical failure *as a whole* and not only as a fragmented piecework of organs and soul. (Gottschlich, 2007, p.12).

I argue that the favoured technological or economic directive of hospital management of modern medicine misses the quintessence of the art of medicine. The attitude of empathy and devotion towards the patient who feels already ashamed by his illness needs no further humiliation by the immoral act of denial of medical harm (Lazare as cited in Pillsbury, 2006, p. 173). Beneficence is more linked to pastoral care than to profitable care and therefore the apology of a physician who takes over responsibility of medical harm is ethically more desirable than feeding the concerns of whether

[3] Um erfolgreich heilen zu können, muss ein Arzt vor allen Dingen zum Zuhören erzogen werden. Aufmerksames Zuhören gehört zur Behandlung […].

an apology could count as admissible evidence. Prosecution laws, however, might need to be changed: there would need to be adjustments medical morality. Even though the above described proposal might not be economically beneficent, this should not be the reason for immoral conduct (Pillsbury, 2006, p. 175).

I assume that apologizing and asking for forgiveness are maybe more important or beneficent than financial compensation alone. This would pave the way to real progress and change of paradigm in modern medicine in the direction of innocent patients suffering from medical failure. It would as well support physicians whose aim is to walk the talk of the medical ethical principle of beneficence in the above described meaning even though this principle might not sound as spectacular as management slogans and strategies.

A strong counterargument for the strengthening of communication is time constraints. Physicians have only limited time for each patient and the trend goes to the quick fix of a medical problem which means that tests and diagnostic measures are often ordered *before* carefully taking the patient´s history in order to save time. A series of imaging or other diagnostics are considered to be more time-efficent than the labourious listening to a patient´s redundant story (Sass and Kielstein, 2003, p. 28).
At first sight this counterargument seems valid, but I rebut that this claim is true.
Firstly, I wonder whether images and tests have the same validity for symptoms that may necessarily need imaging or comprehensive blood testing. It is therefore crucial to listen to the patient first. I further rebut this counterargument by suggesting that a calming and comforting encounter between patient and physician could save time for a doctor´s assistant as well as for the doctor, especially when imaging requires a motionless patient and the series may have to be repeated if the patient is anxious. I thus claim that this priority raises trust and satisfaction on both sides. The validity of diagnostics is valued higher by physicians, even though it is often self-delusion (Füeßl and Middeke, 2014, p. 503) and I make the point that this may not achieve beneficence in the same intensity as careful history-taking.

The questionability of a defensive medicine where doctors hedge themselves in a very extreme manner has to be mentioned here, too. This development leads to overcautious treatment which is against a physician´s experience or his knowledge but which has resulted from patients´ liability claims. This creates a situation where patients do not get the treatment that could heal them and physicians who withdraw themselves. This is beneficent for neither side.

Finally I want to draw the attention to a further aspect of beneficence and responsibility. Even though there is the physician´s duty to be responsible before he acts, one should bear in mind that retrospect responsibility has its own aspects as well. Due to many possible entanglements a physician could be the last one in a row who is guilty of creating a tragic mistake. He could then be exonerated partially

(Kreß as cited in Bauer, 2015, p. 70). This may sound on first sight contradictory, as the principle of beneficence is intended to prevent harm; however the special burden in such a case has to be incorporated.

In the case of medical harm beneficence gets finally a further task: the task of dealing with what could not have been prevented.

This is the case when there are only treatment options all of which are accompanied by high risks. Every alternative is balanced, the six-eyes-principle and second opinion recommendation were consulted, all scenarios were discussed but regrettably the treatment led to medical harm because of the high risks involved. In such a case, benefice will ensure the best possible and available care for the patient, who has to live with the result of the treatment, in order to enable the best possible quality of life with the resulting situation. A physician´s attitude of compassion and empathy for the patient in the face of the inevitable, as well as his personal engagement, are likely to convince the patient that the whole sequence of treatment has been conducted in the spirit of beneficence.

And so the circle of beneficence is complete: it started with its mandate of preventing harm, it went on with removing harm and now it comes to the helping aspect of beneficence: do the patient good, even in the case of medical harm.

However we have not yet discussed what it means for a physician whose directive is avoiding harm (nonmaleficence) and preventing harm (beneficence) who meets the patient who takes patient autonomy seriously and asks the doctor to do everything possible and where the everything-possible-demand is neither avoiding nor preventing harm. The question of respect for autonomy and medical harm is discussed in the following part.

Respect for Autonomy

Introduction

Patient autonomy as a principle in medical ethics has been valued very highly over the last decade due to the fact that patient´s rights were more in focus than ever (Jennings, 2017, p. 1). This development was enforced by legal initiatives that strengthened patient´s rights (Bundesgesetzblatt, 2013). Yet Beauchamp and Childress state that autonomous choice within healthcare is limited because of the fact that a patient is dependent on the authority a physician, a professional in his field, represents (Beauchamp and Childress, 2013 p. 106).

Informed Consent is the basis of the respect for autonomy although decision making is influenced and facilitated by how much or how little a patient understands his situation (Beauchamp and Childress, 2013, p. 115ff) and I add: by how and what kind of information the patient gets. Principally, physicians should inquire the patient about his views before the decision can finally be taken and authorization given to act in favour of the chosen plan.

A further aspect is shared decision making as an expression of respect for autonomy. This is a recent development where patients are included in the decision-process, and where for example not only study results with prospective mortality rates are included, however the individual life situation is taken into consideration. Euteneier advocates for information that is characterized by empathy for a patient even though a physician cannot put himself in a patient´s shoes (Euteneier, A., 2015, p. 72).

Discussion

Before I investigate the traditional view of respect for autonomy I want to start with the actual discussion of patient safety which was fomented by increased patient rights. I do this in order to forge a bridge between these two different approaches to the respect for the patient´s autonomy and his treatment as this can show critical points which have their origin in the idea of respect for autonomy.

The human factor, whether physician, nurse or patient, is the resource of the future and therefore it is not surprising that healthcare is seen as a market with sellers who provide a service to a customer. I have already remarked critically upon this issue. Nevertheless, the satisfaction of the customer is what motivates the system to a more or less extent. This shows how central the role of the patient in this system has become and why respect for (patient) autonomy is on the top of the agenda.

Yet the impression one gets, if patient safety and risk management is looked at, is different: The healthcare system is a system of professionals made for professionals. Having taken in Euteneiers handbook to describe the factors which influence quality as well as failure, one can conclude that the professionals´ concerns, the professionals´ ideas and their achievements form the progress and shape the system. Most of the literature within this issue is the defence and answer of a professional healthcare towards the legal claims of patients. However, what is the “hidden agenda” behind defensive medicine respectively patient safety? German law strengthened the patient´s respect for autonomy in 2013. Since then, the patient´s rights have been protected against medical harm more than before and it enforces the patient´s demands and claims. The reversal of the burden of proof for gross medical errors became changed in favour of the patient, a management of complaint and objection in hospitals had to be established by law, the duty of documentation was enlarged and many more which were already discussed more detailed in the legal aspects part. Nevertheless, what does patient safety defend? It defends claims against all the claims that could be made against the sources of mistakes, whether it is hygiene standards, rule-breaking and compliance and all other aspects named in the first part of the thesis. Thus the question is why something is defended that should basically be presupposed and provided unfettered? One can only appreciate that basic healthcare issues are now discussed and resolved because of increasing awareness of respect for patient autonomy. All concomitant measures can only be effectuated if the communication between healthcare professionals as well as physician and patient is improved. In the first instance it was

necessary that legislation strengthened the patient´s rights. Nevertheless, I argue that this is a token of poverty that medicine as *the* science per se which deals with human beings when their state of health makes them most vulnerable, needs legislation to firstly recognize the importance and significance of the suffering of these patients.

Yet one wonders *what* role the patient plays in a system of objective guidelines, procedures, treatment and safety? The subjectivity of a patient needs to be able to be fitted into an objective symptom catalogue and the subjective life of a patient is to be squeezed into objectified interpretation of personalisation. This feat appears to be a sheer impossibility.

If the patient cannot be shaped into this system, the questions of respect for autonomy arise: Is informed consent an expression of communication between physician and patient or "just" document signing? Does the patient or the physician know best what is beneficent for the patient´s health? Is autonomy more or less than self-determination? What is the theory and the practice of respect for autonomy when medical harm occurs?

All these questions return to the basic idea of respect for autonomy: The physician informs the patient of benefits and risks of treatment, the physician balances the two and finally the patient makes a decision. I will now investigate these questions in the light of the occurrence of medical harm.

Firstly I argue that patient autonomy is more than the above described informed consent. Secondly I argue, that patient autonomy means that the patient, a person with a quality of life depending on his health needs to be perceived more. The patient has not just an obligation to be a "reporting part" for the improvement of patient safety and risk management as Euteneier mentions. These two arguments presuppose a change of paradigm in the system of *medical professionals* towards a system of the *patient*. The patient is, above all, the focus of this system which has asked him to function according to objectified criteria which changed every few years. Subjectivity presupposes itself to be communication rather than to be function: it is built on encounter rather than on working through lists (Gottschlich, 2007, p. 120). Therefore I make the point that informed consent, even though this is the common practice, is not done with signing a document after the patient was presented benefits and risks only in order to please legal requirements. Informed consent should have more the character of informed decision-making or even better shared decision-making. This is a vital distinction as the focus is on the *individual person* and far from *general criteria*. Informed consent is not a product but rather a process.

Therefore the question whether the physician or the patient knows better what is good for the health should take into account that the physician shares the professional knowledge with the patient, involves the patient´s wishes, preferences etc. when he explains benefits and risks and finally the patient and the doctor make a decision together as it is a misjudgement to believe that a lay patient can take over the burden of a decision where a physician needed years to understand the causal

connections of treatment. I assume that the more the "act" of informed consent proceeds like this, the less likely it is that a patient accuses a physician of a medical mistake. This is because this proceeding fosters first trust and then equality of the involved parties. It is counter to the traditional physician-patient relationship of subordination and super-ordination or paternalism, where the physician advised and the patient signed. I agree with Beauchamp and Childress as well as Entwistle et al. (Entwistle, 2010, pp. 741-45) that autonomy is relational and that it should remain like this. This goes for the treatment options and decisions as well as occurring failure. Relational autonomy means to some extent an autonomy which is based on a relationship. And a good relationship is based on respect – respect for autonomy. I argue for autonomy-supportive physician attitudes which mean that a patient´s preferences, their individual personality and their personal evaluation are respected (Entwistle, 2010, pp. 741-45).

This is maybe more than the self-determination aspect of respect for autonomy. A patient with whatever health condition is not as independent as patient autonomy leads to believe, however it is the challenge of handling the interdependence without undermining it by superior knowledge. However, a patient who has difficulties in understanding and who has unjustified expectations is more influenced by third parties and is more likely to accuse a physician for medical malpractice (Bauer as cited in Euteneier, A., 2015, p. 69). Even though in the case of an accusation of medical harm a patient may have a lawyer at his side it would be greatly preferable if the patient´s physician were to take over the role of defending the patient. This stands maybe in contrast to the already described defensive medicine, where informed consent documents are primarily seen as a tool of risk management. It is more than that, as it means that a physician shows a transparent behaviour, chooses his words wisely and shows regret in a case of medical harm, as if not, the physician becomes the second victim of medical malpractice. This can become a vicious cycle for the physician´s career. Nevertheless, there is a gap between the ought to-theory and the do-practice since no-one likes to admit a mistake and no-one likes to be blamed or be guilty, least of all when someone hurts someone else. Physicians who suppress the truth may be afraid of a loss of reputation, may experience a perceived lack of time, or may not have the ability to empathize and their choice of unfortunate words may add to this issue. (Euteneier, A., 2015, p. 69) However respect for autonomy should be based on distinct ethical rules like telling the truth, respecting privacy, protecting confidential information or obtaining consent (Beauchamp and Childress, 2013, p. 107).

Thus I argue for an unconfined investigation in a case of medical malpractice for the sake of both sides, however I strongly support an out-of-court settlement because of two reasons.

First I am convinced that physicians who listen attentively to the affected patient are likely to accept this approach for their own sake, as I assumed earlier that patients may see financial compensation only as one part of dealing with medical malpractice. In fact, the even more important aspect is of a

reconciliative and rectifying nature. It is reconciliative because they want to get the disclosure of information on what has happened by their physician, that he regrets and apologizes for what has happened. It is rectifying because they want their experiencing and suffering to be seen as it not only being subjectively sensed but rather being scientifically proved as medical harm. Reconciliation and rectification may not be given adequate room during a court case because the focus will be on the financial aspect. The media may then be used for the reconciliative and rectifying part, because the patient needs "someone" that listens. I doubt that the media are the appropriate means in many cases of medical harm even though I agree that they are very effective in distributing sensation and I agree that, in cases where patients do not get their right, they can put pressure on the healthcare system.

Secondly, I support an out-of-court settlement since there are fewer patients who seek to plot revenge for the harm and suffering perceived than those who look for a way to find one´s inner peace. Inner peace, I state, is rather possible if the two affected parties talk to each other personally, even though this can be enormously stressful for both parts, rather than passing on this job to a lawyer. It may help to involve mediators who supervise the conversation. The aspect of reconciliation and rectification may be the highest art in the realm of medicine and it goes far beyond what modernised and technologised medicine provides. This aspect is the expression of lived respect for autonomy as the patient´s perspective is highly respected. It is also the pastoral care aspect of healing which was inherent in ancient times, when physicians were priests. Even though forgiveness and humbleness may sound to be religious terms, I make the point that it is these two virtues that are of very high value when it comes to medical harm. There is scientific proof that forgiveness has a healing effect (Worthington, 2005, p. 170). I argue that medicine needs medical ethics that includes this aspect if it wants to serve the pretension of being "ars medicalis", as in arts there is always an intuitive moment that is not explicable with systematics but with that which is beyond it. Therefore the secular art of medicine can profit from the universal spiritual aspect of medicine of ancient times. Dealing with harm means partly dealing with mourning.

This enables the patient to come at peace with what was done to him and thus this opens the way for the future even with the remaining damage or in the better case after the damage could be repaired. Finally the patient may live independently after – which is the Latin meaning of autonomous – instead of interdependent on his negative experience, because he was accompanied through the mourning process by the perpetrator. Yet I state that this is maybe the highest aspiration of the respect for autonomy as the physician subordinates himself to the patient´s suffering. However, by this attitude, both of them can be healed.

I conclude with the following case as it could be acknowledged as a best practice example which can be used as a pattern: The patient was admitted to a renowned hospital because of an acute abdomen. During the night the patient experienced dyspnoea (respiratory problems) but the cardinal symptom

of hypoventilation was not taken seriously by the night nurse nor was the patient cyanotic. Over the hours the condition improved yet the patient experienced remaining difficulties in breathing. Even during the morning round the symptoms were not taken into consideration as the diagnosis why the patient was admitted to hospital was of surgical nature.

Later that day the situation worsened. However the patient was told that there was no chance to talk to a doctor because of reduced weekend stand-by. Finally the patient decided to dismiss himself on his own responsibility as the surgical diagnosis did not seem to be proven and it was re-diagnosed as an irritable bowel syndrome. Some days later the medical report arrived at the patient´s home. Except for the formal data of address and date of birth and parts of the history everything else like treatment and procedures were either missing or incorrect. However the results of the blood proof were attached which showed very low blood oxygen levels as well as other remarkable parameters. The patient then talked to the head of department who apologized in due form and regretted deeply what the patient had experienced, took over the responsibility of what had happened (even though he was not present that night) asked the patient to come for a further consultation and advanced further testing and diagnostics personally as well as the patient was asked to make further suggestions. Some months later the acute abdomen came back, yet the patient had experienced in the first hospital, the reluctance to perform surgery if a cardinal symptom is missing. He then decided to go to another hospital, which diagnosed an ileus and had to perform an ileo-coecal-resection and therefore the potentially life-threatening condition was relieved. Some months later the problem arouse anew and the patient had to be admitted to the first named hospital due to the fact that with the potential life-threatening condition he had to choose the nearest hospital. In the following surgery a part of the ileum had to be resected. This time the head of department was present personally and made sure that everything was documented and performed in an attentive way. During the follow-up-check the head and the patient talked openly about what had happened months ago. The head was very open about the option to take the incidents to court. However the patient communicated that for him money was not of the highest importance but rather that an incident like this would not be repeated and other patients harmed in the same way. The patient stated that it was more important he got an honest apology earlier. Finally they agreed on the wish of the patient to get the chance of following the head´s job for an entire day. The patient thus experienced how, for example, doctor´s letters are written, how assistant physicians are supervised by senior physicians and how performance is improved by addressing standard surgery techniques in morning meetings.

I conclude that open disclosure in an empathetic way may even be far more important than financial compensation when it comes to medical harm. Yet I state that there is a great difference ethically if medical harm is caused by a complication, medical malpractice, a mistake, an adverse event or an

incident. It is as well important to differentiate between short-term or life-lasting effects medical harm shows.

I conclude further that a patient whose autonomy is respected is likely to accept the veracity and honesty of such an encounter and use them as door openers for a second chance. As well, it may develop trust building even after a serious health condition caused by ignorance. This is especially important as one has to be aware of the fact that even though patient autonomy and the free choice of a physician as patients´ rights exist in Germany, these can sometimes be constrained due to medical reasons and therefore a physician´s communicational and emotional soft skills become of high importance and are more crucial than anything else to convey trust. Sharpe and Faden argue in the same direction when they state that "[a] more patient-centred ethos will regard the individual patient´s values as central not only to determinations of benefit and risk but also to occurring harm." (Sharpe and Faden, 1997, p. 115).

Justice

Introduction

In general justice in healthcare is discussed, when the access to it, the financing of it and the delivery of it need to be determined. Different principles, each of which could contribute to justice, have to be balanced (Beauchamp and Childress, 2009, p. 293). However I do not discuss the question of justice of social class. This is because the wide field of other factors which would play in as well like age, gender, upbringing or (further) education, cultural or ethnic properties would need a very detailed discussion and balancing as well. I choose to narrow the scope of justice to more "universal" examples of justice and medical harm that do not necessarily base on the above described factors. It is impossible to apply traditional theories of justice to dealing with medical harm, however, some basic ideas can be considered. This goes as well for more recent approaches. These ideas might challenge the biomedical ethics principle of justice in an unanticipated way.

Discussion

First of all I argue that the application of the justice principle to the medical harm issue is a multi-layer or multi-perspective issue which can only be addressed and approached adequately if the best of ideas of justice theoretically are reflected upon and balanced. Even though the general background of justice in healthcare, which is the just distribution of resources, is of high importance, justice and mistakes in medicine *go beyond* this. Therefore compensation for harm in monetary terms as well as the question of reconciliation play a key role. The multi-layer or multi-perspective of mistakes in medicine can be caused by the endeavour to maximize health. This is the case when either the physician says "We do everything that is possible" or when the patient asks the physician to go on with futile treatment. Neither of them faces the truth of value-based medicine but evidence-based medicine. Value-based treatment would place the patient´s well-being on top of the agenda even

though it could mean stopping a treatment and focusing on palliative care in order to relieve suffering rather than putting the patient under stress without being sure of a positive outcome. Then the well-being idea of justice would outweigh the principle of utilitarian justice. It would then prove to be beneficent for the patient even though the patient´s autonomous preference – do everything possible - is not converted. However it would mean that the physician´s communication skills are asked. It would presuppose that at an earlier stage of the disease he had already discussed all available treatment options and made the patient aware of the fact that at stage x no further aggressive treatment may promote amendment and that he will then do his utmost to relieve suffering and make sure the patient is well-looked after. It might sometimes be necessary to include psychologists, pastors or ethicists to talk to the patient (and relatives). Such encounters could for example focus on capabilities the patient still has and which he could bring into play. Therefore the quality of the individual´s life can be strengthened even though bodily health as a capability is no longer achievable. I state that these aspects count as well for occurred medical harm where a patient is offered a perspective to accept his handicap or his permanent disability. Some examples of these handicaps or disabilities are, when, as the result of a surgical mistake, an athlete is turned into a wheelchair user or when victims of severe adverse drug effects, like the thalidomide victims, are born with malformations.

The thalidomide example can be taken as proof that the egalitarian idea of providing all patients with the same treatment is not acceptable. First because disabilities and malformation differ enormously depending on the time when or how often the mothers took the drug. As well, it is now more than fifty years after these children were born, that their health conditions and needs of support reach from early retirement payments to nursing cases with permanent round-the-clock care. If everyone got the same care because of the fact that all of them suffer from the effects of the same drug it would be extremely unjust. Fair opportunity must be the benchmark. Here the maximization of health and care is the highest precept in order to compensate for the inequalities. Even though this case is still seen as a precedent it is an example where a communitarian principle, that the individual is subordinated to the community interests, can be disregarded in a way. The pharmacy company as well as the government *shared* compensation payments fifty years ago and again in 2009 as the life situation becomes tougher due to internistic long-term effects of the drug that show effects only now (Enns, 2009, pp. 40-45; Deutscher Bundestag, 30.05.2008).

The above mentioned aspect of compensation is not limited to the justice aspect of monetary payments even though they are essential for many victims of medical harm to earn a living. The monetary payments have to be followed by not only regret and condolence but by formal apology. It took 50 years for Grünenthal Pharmaceutical Company to apologize (Marquart, 31.08.2012). The reasons for this delay may be manifold and inexplicable. However it shows how difficult it is to admit mistakes in medicine. This underscores the expression of the title of the master thesis: there is a

culture of (long-lasting) denial. And there is a code of silence. Even though a silence lasting 50 years is not the standard, it casts a shadow on the white coats of the medical realm. No matter how dreadful the thalidomide tragedy and scandal is until today, it yet shows that compensation, rectification and reconciliation is possible even though it might take half a century. However I wish to point out that there are cases where the victims did not get financial compensation nor a full formal apology. This situation is illuminated by the following case.

The patient suffers from severe adverse effects of a drug over years. After five years the patient thinks about taking his case to the court. The amount in litigation is set on 5000 €. As the case was past the statue-of-limitations which is a limit of three years and was therefore unlikely to be successful, the patient withdrew. In addition to that the amount of 100.000 € out of personal savings which was needed to finance treatment and living costs for almost ten years until he could go back part-time to his job which would not have been covered by a lawsuit either. The patient wrote to his physician after three, five and seven years and asked for answers to questions alongside the treatment and missing documentation. The patient did not receive a formal apology either. So the question that can be justifiably raised is: What kind of justice is applicable or detectable in this case?

The goal of maximization of health or welfare is not applicable, as health was not promoted by the treatment (even though intended). The goal of egalitarian dealing of victims of severe side effects of drugs is not applicable as not all severe side effects of drugs are settled in the same way as the thalidomide drug. The goal of well-being or capability can be applied, in part, as the patient had physicians who cared for him so he could finally accept his limitations and enjoy what a limited life quality still had on offer.

However all justice approaches do not meet the desire for rectification and reconciliation. I therefore argue again for the importance of apology which goes beyond restored justice. This is active dealing with mistakes instead of cultivating the attitude of denial even though it may be reasoned by cost reduction.

I argue that medicine is not primarily an applied economic science but rather an applied natural science when the principle of justice is applied. I go even further and state firstly that if medicine as an applied natural science without taking its “scientific object (or better subject)” more important than anything else around it, may no longer be entitled as “healing” which is the translation of the Latin origin of medicine. Secondly the patient, which in the Latin origin has the same meaning as “being patient”, was *too* long *too* patient within the “healing process”. He should now, at long last, be accepted as a trustworthy partner and not only as the object or subject of this science. The patient could play a key role in the change process that questions the attitude of denial of medical harm.

I argue that mistakes are not the problem of unjust people but rather of unjust systems. I call the healthcare system an unjust system where a patient is granted a liver transplant that has an estimated

cost of up to $ 200.000 (Holm, 1995, p. 335) due to a severe health condition that is a result of abuse of alcohol whereas a patient who experienced medical harm by a physician, whether it was unintended or careless medical conduct, is not paid financial compensation. This was because he could neither afford a lawyer or was too weak to take the case to court at the time and when he was strong enough, the statue-of-limitation is past. Justice can as well be questioned when, except for after a gross mistake has been made, it is still the patient who has to supply evidence as medical harm is denied by a physician or hospital until a judge finds them guilty. However I do not want to deepen this issue, I just wanted to raise awareness in this area, even though I am very conscious about misuse of compensation claims, too. My intention with raising the issue of justice and the culture of denial of mistakes is to stress the point, that attitudes and behaviour towards the denial of medical harm are not to be changed by justice principles but rather by devotion and commitment towards the medically harmed patient and by patients accepting honest apologies and reconciling offers instead of challenging financial compensation first and foremost.

Yet I want to touch upon the challenge of the issue of just distribution of healthcare in times where money is a critical resource. One should first of all focus on areas which do not produce extra costs but instead use the potential of the available resources in an as adequate and just way as possible. Therefore I propose to adduct the physician-patient relationship from this perspective again as it might offer a proposal to tackle the problem of dealing with medical harm.

It can be looked at from three different points of view in order to justify the argument that the improvement of the physician-patient communication and the involvement of the patient´s experiences contribute to cost reduction before, and after, medical harm.

First, if the patient can tell his history completely at the beginning of the treatment or discussion on medical harm, it seems likely that all relevant details, previous treatment trials as well as test results can be documented. Therefore multiple and repeated history telling, documentation and imaging procedures can be reduced to a medical minimum. This is in the interest of the physician and the patient equally. There is an argument that different labs or institutions use different reference values and therefore test results to be repeated. However from the justice-principle perspective or from the economic point of view this practice has to be questioned. If the development in medicine goes into the direction of standardization it could be a very effective idea to standardize labtesting and use the released resources for more intense physician-patient encounters instead of standardizing these to a time minimum. This seems as well plausible for the costs of a costly MRI series which is sometimes repeated within a few days, just because the patient had been to an outpatient practice and is then admitted to hospital for surgery for example. Every hospital wants to have their own images and their own lab results. By far may a double imaging series not compete with costs that are originated by an

extension of the physician-patient encounter plus preliminary further training for the physician in this area.

Second, if medical harm occurs and the communication between the physician and the patient is successful, the case is not taken to court. Financial agreement without court fees is much more economic and fewer staff in a legal department of a hospital need to be employed and remunerated.

Third, if the communication is successful not only the reputation is no longer endangered is has even a monetary effect as the case does not get media attention. A media spokesman could use his competencies more in the area of spreading the good image of transparency in this hospital instead of defending a questionable immoral practice, which in sequence may damage the reputation of an institution or person. This defensive action might add even more economic pressure in the long run when patients favour treatment in other hospitals.

Proposal and Conclusion

This Master thesis is a plea for an ethically defensible dealing with medical harm that takes seriously the principles of nonmaleficence, beneficence, respect for autonomy and justice.

Nonmaleficence in the context of dealing with mistakes means to avoid decisions that are not based on standards of due care and to be careful with the principle of freedom of conscience in order to guarantee the highest standard of evidence-based care.

Beneficence should have a prominent position to decrease the eventuality of mistakes by listening closely to the patient´s experience in the process of balancing the benefits and risks of a treatment. I could show that first and basic an improvement of the physician-patient communication is the most beneficent aspect. This would prevent, to tackle and to reconcile occurrences of medical failure as its primary task is to prevent a breach of confidence and trust. However beneficence could have a mandate to restore the patient-physician relationship after medical harm has occurred, by doing the patient good, in order they can move on – either together or separately. Beneficence means, as well, to give the patient information about strategies to avoid recurrence of medical harm. I could show that there is a discrepancy between the claim of communication and the reality which needs to be closed in the future.

Respect for autonomy is practiced when open disclosure and explanation of medical harm is practised, when the patient´s preferences for adequate restorative and/or compensatory actions are taken into consderation and when fair and square apologies are uttered. This act needs humbleness, honest contrition and respect towards the patient´s suffering and ailment by the physician on the one hand. On the other hand it requires and involves the patient´s will of accepting such an attitude in order to find a way of living with what has regrettably happened and to become reconciled with the living situation he was put in by a (serious) incident. However the conclusion that can be drawn out

of this is the realisation that communication is not a means to an end however it is the end of dealing with mistakes in healthcare as it takes respect for autonomy seriously.

Justice and the culture of dealing with medical harm is a very sensible issue. However what counts for the other three principles counts for justice, too: the more the physician listens to and the more wisely he communicates with the patient, the more likely it is that resources can be distributed justly. This means that costs due to medical harm can be reduced and deployed for the sake of the patient or elsewhere if cases are settled out of court.

I stressed the aspect of communication between physician and patient quite powerfully because of the developments in modern medicine: patient safety and risk management are forced and accelerated by technological and scientific achievements from other high risk organisations like the aviation. Yet I am convinced that to make a patient "fly" needs first and foremost personal affection instead of standardised attention, it needs subjectification instead of objectification and therefore it needs respect for the patient´s autonomy and careful communication in medically difficult situations in order to offer treatment and dealing with medical harm that honours nonmaleficence, beneficence and justice.

Last but not least I could show that it is true that medical harm creates victims on both sides: the patient is harmed physically and emotionally and the physician feels guilty and incompetent after such an incident, therefore both of them are harmed and stand in need of healing and reconciliation.

Since these conclusions sound utopian I will sketch a hospital based on a patient´s experiences as the final part of my proposal and conclusion. This hospital may have the prerequisites and opportunities to prevent, tackle and reconcile medical harm.

A patient with years of misdiagnosis and failing treatment which has created loss of employability, savings, physical and mental integrity and trust in medicine is admitted to this hospital for further surgery. The patient´s clinical story started with a lack of communication between his attending physician and his denial of malpractice later after a non-guideline-conform medication.

The surgeon who was willing to perform further surgery was very friendly and listened carefully. He confirms that in case of necessity he will take over the responsibility of performing a second surgery as well, but performs a nonmaleficent laparoscopic surgery first. The mail contacts are enlightening and understanding and the surgeon passes on responsibility towards the patient when it is clear that even though the situation needed a quick decision, he asked the patient to manage and cope with the condition with everything available until the date of the surgery. This gave the patient the feeling of being involved and integrated in the treatment which gave him extra strength.

The morning of the surgery is as busy as in other hospitals however the tone and the atmosphere is very friendly, extraordinarily personal and cordial. The patient who had walked himself together with the ward nurse to the operation theatre, climbs himself on the operation table which emphasizes the

fact that it is the patient´s will. It is a visible sign of respect for autonomy which followed informed consent to have surgery performed. The surgeon is already present while the patient is still awake. The day after the operation the surgeon has the medical round as is usual in a hospital. The surgeon is informed by the nurse about the actual condition. Then he asks the patient to report about the persisting health problems in as precise and detailed way as possible. He does not interrupt the patient. When the patient has finished he asks some more questions and finally he makes the proposal of a more intensive surgery that would be beneficent for the patient as it means removing harm of previous surgeries. He has the patient´s personal plans and situation in mind and therefore takes this into consideration when he reaches a decision. It was clear to him that an immediate surgery would negate the patient´s plans, plans which he valued as highly for the patient as the medical solution. This respected the patient as he was more than just an indication for surgery, but rather an individual with a life revolving a health condition. The shared decision-making however makes the patient a partner in this process.

The care on the ward is very attentive and patient-oriented, is very personal and empathetic in addition to the fact that they follow care-plans even though they are more professional and less time-intensive as in other hospitals the patient had been before.

This conclusion is neither an illusion nor utopian however it is the daily practice in the Starmed Klinik in Munich. The Starmed Klinik is a private owned hospital with 12 beds which guarantees the same treatment and service for private and statutory insured patients.

What is possible in this microcosm is transferable to the macrocosm of maximal capacity hospitals in Germany as cost pressure is said to make it unable for small hospitals to compete with big hospitals. However it seems to be a proof over more than ten years that it is a question of putting the four biomedical ethics principles into practice.

This hospital is the demonstration that the proposal of this master thesis of intensified physician-patient communication as well as taking in patient´s experiences and involving the patient actively works successfully. Its special distinction is to radically name and face previous medical harm without blaming the attempts of others however putting the patient´s experiences first and give it the highest priority without risking the principles of nonmaleficence or beneficence. The argument that the speaking (or better listening) medicine is not paid adequately and therefore professional healthcare focusses on what fills the cash boxes can be refuted by this best practice example as the patient does not get an extra bill for the extra lengthy consultation times yet the budgeting and remuneration of this hospital is based on the same financial statement as all hospitals in Munich.

Communication, as the foundation of medical care, has not lost anything of its basic importance even in days of electronic patient administration and robot assisted surgery. However it is the healing power of breaking the code of silence and the restoring of mutual trust that is decisive to deal with

the occurrence of medical harm. This constitutes the dignity of a culture of dealing with instead of denial of medical harm in practice and theory.

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