Introduction

According to literature, (Brennan et al 1991), (Wilson et al 1995), (Thomas et al 2000), (Vincent et al 2000) (Davis et al 2001) Shioler et al 2001) (Baker et al 2004) (Michel et al 2004) around every tenth patient is harmed through hospital care. The Institute of Medicine (IOM) report (Kohn, L.T. 2000) states that between 44000-98000 Americans die each year because of adverse events (harm caused to patients by medical care, and not by the underlying illness. The report also states, that this is roughly the equivalent of two Jumbo passenger jets crashing every day. Since the Institute of Medicine’s report, patient safety policies have been introduced worldwide, the European Union has issued a declaration of patient safety (Luxembourg declaration on patient safety), and the WHO has established an office dealing with the subject, claiming that healthcare related adverse events have reached an epidemic proportion worldwide.

Since 1999, healthcare has drawn heavily on the recommendations of the IOM, and other leading professionals, and in many countries national error-reporting systems have been established, risk-management was introduced, or had a refined focus on managing the risk of adverse events, and a no-blame culture was advocated.

Patient safety has acquired a myriad of definitions, but the most widely shared element of these different definitions of patient safety is freedom of adverse events in healthcare setting (based on Kohn. L.T. 2000). An adverse event is any event in a hospital, where a patient is harmed. Examples include any type of medical error, administrative error (operation of wrong patient for example) or hospital-acquired infections.

In order to reduce these events, practices from aviation and nuclear engineering have been borrowed. These include a systemic thinking about the nature of the incidents, risk management, (a specialty for identifying risk, investigating incidents, and determining the frequency and effect of adverse events), and a reporting system. A change of culture is also
considered necessary, to reduce the negative effects of professional and organisational culture, in order to achieve a culture of safety. The emphasised element of this culture of safety is a no-blame culture where individual errors are not punished, but the errors are shared, and lessons are drawn.

Patient safety was an acceptable goal to both the medical professionals, and to the patients. The existence of medical error is denied by some professionals, (Rosenthal, 1995) and for this reason the term is not acceptable. Besides this fact, no one seriously cares about errors, when they do not reach the patient. The whole process is judged by outcomes; therefore, the emphasis was moved to adverse events that deal with the actual outcomes.

Since the 1970-s, well-publicised studies have described the widespread nature of medical error, (see Millerson 2003) articles have emerged in the professional medical journals, but none have been able to trigger such a phenomenon. This brings us to the question – why have the medical profession not done anything against adverse events? For years to come, journalists (Millerson 2002) have accused the medical profession of doing nothing to reduce adverse events. This was not necessarily true, because quality systems, risk management, and even adverse drug event reduction programs have been developed, and even used in a variety of hospitals. However, the fact is, that none of those studies had anything near in effect to the report of the IOM.

An explanation may be sought in the rising cost of malpractice, that has become a factor to be reckoned with, and harmed patient causes an unnecessary financial burden on health insurance, especially if the event happens at this magnitude. Besides the economic problems, medical error causes a continuous conflict between the hospitals, medical professionals, and every tenth patient, that can be fought out in different political and non-political arenas.

The subject has received the most visible scholarly attention in the United States, and other Anglo-Saxon countries, mainly by healthcare research scholars, (medical professionals, lawyers, organisation psychologist, medical anthropologists and sociologist, health management scholars). Far less can be read in the international literature about other countries. Although the public perception of healthcare in Hungary is awful, this question is rarely raised in the Hungarian scientific literature. Although there is an emphasis on quality in the Hungarian Healthcare system, it is fragmented, and it cannot be said, that a conscious
safety policy is implemented. A great shortcoming of the previous literature is that it nearly exclusively focuses on the intra-hospital elements of patient safety, and does not seriously link the problem to the more general phenomena of society, or tries to put in a policy context.

Since there is a gap in the literature, this paper tries to view the problem as a policy problem, and tries to give an actor-centered framework of the patient safety policy, based on the systemic factors and environment that affect the actual policy in a given country.

The main hypothesis of the paper is that error in medicine is a technology-induced, modern risk, there is a societal demand to lower this risk, and the different states act in order to protect their citizens. For this reason, this paper tries to outline the systemic factors of patient safety, and apply it briefly for Hungary, and the dealing with medical error at a time before the actual development of a patient safety policy.

Method

1. The theoretical problems of medical error will be highlighted, in terms of the changing nature of the macro-societal developments, with specific reference to health becoming a post-material value, and the nature of the risk society (Beck, 1986) then we turn to the nature of the medical decision making process, and how this is viewed by the patient. Thus, the problem is investigated at the individual level. The first specific hypothesis at this point is, that the perception of medical error is drastically different between the professional medical community and the public.

2. This is followed by a brief overview, of what patient safety is, explanation of risk management, reporting system, and no-blame culture, patient perspective and litigation of adverse events, based on a literature review (Makai Gulácsi 2005). The external environment in terms of globalisation and the European Union will also be explained. In case of Hungary, the historical process will be carried until the present day. The second hypothesis is that patient safety policies are a product of globalisation and Europeanisation, and have the same direction regardless of systems. This general framework will be tested on the Hungarian system.
3. The main issue of patient safety will be presented: the no-blame culture, and the issue of medical error perception will be investigated in depth. The third hypothesis is that the present state of the art patient safety policies are ineffective.

Effect of societal changes on the individual actors

Post material values and the risk society

Why was a long known fact (that hospitals may not be all that good for you) of this magnitude taken so long to reach the arena of public policy? This brings us to the questions of post material values. The first problem to be mentioned is the emergence of health as a post-material value. It is not mentioned specifically in Inglehart’s book on the silent revolution, (Inglehart 1977), but can be deduced from his concept on quality of life. The importance of health has not only increased in terms of prevention in daily practice, but also hospital care has become more scrutinized. In the past, (Schimmel 1964) adverse events in hospitals were dealt with as casualties of progress. By 1999, this argument has not even surfaced, but immediate action to reduce these was called for. (Kohn 2000) since the 1960-s, a significant value shift has taken place. In the meantime, the first generation supporting these post-material values have gained influential positions, the United States president of the time (Bill Clinton) for example was part of this group.

An other major train of societal thought is based around the notion of the risk society. (Beck 1986) In his book, Beck describes the proliferation of human-induced risk. These new risks also have the power to shift reality, and a nature to materialise in places previously though safe. “The level of exposure on the self is no longer discernable with the own methods of knowledge and experience” (Beck 1986 p. 70.) Places of safety have been transformed into places of danger. “The harmful, the dangerous, adversarial lurks everywhere, and if it is friend or foe is outside of the own capacity to judge, and is left to the hypothesises, methods and controversies of the foreign producer of knowledge” (Beck, p.70). Medical error, and harm caused by medical treatment is certainly such a contributing to the risk society. Hospitals have become from a source of health and recovery, into containers of death. Doctors, who were once viewed with hope by patients, are now viewed with fear. As a result, society and public policy has acquired a risk-averse bias, and has made it a basis of public policy. (Wildavsky 1988)
Medical professionalism in the risk society

Particularly applicable to the medical profession is the “gezet der irrtumslosigkeit” (the law of infallibility) that is particularly ingrained in the medical culture. (See for example the problematic nature of expert opinion in the malpractice cases. (Beck 1986), (Sándor 1997) (Liebman - Hyman 2003)). This phenomenon was observed by scholars in many different environments, so it comes close to a universal law.

This is the image of a scientific community (in this case the traditional, old-type medical community) presented to the public. In the case of medicine, this emphasis on trust and error-free action is reinforced as a perceived necessity also from another direction: since medicine and healing are rooted into magic, the element of trust is even more important, than for a natural scientist. “Medicine after all was born in magic and religion, and the doctor-priest-magician-parent unity that persist in the patient’s unconsciousness cannot be broken” (Katz, 1894 p. 40 in Lupton 1994 p. 106.)

The other reason for the necessity for trust is the fact, that physicians have a monopoly to perform certain actions in the name of healing, that would be criminally persecuted in other circumstance. Doctors have a societal monopoly to inflict pain, and in some cases create intended injuries in order to prevent more serious conditions. The best example for this is the amputation of the breast of woman with breast-cancer. Patients would not undergo such treatment if the trust would not be put into the physician at hand. This trust entails a relationship, where in exchange for trust, healing in a magical form is expected. This magical element is emphasised by certain symbols (white coat) and repeated rituals (examination). The magical relationship does not entail such concepts, as risk, or failure. After all, who would go to an unsuccessful shaman? However, risk and failure do exist. For this reason it is interesting to investigate the nature of medical decisions, and how the underlying risk is treated.

The risk of medical care was unknown to the public for a long time, in consistence with the scientific norm, as described by Beck: criticism is directed toward the inside of the discipline, and towards the outside, the scientific community maintains a strong sense of authority, and infallibility. In the case of medicine, this myth of infallibility is even stronger, since medical
practice has even more shaky scientific foundations, than most natural sciences. The scientific basis of medicine is less certain than for the natural sciences. Despite this fact, in medicine, the "unfelhbares Rationalitätshierarchie“ (infallible hierarchy of rationality) is even more pronounced, than between the simple citizen and natural scientists, in the relationship between the patient and the doctor. In the past, medical practice has been conducted without actual evaluation. Only recently, has there been some evaluation of actual medical practice, through the proliferation of evidence-based medicine. It has been investigated, that around 33% of medical interventions have scientific proof of success, a certain number are known to cause harm, and a great numbers have an unknown effect. (Gulácsi 1999) In this sense, we can talk about a scientific experiment on humans, in case of every single medical intervention, that does not have a sound scientific basis.

With the respect to the above, the medicine has been successful in healing diseases. In fact, as natural science in general, medical practice has become a victim of it’s own success “Nicht das versagen, sondern dem erfolg hat den Wissenschaft enttront” (Beck, 1986 p. 266) In medicine, we see the same pattern, medical practice has become capable to heal previously incurable diseases. This has created an expectation, that medicine has only success, and no failures.

With this expected perfection ingrained into medical thought, we had a medical profession, without the slightest regard for patient consent, not even before an operation. (See for example Millerson 2002) The risk of a given medical intervention was not revealed to the patient. Here we see another phenomena observed by Beck in other natural sciences: the different perception of acceptable risk by the professionals and the public. In case of the risk entailed in medical intervention, it was decided by the professional, what acceptable means. In the 1960-s, the risks of hospitalisation were regarded as a cost of progress. (Schimmel 1964) This process is described by Beck as the Feudalisation of the cognition. Only the professionals were thought to be able to distinguish between acceptable clinical risk and unacceptable clinical risk. This has even been the case in case of risky operations (Millerson, 2002).

Concerning hospital risk, the level of accepted risk differs radically between the profession and the public. The level of unavoidable harm also differs. (Rosenthal 2002) What is considered unavoidable? A good example for this is the catheter related infections. A new
technology has reduced these infections to their half. Previously, this has been a “natural” risk of using catheters. “For some time, they have been accepted as non-preventable, accepted risk of using catheters.” (Rosenthal, p. 260.) In the perspective of the public, the accepted infection rate is 0. “The health care industry performs miracles every day, with rapidly advancing technology and medical treatment. This has endangered very high expectations of care amongst consumers –who are the context in which healthcare occurs - and little tolerance for care that deviates from near-perfect quality.” (Dawson, p. 140) The professionals find a certain number of adverse events as acceptable risk of treatment, while the public no longer sees anything as acceptable.

The concept of acceptable risk brings us to another concept: unavoidable harm to the patient. This comes very close the concept of medical error, and is the opposite: avoidable harm. What is considered unavoidable is also left to professional judgment. In determining error, a system of scientific proof is also of subjective nature: error is determined by expert opinion. The consequence is, that there are no real scientific criteria for what constitutes a medical error, or adverse event, and where a complication starts. This leads us to the inherent uncertainty of medicine. Some errors produce adverse events, some do not. Only the outcome is important. And the outcome is uncertain. “Actions that appear entirely reasonable at some point may be identified as errors when an adverse outcome ensues. Conversely, actions recognised as errors may not result in an adverse outcome.” (Rosenthal p. 260.) This is a very important aspect, of why medicine denies the existence of medical error: the intervention is judged post-facto, and with the adverse outcome in mind. Thus complication and error become indistinguishable, and as a result there is a conflict over the classification, that is usually fought out in court, on the basis of the adverse outcome perceived by the patient, and settled in court. To put it simply: for a physician, everything is an unforeseen complication, while for a harmed patient, everything constitutes medical error.

The main changes from this original set-up were the patient information and consent before an operation, and in general patient information about the risk of treatment, allowing the patient to decide to take the given risk or not. Also, the evidence-based medicine proliferated in health systems, and decreasing the unscientific nature of medicine to some degree. Consumers of healthcare systems became more pronounced, and the substandard care was attacked in court.
But one aspect of medical decision-making was retained: the uncertainty, unpredictability of the practice. The decision phenomena in medical practice is based on multiple sources of information, for example: textbook knowledge, evidence-based studies, touch, pre-operative assessment, data on machines, clinical notes and records, and local experience. (Mort et al. 2005) This information may be contradictory, insufficient, and it has to be put together often in a very limited amount of time. All of these sources of knowledge are sources of error. This makes the outcome ultimately probabilistic, and does not allow the prediction of every complication or adverse outcome in every case. This unpredictability is the real protection of doctors from effective regulation, and standardisation of practice –however useful that may be in certain setting of medicine. Unfortunately, it also protects unqualified doctors, who can hide behind this veil of uncertainty.

On the level of individual actors, we have left the nurses for last. A growing proportion of care is performed also by nurses. The nurses have become in education and professional skills close to the doctors. They are also responsible for a large number of adverse events, but the attitude is different in general. Nurses are willing to report the errors, and are more willing to learn. See (Williams 2003). Nurses stand in between the patients and the doctors, when it comes to defining medical error. With their growing medical knowledge, nurses are almost as able to identify medical error and are certainly qualified to identify nursing error. The main difference to doctors, that they are willing to deal with it

In brief, patient safety has emerged as a product of the risk society, and there is a radical divide between the public perception of medical work, and error, and between the medical profession’s perception. This phenomenon was regarded for decades as a problem of personal grief and pain, but the growing importance of healthcare and the increased sensitivity of society has led to the emergence of a societal problem.
Concrete factors

Besides these rather complex background factors, there are also some easily discernible factors in the case of healthcare, that contribute to an increased awareness of medical error and hospital risk. First of all, there is growing demand for a cap on government spending, reinforced by the neo-liberal economic rationality of the past decades, as well as the increased democratic accountability of government spending. This phenomenon has become important, since the end of the “golden age of growth” after the second world war, and the period of relatively slow growth since the 70-s. (OECD data) As a result, healthcare budgets have also been effected. This has caused the growing interest in the effectiveness of medical care. The public management movement (Osborne-Gabler 1992), and the increased search for effectiveness and efficiency eliminating “negative healing” also reinforced this phenomenon (Gulacsi 2001).

In the United States, the problem had a slightly different character. With market-driven providers, the medical costs have skyrocketed. (For an early observation see Wildavsky 1979) The cost-containment was sought after from a simply market-driven direction. One way of cost-containment is the reduction of harmful interventions. Since harmful interventions leave patients in the hospital for longer time, and need extra recourses to heal them, the insurance
companies have put pressure on hospitals, to reduce this practice of generating demand. Besides these, the United States has experienced several times a “malpractice crisis”, one in the 1970-s, one in the 1980-s, and once after the millennium.

The political nature of dealing with medical error comes, when one sees as the duty of the state as combating disaster. If some phenomenon, that has a death toll equating to two daily jumbo-jet crashes is not a disaster, then what is? The state is unable to provide a basic need, namely that healthcare perform it’s basic functions, and leaves patients better off than when admitted, and not worse off or dead. The failure of this basic function may even undermine the legitimacy of the state as a provider of services. If public perception of healthcare is not of high quality, then this may have an impact on this legitimacy of provision. (Of course, the leading studies have been conducted in private institutions as well, producing just as horrible results.) Since the welfare state and the services account for a significant part of the legitimacy of the state, this may even have a limited effect on the legitimacy of the state itself.

From another perspective, the state has a basic responsibility for providing physical security. This may undermine the legitimacy of the state as a whole, not only as a legitimate provider of services. If this perspective is taken by any actor or any set of actors, it may constitute a significantly larger decline in legitimacy of the state, than described above.

**Global emergence of the issue**

Global circulation of the medical literature has allowed other countries access to the main articles. The subsequent studies were in some form modelled on the Harvard Medical Practice Study (Brennan et al. 1991). The first studies outside the United States were carried out in Anglo-Saxon countries, (Australia, New-Zealand, United Kingdom) and only then have we found an adverse event study in Denmark. The patient safety policies have spread to other countries as well, like the Netherlands. After the WHO has recognised the issue as a priority, the European Union has recognised the issue. The European union has issued a declaration of Patient safety in april 2005 stating that “Access to high quality healthcare is a key human right recognized and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services.” (Luxembourg declaration of patient safety 2004) Only as a result has the question been considered in earnest in Hungary.
National Systems

The first problem is the nature of patient rights guaranteed by the state. Do patients have access to healthcare in general, or to safe healthcare? If patients only have the right to healthcare, are patients allowed to choose the risk they take? There are no differences in the investigated countries on this second aspect. Patient rights are well established even in the system where they have emerged last in Hungary. On the first, there is a difference between the actual laws on patient safety, and the claims. Neither the Danish, or the American law acknowledge the right for a safe healthcare institution. This is only done by the Luxembourg declaration, with a questionable legal value.

The next relevant question in the patient safety policy is the nature of the patient compensation. Is this patient compensation done through a system of tort (malpractice), or is it done through a system of specific insurance for the people harmed by the medical system? (No-fault compensation system) Such a system exists for example in Denmark and New-Zealand. (Davis P. et al, 2003) The other model is applicable to the United States and in a modified form to Hungary. This influences the relationship between the patients and the providers, and touches the core problem of the relationship, was the harm foreseeable, or avoidable. The no-fault system foregoes this problem, requiring only the harm to be proven.
The availability of liability insurance is also a relevant question. If it is easily available, then healthcare providers can easily shift the risk, and do not have to engage in patient safety activities. If it is not available in a proper manner, then the risks in the hospital must be curtailed. The American case here again an exception: instead of suing the hospital, as the logic of the process would dictate, patients sue individual doctors. (Kachalia, A. 2003) (Sage, W. M. 2004)

An other related problem is the nature of healthcare provision, and the welfare state. If the malpractice system operates in an environment where the individual is entitled to a generous disability benefits if permanently injured, and the additional medical costs are covered publicly, then the adversarial nature is lessened as well, since patients are not asked to pay for medical costs caused by the institutions themselves.

The next phenomenon is at what level the public-management and the bureaucratization of healthcare can be found. Who runs the hospitals, medical doctors or managers? Since patient safety is a systems issue the level of organization of the hospital is crucial. Here, the question is, to what level has the autonomy of the medical profession been curtailed? How far have been the processed regulated? If in a country, the hospitals are at a low level of bureaucratization, the logic of the medical profession prevails, that does not wish t deal with errors. If the processes have been regulated, and bureaucratized, then a bureaucratic rationality prevails, but the capacity to monitor the processes and actual implementation lies in the medical world.
Policy Actors

The main actors of patient safety arena must operate under different systemic arrangements. Conversely, they are exhibiting rather similar behavior. The sum of the individual conflicts, the behavior of the individual-level actors is felt on the policy level, where they are influenced by other actors. First, we have the hospitals, with a goal to safeguard their financial interests, and a goal to save the reputation. (Kachalia 2003) It is in the interest of hospitals to ignore the errors of care, and even cover up, when a malpractice system is in operation. If the hospitals must pay automatically in the event of harm, then harm reduction gets an economic incentive. From the viewpoint of reputation, hospitals have again an incentive to cover up, in order not to scare away patients. The reasons for investigation and dealing with errors lie in professional ethics, and effective governmental regulation.

The scenario above is only valid, if the insurance companies are not effectively able to cover hospitals for the risk induced by their professionals. If the risk can be shifted, it will be, and error reduction schemes will not be in effect.
In the policy arena, we also have the professional organizations of the physicians, and the professional organizations of allied health professionals. The Doctors have the traditionally stronger lobby power, but this power may vary considerably in the different countries. At the actual ground implementation level, doctors define the rule of the game.

On the other side of the policy field we find the patient organizations, and individual patients picked up by the media. The media as a rule is against the medical professions. This can partly be explained by the tabloidisation, but it definitely sets up a claim to punish bad-performance doctors. The role of patient organizations must be uncovered by further research. In other countries, the media may not have any effect on the issue. On this side is also the lawyer group, specializing in malpractice.

The next actor is the Health bureaucracy. In the American case, there is quasi-health bureaucracy. The Joint Commission is regarded by some as the informal health bureaucracy. (It also performed a leading role in the development of the patient safety issue). In Europe, there is normally a governmental body for healthcare, let it be a ministry or a Quasi-governmental institutions. If the no-blame is adopted, the medical profession has won. If a system based on blame is retained or adopted, on the surface, the patients win. But patient safety loose.

The government action is also a question. The main question is, who has better access to the government? The doctor-lobby or the patient lobby? If there is a law on patient safety, we can be certain, that the issue has reached a level of visibility. In connection to the different laws, the patient safety experts: (medical doctors, lawyers, researchers, psychologists, etc.) influence the thinking of lawmakers.

On a global level, the WHO and the EU DG Santé are relevant Actors. They have an influential role in the dispersion of knowledge, through organizing conferences, and funding research. The DG Santé also deals with patient safety as a part of the High Level Group on Healthcare.

System and actors of medical error and patient safety in Hungary
The compensation system in Hungary is based on a system of tort, with all of the difficulties that accompany such a system. The main problem of a tort compensation lies in the fact, that expert judgment is required in malpractice cases, and the litigation takes years to finish. Expert witnesses are difficult, since doctors have to decide if a colleague was at fault. Exactly because of this difficulty, such cases last years. Despite these difficulties, 80% of such cases are won by the claimants. (Figyelőnet) This counter-intuitive behavior. The Hungarian malpractice system switches the burden of proof to the doctor: he or she must prove that she has not been negligent in the creation of an adverse outcome.

The cost of malpractice is the driving force for the dealing with medical error, as well as the other constraints. The record for a single case is near 400 000 Euros. There are 300 such cases in Hungary per year, and the trend is growing (Dósa 2004) (Figyelőnet 2005). Liability insurance has become scarce and insufficient for this magnitude. The hospitals are obliged to have liability insurance. Liability insurance is insufficient, covering only up till 20 000 Euros for one damages/hospital, and a maximum of 40 000 euros a year. As a supplemental phenomenon, healthcare is viewed as dismal. (Rácz, J. Minister of Health 2005) (This is a simplified statement: 61% are satisfied with their General Practitioner, 47 with the outpatient care, and 36 with the hospital care. The rest find that there is a problem. Tárki report 2003)

Healthcare is organized in state-insurance model, and the providers are state-owned in the majority. Healthcare has become more managerial in the last decade, as interest in healthcare organization, financing, and quality is growing.

Patient organizations have not been very effective at advocating the issue. Individuals, on the other hand have given a petition to the parliamentary commisiion on health, have organized demonstrations against doctors committing medical error and the current system.

In terms of the media, medical error is reported regularly, or the malpractice system is referenced, every month in the main national newspapers. In 2004, a wrong patient has been operated, causing the death. Since, the Ministry of Health has made it obligatory to have patient identification schemes in each hospital, half a year later. Errors are dealt with in the framework of quality management systems, and externally, if at a given specialty, serious deviation in practice appear, the given part of the hospital may be shut down. (15/2005 ministerial decree)
Exact because of this shift away from the focus on error, a no-blame culture is advocated. The case against blaming the individual is presented, and is recommended for policy. In this view, the most important factors for attributing adverse events as the individual professional’s failure is deeply embedded in the human psychology. (Reason et al, 2001), has identified a so-called “vulnerable system syndrome”, that states, that “there is a recurrent cluster of organisational pathologies that render some systems more vulnerable to adverse events than others.” (Reason et al, 2001 p. ii21) According to Reason, three pathological actions that constitute the syndrome.

Blame is the fundamental syndrome. Blame is caused by the following hypotheses in the world: First, Human error is accepted as an explanation, not as an outcome that needs to be explained. The human error attribution is a very common human perception; the professional in question was stupid, reckless, etc. When hearing the professional, and him or her, why has the mistake occurred, it is always a litany about constraining factors. The second factor is the illusion of free will. The individual in question is seen as someone who can choose between correct action and erroneous action. The third is the just world hypothesis. According to this one, dating back to the ancient times is that bad things happen to bad people. Last, but not least, hindsight bias also creates blame. The event with hindsight knowledge seems to unfold clearly to the outcome observed. The reality and the complexity of decision-making is lost.

According to Reason (2001), this way of looking at errors is wrong, because “the institution fails to learn that errors and non-compliances mark the beginning of the investigation, not its conclusion” (Reason et al, 2001 p. ii23.) The situation where the event happens is the determining factor, not the person. Secondly, the organization wastes time on trying to change the individual behaviour of the professional that is far more difficult, than changing the situation where the error occurred. Blaming also leads to denial. This means, that the bad apple has been eliminated, and the organization does not have any data on the true incidence of adverse events.

Denial has an even worse effect: it causes adversarial behaviour of the management towards reporters. “Pathological organizations muzzle, malign, or marginalize whistle blowers, shirk
collective safety responsibility, punish or cover up failures, and discourage new ideas. In short, they do not want to know.” (Reasons, 2001 ii24) Just as the medical profession disputes claims, that it may be responsible for errors, in the same manner, management also tries to push the blame away from itself.

Because individual blame is useless, the literature suggests a no blame culture in hospitals. This means, that errors must be brought out into the open. One way for achieving this aim is through the creation of an error reporting system, where reports are handled confidentially. This means, that it must be credible to staff, that if they report an error, either their own or the error of a college, there will not be any disciplinary action taken against them. The goal of these reporting systems would be self-reporting. In other words, there is a kind of amnesty for errors. In such a culture, staff can identify and report errors, without repercussion. Fear of repercussion is one of the main reasons for not reporting an error. For example in the US, underreporting was up to 2000 50-96% annually. (Barach and Small 2000) This is caused by a pathological working culture that is based on hierarchy and individual responsibility for the patient. In such a setting, errors are not recognized, not corrected, and as a consequence, are repeated. If the individual physician who commits an error is fired, someone else will commit the same error, if the systematic nature is not recognized.

Such a culture was the basis for patient safety improvement in all of the articles dealing with in-hospital patient safety, which means, a pathological culture was typical to nearly all hospitals, until a few years ago with an exception of a few pioneers. In this light, it is not surprising, that many articles deal with culture change, or try to measure culture in some form, and trying to find management tools for changing culture. Normally these articles are case studies in an individual Hospital, but in some cases there is measurement of culture for a whole number of hospitals in different US. States. Such cultural reviews include “Preventable in- hospital injuries under the no-fault system in New Zealand” (Davis-Lay et al. 2003), The culture of safety: result of an organization-wide survey in 15 California hospitals (Singer, Gaba et al. 2003).

This view of the issue is simplistic. It has been investigated, that doctors, who can commit a larger variety of medical error, then nurses, report less events than nurses. (Lawton Parker 2002) Waring describes the phenomenon (Waring 2005) in a quantitative way. According to his study “research revealed that far from working on the premise of “perfection” (Leape,
1999), doctors regarded errors as an inevitable and sometimes beneficial dimension of their work. It was found that the majority of physicians believed all human activity was prone to error” (Waring 2005 p.1931) Such a view calls into question the usefulness of a reporting system. “Given that errors were regarded as inevitable doctors often regarded reporting as ‘pointless’ or a ‘waste of time’ on the grounds that these mistakes could never be fully eradicated and instead they should just be accepted. In consequence participants could see little purpose for incident reporting.” (Waring 2005 p. 1932) For this reason, it was necessary, to look deeper into the medical decision-making process, and why this is the case.

If this study can be generalized, then the no-blame culture becomes pointless. If the medical profession explicitly refuses to deal with an issue of such magnitude, then the concept of medical error may very well be of use, in order to pressure the medical profession to change the way it works.

The second major issue is the professional rejection of healthcare bureaucracy. This is a well documented phenomenon, and it is crucial in understanding the nature of this problem. “When the doctors were asked about their experiences and involvement in incident reporting their responses referred to the excessive time required for form filling that could be better spent with patients or the menial nature of paperwork that was somehow beneath medical expertise”.(Waring 2005 p. 1932) Again we have beautiful statement about a fact that touches the deep core. A doctor views himself or herself as above any human regulation. Thus, the legitimacy of the outside evaluation is called into question (Waring 2005). How does a practice acquire legitimacy in the eyes of the professionals? Through being professional, and medical. We are back to square one.

This may also be considered from a perspective of power. The managerial interventions are an act of power. The medical community may try to preserve it’s own power with non-compliance.

In actual policy implications, we can observe laws protecting the adverse event reporting from the courts (United States) and national systems of anonymous reporting (Denmark, United Kingdom). No-blame is taken up in recommendations of the WHO as well. (guideline for reporting) In Hungary, this no-blame is not implemented. In Hungary, a month after the Luxembourg declaration, a ministerial decree was issued, stated, that if the monitoring official
for a given medical specialty finds too many, and repeated medical errors in a given hospital, the he or she may close it. (Eüm. 2005/15)

Besides the no-blame and the reporting system, the literature and practice show the role of risk management in patient safety. This kind of risk management safeguards the financial assets of the hospitals by investigating the events in the hospitals, identifies risky procedures and finds safer alternatives. As a policy, access to a risk management official may be made mandatory for all hospitals. This has been done in Denmark.

The most open question of this policy is the culture change. This is the most difficult problem, but it may be influenced by training, and education. Changing a professional culture is both the most important, and the most time-consuming element. In order to change the culture, the whole socialization process of medical professionals must be changed, to a culture, where error is still considered natural, but comes within the boundaries of human intervention.

Conclusions

The two main hypothesizes, stating that there is a difference between the public and the professional community’s perception of errors is only proven analytically. This should be verified in an empirical manner as well. The second main hypothesis, that patient safety has become a global phenomenon should also be investigated in more detail in the future.

Medical error and patient safety are a global problem. There is a rift between the expectations of the public and the capacity of the healthcare system to deliver excellence, and safe care. This fits perfectly well into the notion of the Risk society, where the society is surrounded by risks in places previously thought safe. For the resolution of the problem, patient safety practices have been developed. The success of these is uncertain. There is a major difference in how the professional community views errors –as a natural product of their work- and how the general public perceives –medicine should be free of errors- and this has not been reconciled so far.

Patient safety cannot be achieved either with allowing a professional community to go it’s own way, or through bureaucratic measures, or through a system of tort. Tort is useless because in a tort system the professionals are afraid to discuss errors, and thus are bound to
repeat them. Professionals have a resistance towards bureaucratic interventions, and are unwilling to deal with the problem of medical error. This means, that there seems to be no solution for this problem. If something is viewed as an incident by the public, it may be viewed natural by the professionals, an not reported. Another reason may be a deliberate uncooperativeness of the professionals, in order to preserve the current power. In such an environment, the change of the professional culture seems to be in the distant future.

The follow up agenda of this research would be an empirical investigation of several European countries in terms of what effected the management of medical error and patient safety.

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ABSTRACT

Patient Safety: A policy framework

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Background Patient Safety is a global problem, since according to different studies, roughly 10% of patients are harmed by the care they receive in a hospital, and between 44 000-98 000 patients in the United States die from medical error alone. Healthcare professional circles have reacted to this fact as a cost of progress, for decades, from the 1960-s, when it was first discovered, until the 1990-s. In 1999, the Institute of Medicine published it’s report To Err is Human, and had a profound effect: patient safety became a priority in the United States, some European countries, the World Health Organisation and eventually for the European Union. The latter has issued a statement in April 2005 claiming high quality healthcare as a key Human right, and calls for concerted action on the European level on the subject of patient safety. An issue became the centre of attention that has been widely ignored by the healthcare professionals, the general public, and the political sphere, namely that hospital care has victims, causing a serious inefficiency in the hospital care. The goal of this paper is to give meaning to this societal phenomenon from a public policy perspective, and to develop a framework for dealing with the issue, that can be later be used in a comparative way.

Objective: To give a short overview of the subject from the related health services and medical literature, and to identify the relevant factors that have lead to the policy outcomes of the different states, in terms of actors, systemic environmental differences both in the general legal framework, and in the healthcare system.

Method: The objective was attained by a qualitative analysis of the historical development of patient safety policy in the United States, Denmark, and in Hungary. One country was selected from an Anglo-Saxon model, one from a Continental, model welfare state, and one from a Central-European region.

Results: The following main factors have been identified, as potential relevant factors for initiating a patient safety policy: cost of malpractice, post-material values, public management, tort system, insurance, media, professional studies, professional reaction, professional accountability, professional culture and values, international organisations, Europeanisation.

Conclusions: Patient Safety as an issue has generated very similar policy actions, despite the varied environments. This points to the notion that the international factors have more effect than systemic factors. The reason for this similarity is to be investigated in detail in the future.