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# Medical Ethics in the Czech Republic – Experiences in the Post-Totalitarian Country

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## 1. Introduction

Countries in Central Europe undergo various transformations in society and economics; interpersonal relationships change, and new civic and political structures emerge. All changes take place in a relatively short period, and they are directed to establish the same organisation of public affairs that is common in Western Europe. For this reason we can also see these countries as a natural sociology laboratory; ongoing processes are more transparent and some universally accepted theses could be re-examined.

Bohemia has been an integral part of Europe for centuries, and was therefore culturally tightly bound with other European countries. For fifty years its European identity (1939 – 1989) was interrupted by totalitarian regimes, of which the Communist regime was the most influential; it lasted from 1948 till 1989. Communist ideology was egalitarian and intentionally preferred society to individuals, therefore the Communist regime was characterised by strong paternalism of political and state administration. The Czech society is traditionally quite egalitarian with strong aversion against big social differences. These tendencies were strengthened by the Communist regime in its underlying egalitarian theory. Some positive human rights, such as a right to health care, to a job, and to housing, were fairly met. Social security was on a high level. The price for this was almost a complete lack of civil liberties. Basic civil rights, such as a right to free speech, to free association, and to free movement were abolished. In the paternalistic, ideologically driven regime not only civil but also working initiative markedly declined. The well known result was economic retardation, worsening of the environment, and life expectancy also stagnated. Due to the absence of civil liberties all the negative effects were kept secret.

From an ethical point of view the most devastating effects of this regime was the breakdown of public debate and the disregard for language. Public debate is no simple enterprise; it must be practiced in the society, and be adapted to the changing social and technical conditions of each generation. In the second half of twentieth century citizens in Western countries were more and more forced to negotiate in politics, civil communities, at offices, and in health care. Thanks to this necessity they gained good skills in negotiation. In countries with a Communist totalitarian regime arguments were of no use; what was much more important was favour of powerful politicians and later on also a position in informal

exchange of scarce services and goods. Public debate was systematically suppressed, causing people in post-communist countries to lack skills in everyday negotiations. They even lacked an awareness of the necessity of negotiation, and the capability to negotiate. For example, the political scene has been seriously polarised in past years. There are no visible attempts to make political agreements across the political spectrum. In the latest elections (June 2010) voters showed their strong dissatisfaction, and the traditionally strongest parties lost. Two entirely new parties entered the Parliament and created a government with a weak right wing party. In some areas the parties' programs distinctly differ, but in the realistic understanding that the trust of voters could be easily lost, the three parties manage to negotiate solutions acceptable to all of them. Only rarely are their competencies in negotiation acknowledged in the media.

After 1989 the Czech Republic changed its political regime in a very short time, and became a country in transition from totalitarian to democratic. Restoration of democratic institutions was quite a simple task, since there was a history of its existence, at least in the interwar period 1918-1939. Also the nongovernmental sector has boomed rapidly, and the stakeholders of civil society began to actively influence political and social life. The most difficult part was the restoration of civil thought, the interioration of civil values, cultivation of political culture, and the practice of public debate, though it is constantly improving. (Simek, 1999)

Between 1948 and 1952 the centralized tax funded health care system was introduced in Czechoslovakia to replace the Bismarckian mix of mandatory and private health insurance. As in other socialist countries, a universal access to health care free of charge in the place of use was guaranteed. A hierarchical structure of primary, secondary, and tertiary health care was built up, and stipulated areas of geographical accessibility existed for users. Physicians became state employees and private medical care became illegal. Due to poor outcomes on the population's health status, the socialist health care system became the subject of critical remarks already in the perestroika period (mid 1980's). This resulted in a very urgent need for a health care system transformation immediately after the Velvet Revolution. A new system was outlined, which re-established the public health insurance, mandatory for all citizens in Czechoslovakia, and from 1993 in the Czech and Slovak Republic, which had split. Provision of ambulatory care was completely privatised, although still financed from public health insurance. A large number of regional hospitals was also privatised, so a mix of state-run, regional/municipal, and private hospitals participated in-patient services. In a very short period, the status of providers changed from the employee in the public services towards a free-lance professional or entrepreneur. Values of personal responsibility for health, which have compensated for the unlimited solidarity, were manifested in patients' co-payments for drugs, certain services, consumer's fees, etc. Positively, during the health care transformation a massive technological modernization and availability of foreign drugs led to a steep improvement in the quality of medical care. Simultaneously, attention was also paid to ethical issues and to psychological and moral issues.

### **1.1 Medical ethics as a discipline – Theory and practice**

During socialism medical ethics did not exist as a separate discipline, though the term was often used in the debate on medical practice. The Marxist-Leninist ideology was considered be a sufficient philosophical foundation and reservoir of advices for medical doctors. Due to

the restriction of civil liberties, medical professionals had evolved into a highly paternalistic mode of behaviour to the patient. Patients had very limited freedom of choice of the provider, and no means to control the outcomes of clinical practice. However, it would be too simplistic to depict the practice in black and white colours, since the practice was always diverse although a few responsive and paternalistic patterns have culturally dominated. During the socialist period the deontological approach stressed the medical duties instead of patients' rights. Naturally, one of the consequences of the Velvet Revolution in 1989 was a strict demand to humanize the medical practice and eliminate the patients' submissiveness. In 1992, The Charter of Patients' Rights was adopted by the Ethics Committee of the Ministry of Health and in 2001. The Convention on Human Rights and Bioethics of the Council of Europe was approved by the Czech Parliament, which implied radical legal amendments to enhance legal patients' rights.

Medical ethics as an academic discipline started to develop early after the change of the regime. Universities regained their academic freedoms, and study programs were modernised. Medical ethics issues were implemented in all health care programs. In 1990 chairs or institutes specialised in medical ethics were founded in 4 schools of medicine. In this way an institutional base was established. Important aid came from abroad, mostly in the form of donations of books and libraries. The most important help came from the American "The Hastings Centre." The founder and president of The Hastings Centre, Daniel Callahan, created an Eastern European Program, and dozens of people from post-communist countries were invited to The Hastings Centre for the six-week study stay. Later on Daniel Callahan visited Prague many times; he gave lectures, and helped with the organisation of seminars and conferences. In 2008 he received a doctorate honoris causa at the Charles University in Prague. At this time medical or health care ethics were taught at all schools educating future physicians and non-medical health care professionals. Some research was also developed in the Czech Republic. Further development of medical ethics faced two difficulties: the lack of interest of the public in ethics in general, and the lack of an institutional background outside medical schools. There is no chair for ethics at schools of philosophy in the Czech Republic.

The following texts are a summary of the results of our research done in 1999 – 2009 in four consecutive projects funded by the Grant Agency of the Czech Republic. We put together information, which we just published in relevant journals. (Krizova & Simek, 2002; Krizova & Simek, 2007; Simek at el. 2009; Simek et al. 2010) In the research we have addressed three issues that we use as case examples of how medical ethics in the Czech Republic has manifested in the debate, and how it was implemented in everyday practice.

## **2. Informed consent in the CR**

As we have already mentioned above, a discrepancy existed between legal norms and practice during socialism. The Law No. 20/1966 Coll., "On the Care for the People's Health", has vaguely stated the physicians' duty to inform the sick, but it was the physician who could decide whether and how much information he/she will communicate.

The communication between physicians and patients was identified as a significant problem already in early nineties. "Medicine of secrecy" was identified as the biggest fault of the system (Haškovcová, 2002) and truthfulness was considered to be an important value. Since

then big progress was made and we can say that the Czech health care has definitely abandoned "medicine of secrecy." In this way the most active and progressive of all were paediatricians and oncologists, but also other specialists and general practitioners who began to extensively and consequently inform their patients. At university hospitals informed consent was introduced mainly thanks to regular contacts with Western European physicians and it was used as a way to document patient's consent with more invasive examination and therapy procedures. Since about 2002 informed consent was slowly introduced also in smaller and rural hospitals. (Zamykalová & Šimek, 2007) There were two impulses for its introduction. The first incentive was the start of the accreditation processes of Czech hospitals; implementation of informed consent in the clinical work was an essential part of accreditation requirements. The second, more important but later impulse was the approval of the European Convention on Human Rights and Biomedicine by the Czech Parliament in 2001, which resulted in amendments in the Czech health care legislation. In 2007 the Ministerial Decree No. 64/2007 on health care documentation was approved, and the legal provision of informed consent is the part of this Decree. Informed consent was also embedded in the Law on the Care for the People's Health.

Surprisingly, shared decision making was not the issue at that time. Implementation of informed consent is an example of a "reversed" process in the development of rules. Regulatory and legal measures recommended by the EU were first accepted, and then their meaning and sense were discussed. The dominant issues in the debate are formal aspects of informed consent –the length of texts, their content, and their storage in charts, which therapeutic and diagnostic procedures are subjects of this provision. Interest in the lay public is quite low; discussants are mainly health care providers. They tend to understand informed consent as a tool for protecting physicians from patient's complaints and law suits. Sometimes informed consent is submitted to patients as a merely formal affair and patients sign it without any further explanation during the admission process in the hospital.

The low interest of the public in informed consent was confirmed in our interviews with physicians, nurses and patients. Very often, the communication is short, sometimes patients do not have the opportunity to discuss all details and inquire about therapeutic options, risks, and benefits. On the other hand, Czech physicians quite often complained that patients were not interested in medical information which they tried to give them. In the research interviews patients expressed their wish to have conversation with their physicians but they did not seek information first. Instead, patients searched for the interest of physicians in their case, preferably personal interest and not only in their body and disease. They also wanted to be calmed down. The majority of patients understood the signature of informed consent sheet as a mere formal procedure. In a survey conducted in 2004 (1619 adults) only 42% of the population has correctly comprehended both aspects of the concept of the informed consent – right to information and right to approve/refuse the intervention. 31% of respondents admitted that they did not understand the term at all.

From the very beginning some physicians tried to give the patients a form of general consent with the treatment without the procedures being specified. This approach was immediately criticised by health lawyers and later on abandoned. In spite of this, 65% of respondents in our survey answered positively (definitely yes or probably yes) to this question: "I consent to the performance of an operation of the kind and of the extent that the



surgeon shall decide according to the need that emerges during the operation.” Do you find this kind of formulation acceptable? (Krizova & Simek, 2007)

Even though the situation has significantly improved, insufficient practice in how informed consent is carried out persists. The patients' age and education also affect the attitudes. Less educated and older patients still represent the passive position, whereas the younger and better educated users demand on more information and are more active in the decision process. Younger physicians also consider the informed consent as an appropriate demand of the sick. Despite the fact that much has been improved, some negative effects still prevail since informed consent is often deemed as the means of legal protection for the provider (physician, hospital) and less as a means of self-determination of the patient.

In Czech health care family members are quite often better informed than the patients themselves, and patients mostly agree with this practice. Maybe it overcomes some difficulties in communicating serious information. The family member translates the physicians' wording into the family's common language. On the contrary to physicians, family members recognize individual goals of their neighbours and honour their preferences in values. In this context, “shared decision making” takes place within patients' family and not during the informed consent procedure.

We can conclude that the Czech Republic is still behind in its development, and that it is only a matter of time until the Czech public will appreciate the informed consent institute adequately. Another possibility is to ask some questions. Informed consent has its origin in conflicts between physicians and patients and even in lawsuits between them. (Appelbaum & Meisel, 1987) We do not remember sharp conflicts between physicians and patients in the Czech Republic, lawsuits are quite rare. In our interviews patients emphasised trust as an important part of their relationship with physicians. Due to historical reasons, the division line is not between patients and physicians, but between good and bad physicians, and between good and bad health care facilities. Information about objective outcomes of Czech hospitals (mortality rates, waiting lists, etc) is still in secret. Patients themselves must assess the quality of health care providers, so the claim for a good and sensitive expert physician survives. The conversation assessment of the quality of the physician is much more important than information given. In this way the almost forgotten question of personality traits of a good physician was revived. An important reason for Czech patients not accepting informed consent could be their wish to have physicians of high quality. Through their signatures patients simply confirm that they trust their physicians or health care facilities. (Simek et al., 2009)

In theoretical reflections of the process we can refresh an old problem from medical deontology: What does it mean to be a physician of high quality? What kind of a physician can a patient trust?

There is no doubt that a good physician must be an excellent expert in biological medicine. To become a medical expert he needs a certain level of intelligence, good memory, a strong will to study hard, and later on to work hard. A physician needs a sound reason for clinical thinking and the flexibility necessary for lifelong learning.

Moreover, physicians (and nurses) constitute distinct professional communities. Some guiding principles of these communities are different from principles common in the

majority of society. An important principle in health care is beneficence. It means "act in the best interest of your patient". It clearly differs from the common rule of market (and consumers) society "following your own interests will help the well-being of the whole society". A good member of the medical community should possess special skills and strengths. To this we can apply McIntyre's definition of virtues (McIntyre, 1985) in close connection with practices of the given profession or community. Explanation represents a special problem in medicine. We can revive the term of "hermeneutic competence" promoted by Dirk Lanzerath. (Lanzerath, 2003) Eventually Chris Gastmans et al. In their effort to grasp the fundamentals of nursing ethics, came to the conclusion that caring behaviour is the integration of virtue and expert activity. (Gastmans et al., 1998)

### **3. Issue of resource allocation, priorities in medicine, and rationing in the CR, before and after the change**

Health belongs to basic needs. Health is an essential condition for fulfilling other needs and only a healthy person can follow his own personal goals. Therefore, in our Euro-Atlantic civilisation justice and equity are highly recognized values in health care. Realisation of these values is more and more difficult. Thanks to scientific and technological progress possibilities in health care grow faster than available resources. Another problem stems from big differences in economic power of various countries. Exhibiting patients' autonomy and justice in health care presuppose minimal economic standards and democratic conditions. According to the OECD report in Germany, yearly expenditures per capita are more than two times higher than in the Czech Republic (In 2008 Germany 3208 Euro, Czech republic 1528). In Romania only 687 Euro. (Lafortune, 2010) Interpretation and realisation of concepts of justice and equity must be different in different economic conditions. In less developed countries the range of health services must be smaller; its availability in big cities and in rural areas can hardly be the same. Nevertheless, not even rich countries can provide existing diagnostic and therapeutic procedures to all without any delay, and even rich countries have rationing and priority settings.

Rationing mainly describes the process of distributing scarce health care services within a population with the effect that is not sustainable to provide each patient with all health care services he/she might benefit from. From this point of view, it reflects on a universal problem of each modern health care system that is caused by a growing discrepancy between the population's health needs and disposable financial resources. Especially high-cost health care services that are conditioned by expensive technological equipment may be subject to rationing. Nowadays' "rationing is indeed international and not just a by-product of state-commanded health care systems". (Klein, 1998) Under every constitutional "right to health care", a pragmatic necessity of how to implement it is hidden. Due to limited resources, rationing requires the selection of the best indicated patients, or putting the patients on a waiting list. The economic situation of the particular country only makes this strain either smaller or greater.

It is necessary to distinguish between political and economic decisions on macro- and/or mesolevel and professional medical assessment of health needs and clinical decision-making in the course of therapy at the microlevel (Michaeli, 1999), while both are interfering with

each other. For politicians it is not popular to inform the public about urgent limitation of care for financial reasons, because of fear of social tensions and public protests that usually follow such political statements. Confrontation of these two perspectives – the political/economical one with that of medicine – leads to a conflict of interests that can be reduced by specific agreements between politicians and physicians.

With regard to the rules, two forms of rationing may be distinguished. Explicit rationing relies on clearly defined indicators and rules, while implicit rationing is based on non-obvious intra-professional norms and rules that are elaborated by medical professionals themselves. Explicit rationing presupposes an open information exchange and usually leads to the dissatisfaction of the population. Apart from the negative social impact, the tendency of explicit rules leading to a strict standardisation in health care provision and low sensitiveness to individual patient's differences may be another disadvantage. D. Mechanic says that "explicit guidelines are likely to fall short relative to the complexity of circumstances surrounding serious illness, or to be so detailed that they are impracticable" (Mechanic, 1995). Explicit rules promise distinctive transparency and accountability in medical decision-making, nevertheless, there is no doubt that aggressive interventions of economists or managers in a regulatory way may be counterproductive.

Implicit rationing usually results from a controlled supply and limited technological equipment, and is traditionally managed by means of waiting lists or denial of care. The professional assessment of health needs and medical prognosis often includes judgement of intelligence, family circumstances (hygiene), social status, profession, and/or personality traits. Physicians are supposed to be the best-qualified persons to decide for the provision of health care services. The fundamental value that is rooted in the background of implicit rationing is the deepest trust between the physician and his patients. Disadvantage of implicit rationing is its discreteness and loss of public control over the medical decisions. It can lead to a false social illusion about universal rights to health. In vulnerable societies (like the transition societies in Central and Eastern Europe), the black market can govern the distribution mechanisms. Assertive patients (better educated, rich, powerful, and motivated) may be preferred. Social bias naturally contradicts the traditional ethical principles of medical profession; that is why physicians do not like admitting that social factors intervene in their decision-making process. Therefore, in spite of the fact that the selection process includes social bias, decisions only use medical argumentation.

In practice, rationing requires a mix of explicit and implicit rules. Despite the fact that explicit rationing has recently been advocated as more appropriate (equitable and efficient), implicit rules of rationing can be, in fact, more equitable than formal explicit rules, because they can respect concrete individual circumstances (e.g. disparity between chronological and biological age). On the other hand, "making the clinician responsible for rationing puts too much power in one person's hand" (Ellis, 1999). Knowing the double responsibility of each physician – to patients as individuals and to the community as a whole – makes the patients unsure about the advice they are receiving. And finally, a feeling of justice in democratic society is principally connected with equal chances, transparency, accountability, and public control. As Robert Spaemann (Spaemann, 1995) says, "Being dependent in the matter of justice on the fact, that the other will be fair is contradictory to the fundamental requirement of symmetry."



Czech people experienced two opposite systems of financing health care. First, a seriously underfinanced and paternalistic communist state system hiding all troubles connected with lack of resources. Political propaganda promised free health care for everybody and high scientific quality. In everyday experiences people very soon realised that all these promises are impossible to fulfil. In the eighties a joke circulated rewording a classical fairytale. The joke well illustrates the experiences of Czech people with state health care regardless of state propaganda. "Socialist health care was born and a big christening party was held. Three strange sisters were invited, the fourth was forgotten. The first strange sister declared "you will be free" the second "you will be for everybody" and the third declared "you will be of highest scientific quality". Then the forgotten strange sister arrived. She could not change the previous prophecies, so she declared: "it never will be that all three prophecies will be in force simultaneously. At least one will always be missing." The Czech experiences correspond with this joke. Health care, which was free for everybody, was not of the highest quality; new expensive technology was not for everybody and many patients were obliged to pay for it. Grey economy became a stable part of health care.

People's attitudes differed. Many citizens expressed dissatisfaction with the grey economy and with difficult accession to modern health services. But there were many patients who did not bribe physicians and did not show any dissatisfaction. Some of them believed that the Czech health care is excellent, because they did not see any other possibility. Some people considered health care to be a component of human fate. When one was in the right time at the right place, he/she was lucky and could survive. If not, it was a matter of bad luck as many other fatal situations. In paternalistic society physicians were powerful agents and the best way how to get their favour was a bribe. The bribe could be financial or in the form of some scarce service. Some goods and services were hardly available. People who could offer something to mutual exchange had a much better life than others. Physicians belonged to this privileged group and so their social status was quite high. In spite of this, the majority of physicians was not satisfied. The permanent search for scarce technology was exhausting, and the grey economy was obviously in conflict with Hippocratic tradition. It is no wonder that the decision of the Czech government to move to insurance system was almost consensually accepted.

In 1992 a public health insurance system was introduced. Very soon it appeared that the modern health care system is rooted in democratic negotiations. Many problems began to be addressed publicly and public negotiation about possibilities to solve indentified problems began. All beliefs in other possibility to solve problems gradually appeared to be false. Initially, Czech political leaders believed in market forces and state interventions were not popular. The insurance system has many market elements; therefore, the Czech political leaders believed that the system will work well without any regulatory interventions. Only a strike of physicians in 1994 forced the Czech politicians to take the risk of breaking down the Czech health care seriously. (Šimek, 1996) Negotiations between health care providers, insurance companies, and state officials began, and have lasted until now under the heading of "tripartite."

In the early phases after the introduction of the insurance system in financing health care in the Czech Republic, Czech physicians exhibited quite high moral standards. As we mentioned earlier, in the first several years after the implementation of the system in Czech health care, an enormous amount of money was spent in the system without any efficient

control. Czech physicians did not misuse relative free available resources for private profits. New modern technology and scarce drugs were purchased without notable regard on the physician's incomes. The physicians' strike in 1994 was not so much a demand for a raise of wages; much more important stimulus was the need to rationalise the flow of money in health care. In that time "salus aegroti" was really the "suprema lex".

An increasing gap between the financial resources (collected by public health insurance) and skyrocketing health care costs have required some urgent regulatory measures. Finally, some restrictions in the supply of health services were implemented. In 1997, ambulatory specialists were given an upper limit of incomes and general practitioners shifted to capitation fee (complemented by fees for special services). In hospitals, fixed budgets have been re-established according to the sum and structure of health care services provided in the previous period (called "historic limits from 1996-1997"). (Krizova & Simek, 2002)

While the first transformation period was accompanied with the boom of Western hi-tech medical care, the shift to prospective payments with upper limits has frozen the escalation of volume of care, and even led to a decrease in provided services in some hospitals. According to data provided by The General Health Insurance Company (GHIC), the volume of hospital services fell immediately to 80% on average while the minimum rate being set by the payer (GHIC) was 75% of the entire volume. Physicians warned the public that it would be no longer possible to achieve the same quality and accessibility of care. Rationing has become a matter of broad mass media campaign. Hospital departments, hospitals, or individual physicians have tried to compensate for their losses by "non-profit charity foundations". Patients, citizens, or corporate donors can subsidise the clinical care by contributions to these charities. It is not unlikely that this sponsoring had influenced access to services that were restricted by waiting time or denial – especially hip replacement, cardio surgery, eye treatment etc. Some physicians admitted that they had somehow taken the fact of sponsoring into account in course of their clinical decision-making. Nevertheless, in their opinion, "they always try to balance the health needs of different patients and not to harm patients in acute need". According to the official statement of the Czech Medical Chamber, sponsoring must not have any influence on the provision of health care services and must not be negotiated at the moment of acute health need.

A special form of sponsoring was organised by private providers who had asked their patients to pay an extra annual registration fee. They pointed out higher investments to their medical practice and better equipment. The fact that some patients do pay these fees may have an impact on medical decisions about referrals to specialists, spa treatment, rehabilitation, psychotherapy or prescription of expensive drugs. The patients may be differentiated by the fact that they showed their loyalty to their physician by registration fees. The way the doctor assesses their medical need becomes influenced by financial incentives and it is not excluded, that the economic motivation of the physician may slightly change his/her clinical view.

Concerning the most expensive technology and treatment, several therapies (e.g. cochlear and pacemaker implants, neuromodulation treatment in epileptic patients, betapherone treatment in sclerosis multiplex) have recently been regulated by a special commission. This care is financed separately from the budgetary scheme. The payment is sent directly from a special fund of the health insurance company to the hospital. The commission is competent

to review the professional indication and upon its acceptance it issues a final approval of the health care provision. The commissioners come from health insurance funds, clinical facilities, the Health Ministry, and the public. The major power is given to the professional medical assessment of the patients' health condition. Only those patients who have already been selected in previous steps by medical professionals are submitted for the more or less formal approval by the commission. Social characteristics may play a certain role; nevertheless, no patient is a priority discriminated on grounds of their social or ethnic origin.

From the beginning of 2008 after the amendment of Act No. 48/1997 Sb., "on the public health insurance" some patients' copayments were introduced. It was a small regulatory fee (30 Czech crowns, a little more than 1 Euro) for clinical examination and a larger fee (90 Czech crowns, almost 4 Euro) for examination at emergency units and charge for each day of hospitalisation (60 Czech crowns, 2.5 Euro). This legal provision provoked sharp political discussion with quite common lack of sound arguments on both sides. In an apparent conflict with law some social democratic county representatives even paid charges for patients in district hospitals from other sources. Nevertheless, the fees brought remarkable sum of money in health care institutes.

To sum it up, in the Czech Republic there are two ways how to overcome difficulties in covering health care expenditures. One is slow introduction of co-payments, both by political decisions and by private initiative of health care institutions. The second is rationing (or priority setting). The political part of rationing is mainly realised through setting economic limits for health care institutions. Economic limits result in two restrictions. The well visible restrictions are waiting lists which have become the standard part of medical care. The less observable restriction represents slower introduction of new technology.

A good example of gradual introduction of advanced technology in accordance with available resources is the distribution of Percutaneous Transluminal Coronary Angioplasty (PTCA) in the Czech Republic. Percutaneous Transluminal Coronary Angioplasty (PTCA) is an effective reperfusion strategy in acute myocardial infarction. Its introduction in therapeutic practice was an important achievement, which helped to dramatically decrease in-hospital mortality from acute myocardial infarction in the last two decades of the twentieth century. In the Czech Republic the first PTCA was done in 1981. In 1999 the method was available only in big prominent centres and for many patients it was not available. Then the four angioplasty centres (they routinely used primary coronary angioplasty from 1995) asked the question how to offer the life saving method also to patients from areas where there were no angioplasty centres. The Cardiocenter of University Hospital Vinohrady, Prague, coordinated a well known and frequently cited study assessing the safety of transporting patients to an angioplasty centre. Transferring patients from community hospitals to a tertiary angioplasty centre in the acute phase of myocardial infarction was proved to be feasible and safe. (Widimský et al., 2000)

In 2000 we did research on the equity in availability of PTCA. It was just proved that transport is safe and life saving, so we asked on distribution of performed PTCAs in the Czech Republic and on practices of transports to angioplasty centres. (Not yet published data.)

There were dramatic differences in performed PTCA between regions in the Czech Republic. In Prague patients there were performed 3 678 PTCA, it is 58.4% of all PTCA performed. It means 306 PTCA done on 100 000 inhabitants. In patients from Southern Bohemia only 173 PTCA were done, it is 2.7% of all PTCA and 24.7 PTCA done on 100 000 inhabitants.

In the second step we made a simple questionnaire survey among Czech physicians. (Final sample was 401 physicians, response rate was 26.7%.) We asked them about the availability of PTCA, about the reasons why some patients do not receive PTCA treatment, and finally, how important informal relationships between physicians in charge are.

The majority of responding physicians (71.4% yes and probably yes) considered PTCA available, only 28.6% of physicians answered no and probably no. There were significant differences between physicians from big cities and from other sites. 89.2% of those who answered no and probably no on the question on availability were physicians from other sites.

We offered several reasons why some of their patients did not receive PTCA treatment. Respondents from big cities preferred the response “the patient came to the specialised centre late” while respondents from other sites preferred response “the patient was referred to a hospital where PTCA is not performed”.

As to the impact of informal relationships between physicians on referral to specialised centre 14.2% of respondents consider it very strong, 32.8% respondents somehow strong, 30% of respondents think that informal relationships are probably not important and only 10.1% of respondents are sure that informal relationships have no impact on referral of patients with myocardial infarction.

Results of our research illustrate the process of development of new expensive technology in dependence on available resources. In the first stage new technology is available only at the big centres and there could not be equity in its distribution. In this stage physicians are aware of the lack of equity, and they are searching for ways to do the process more equitably. Chance and informal relationships of the patient and his attending physician often play an important role in the availability of the therapeutic procedure. The length of the first stage depends on the economic condition of the country, and on the pressure from experts and from members of civic society (patients’ initiatives, media, etc.). There is a difficult ethical dilemma in the situation. Should physicians actively announce to individual patients and the media that there is a lack of expensive life-saving technology? On one hand it is necessary to move things ahead; on the other hand, many people would get information about treatment that they never could use. In any case, at least the experts and politicians should be aware of existing life saving expensive technology on the basis of serious methods of technology assessment. Explicit health care policy should be developed and priorities openly discussed. According to our experiences here are the weak points of development in post-communist countries.

#### **4. Institutions of ethics – The case of ethics committees**

Due to historical reasons the authority of Churches is traditionally weak in the Czech society, and the Czech Republic belongs to one of the most atheistic countries in EU.



According to the Eurobarometer from June 2005 only 19% of Czech citizens agree with the statement "I believe there is a God". In the EU this percentage is only smaller in Estonia (16%) than in the Czech Republic. 30% of Czech citizens agree that „I don't believe there is any sort of spirit, God or life force". In EU only in France more citizens (33%) agree with that statement. (Eurobarometer, 2005) In the Czech history Catholic Church was the pillar of unwanted Habsburg monarchy, Protestantism was the religion of traditional national rivals of Czech people, and so the national Renaissance in the 19<sup>th</sup> century was based on secular education and science. This tendency was to strengthen by a communist regime. Moreover, communist ideology based on Marxist philosophy did not elaborate ethics as a special discipline. For these two reasons ethics as a discipline is undervalued in the Czech Republic. Common Czech people have no ethical language to use in everyday communication, and moral arguments are used rarely.

We could be worried about human relations in a society where there are no recognized experts in ethics, and people do not use the language of ethics. Our experiences are not fatal, ethical behaviour survives even under such conditions. On the contrary, in an ascribed situation natural moral processes are more visible. We can watch the emergence of moral rules in natural groups and the free choice as the key element in acceptance of moral attitudes in Tugendhat sense. (Tugendhat, 1993) We experience an important role of the nuclear family in moral development. Discursive nature of contemporary ethics is also well observable, as well as troubles arising from breakdowns of the discursive process. Common people usually live in their own moral space and if asked, they most often reason their moral behaviour in terms of the golden rule. ("One should not treat others in a way that he would not like to be treated.") By using the golden rule they are also able to exhibit basic levels of abstraction.

As a result of the situation, political and scientific interest in ethics is also very low. For example there are no chairs for ethics at Czech schools of philosophy and people from religious groups in a new generation of health care ethics teachers prevail. Paradoxically, in the most atheistic country of the EU, in majority of (a few) leading positions in health care ethics are theologians and catholic priests. So the only really secular institutions which are explicitly working in the area of ethics are ethics committees. Ethics committees constitute a special new version of ethical community. They represent a rare social group in the Czech Republic, where the language of ethics is used, and ethics is the matter of concern. Members of ethics committees intuitively use basic tools of contemporary ethics - plurality of attitudes, discourse, and search for consensus. For this reason ethics committees attracted our attention and we did some research on their functioning in the Czech Republic. (Šimek et al., 2008)

The ethics committees are currently remarkable institutions. They function as an authority - without their approval it is not possible to do any clinical research study. On the contrary to common authorities they do not arrive at their decisions on the basis of application of definite general rules, but through methods of ethical discourse. (Whittaker, 2005) They are relatively new institutions; the first recommendation to establish ethics committees at research institutes comes from the first revision of the Declaration of Helsinki in 1975. Therefore, there are many uncertainties in understanding their role and function and we can find some studies concerning a comparison of formal aspects of work of the ethics committees in various states of the EU (Davies et al., 2009; EFGCP Ethics Working Party,



2007; Hedgecoe et al., 2006), historical works (Glasa, 2000; Hedgecoe, 2009) or detailed analyses of some of the (discursive) practices of the ethics committees (Angell et al., 2006; O'Reilly et al., 2009).

In the Czech Republic the ethics committees were only created in 1990. It was the initiative of Martin Bojar, then the Minister of Health. He established the Central Ethics Committee at the Ministry of Health, and recommended to all major health institutions to create their local ethics committees. Within a short period of time 20 local ethics committees were established and their number has gradually grown to the current number of approximately 100. (Šimek, 2000) Functions were voluntary and unpaid, and the main qualification was the moral credit of appointed volunteers. Until the adoption of Act No. 79/1997 Coll. on medicines, the Czech ethics committees had been operating without any statutory regulation for many years. (Šimek et al., 2000) In the year 2004 the Directive 2001/20/EC was incorporated into the Czech legislation (current legislation: Act No. 378/2007 Coll. on medicines and Decree No. 226/2008 Coll.). In 2003, under the new legislation, some local ethics committees were recognized by the Ministry of Health as multi-centric ethics committees. Their task is to provide a single national opinion on multi-centric clinical studies. The local ethics committees continue to express their views on mono-centric studies, and give their opinion on the appropriateness of carrying out an authorized multi-centric study in the place under their authority. (Šimek et al., 2008)

Our research started by participatory observation at meetings and at the Summer Schools of Medical Ethics, organized by the Forum of Czech Ethics Committees. Furthermore, we carried out half-structured interviews with the members of the ethics committees, with representatives of contracting authorities, with examining doctors (investigators), and 1 interview with a representative of the State Office for Drug Control. Six focus groups were organized with the members of the ethics committees. To get an overview of the distribution of some of the attitudes expressed in the interviews, a simple questionnaire survey was realized among the members of the ethics committees. The response rate was 11 % so it was only of an illustrative nature.

If we try to generalize our experience, the members of the Czech ethics committees are people willing to selflessly do something more for the "common good". They are not authoritarian in their role; they prefer agreement over all other possibilities of conflict resolution. Like in other European countries (Klingmann, 2009) only about 1% of studies is rejected. Significantly, more frequent are comments intended to modify a project, about one half of projects are adjusted based on comments from an ethics committee. In the interviews and discussions the members agreed that they feel better in the role of an advisor rather than an arbiter.

The chairman of the committee usually has natural authority. The next important person is the secretary. S/he is the guarantee of an error-free bureaucratic part of the work. Discussions of the committee are sometimes more, sometimes less discursive and usually take place in an atmosphere of tolerance; anyone who so desires is given an opportunity to express his/her opinion on the discussed matter. Most often the resolution is adopted by consensus, only rarely is it necessary to vote. Remuneration for the work was never raised as an important issue.

Most members of the ethics committees are health professionals. Laymen (most often theologians, lawyers, civil servants) are members of a committee mainly because the law requires it. The relationship of the health professionals towards the laymen is friendly, but it is possible to see some reluctance of the ethics committees to accept a larger number of lay members. This is not unusual for the Czech Republic. A similar situation was noted in a Dutch study (Caron-Flinterman et al., 2009) and it is possible to notice a call for greater involvement of patients and their organizations that are already in the preparation of clinical trials. (Wrobel, 2009)

There are certainly many reasons for this hesitation. The common basis we see in uncertainties and tensions faced by the ethics committees. (Barke, 2009) A good clinical trial proves common laws valid for everybody, a good care wants to improve the health and quality of life of an individual patient. (Mol, 2006) The ECs members might feel that there is too much that they are not able to control when they assess the ethical legitimacy of a clinical trial application. (DeMets et al., 2006; Taylor et al. 2008) Given the absence of pre-given answers, the ECs have to actively construct what counts as (an) ethical (issue). The legitimacy of their arguments and decisions is built on heterogeneous sources and performs various functions. (O'Reilly et al., 2009)

The health professionals usually see the benefit of the ill in maintaining or improving their biological health. It is true that preservation of biological life and health is the most crucial task of contemporary health care systems, but the benefit of the ill can be viewed from many different perspectives. (Mol, 2002) We can understand that the health professionals' hesitation to accept the laymen among themselves could also be caused by their fear that other views on the benefit of the ill could prevail in the discussion.

Another common characteristic of the members of the ethics committees is their problem to explain in detail, why they do their work, and what it brings them. When asked questions on their motivation for being members of an EC, respondents felt uncertain and uneasy. Answers were usually very poor and largely formal. The members of the ethics committees most frequently named the necessity and usefulness of their work, without specifying in what exactly they see this necessity and usefulness. Education is not recognized as an important aid. In the interviews the need for education was never mentioned spontaneously. Maybe the controversial role of the ethics committees is reflected here. It is very difficult to be an ethical body and an office at the same time. Underscoring the importance of education shows that members of the Czech ECs do not get the message from the outside world that the controversy of their role can be resolved through education.

In 2005 the civil association, the Forum of Czech Ethics Committees, was established. Twice a year the Forum organizes discussion meetings, and in the summer, the School of Medical Ethics. About fifty people take part in these activities. Participation in the discussion meetings is not formal; the members of the ethics committees come with a visible interest in the matter, and they vividly discuss topics of their interest. Even at these discussions there is an atmosphere of an unusual tolerance. Although opinions sometimes largely differ, serious disputes do not arise.

From a theoretical perspective we can see the Czech ethics committees as more or less informal communities of people having similar sets of attitudes, tasks, and practicalities.

Contemporary sociology offers some concepts that could help us better understand what is going on (or could be) in the development of ethics committees. (Simek et al., 2010)

Ethics committees could be understood as an ethical community. An ethical community is originally the concept of I. Kant. (Kant, 1996) (Wood, 2000) We cannot fully apply the whole concept; instead, it could be an inspiration for us. The term could be used only in a weak sense.

In the current world of secularization and globalization, religious communities lose their strong influence. People who share the same values rather create informal groups or communities. The members of the ethics committees form a community of people willing to devote a bit of their time and effort to the common good. Their participation comes from free decision, and their motivation is largely moral. In their effort they do not seek prestige or material benefit. In this sense, the members of the ethics committees fulfil some of the characteristics of Kant's "ethical community". There are also substantial differences. Kantian ethics is based on duty, to be a member of an ethics committee is a free choice. Religious position is not the unifying element. A community of ethics committees' members is not and will not be universalistic; it will be bound to a particular common task and to a particular common area. The unifying element of this community is a common specific work task – the protection of subjects of clinical trials.

Another concept that could be applied is the concept of epistemic community. Peter M. Haas defines an epistemic community as "a network of professionals with recognized expertise in a particular domain and an authoritative claim to policy-relevant knowledge within that domain". (Haas, 1992) There are four elements in his definition and the Czech ethics committees fulfil two of them.

They have a shared set of normative and principled beliefs which provide a value-based rationale for the social actions of community members (principles of the Good Clinical Practice and related codes and legislation). In the ethics committees one can observe a common policy enterprise – that is, a common set of practices associated with a set of problems to which their professional competence is directed, presumably out of the conviction that as a result, human welfare will be enhanced.

The other two points of the definition – shared causal beliefs and shared notions of validity – are fulfilled by scientists and experts in the ethics, who, on an all-European scale, work together to define principles of the current research ethics. These experts meet and discuss at preparation of documents, as well as at various conferences, and they publish in professional journals. In this way they create an epistemic basis for addressing the problems of security and preservation of human dignity of the research subjects. (Salter & Jones, 2005)

The Czech ethics committees can be considered a local embodiment of the international epistemic community of investigators and bioethicists, who on the supranational level of European directives and international harmonization efforts defined the framework and rules of their operation.

The last inspiration we can find in the concept of communities of practice. (Wenger & Snyder, 2000) The communities of practice are characterized by three main features: 1)

interest and even passion for a particular area, 2) community – they engage in joint meetings and discussions, help each other, and share information, build mutual relationships, meet both in person and “online”, and 3) experience and practices – they are united not only by the interest in the same thing, but also by sharing sets of conduct, by the way they deal with things and situations, by the effort to learn to do things differently, to learn things they care about, to do better.

The ethics committees basically operate on these principles. Within the framework of the regular meetings organized by the Forum of Ethics Committees as well as email conferences and website administering, there is an exchange of views, a mutual enrichment, and learning from the experience of others. Discussions are often vivid, and the ethics committees do not agree on many things. However, they share the effort to change something, to learn from each other, and to improve. They also enter into discussions with those from the “other side”, with the contracting authorities, and these discussions are interesting and beneficial for both parties.

The ethics committees are new institutions and their roles and functioning are not yet fully stabilized. The basic existential dilemma is their dual role. It is not easy to keep balance between the role of the ethical agents and the role of officials and experts. Moreover, the role of an ethical agent is difficult. Ethics committees assist at keeping ethical standards in the field of continually developing clinical research. For this they need a certain range of knowledge, but also ethical creativity. By ethical creativity we mean an ability to apply, in a creative way, recognized principles of good clinical practice in new unexpected situations. It must be rooted in ethical honesty; creativity can have different meanings.

The ethics committees are, and will increasingly be, under pressure for transparency and accountability of their work, and they will have to open to a greater number of laymen. (Avard et al., 2009; Kelly, 2003) This represents a challenge for the future. The members of ethics committees will need to better elaborate the discursive part of their work. They should better understand what they are doing and why they do it. They should learn to use arguments to justify their standpoints and decisions.

Here are reasons why they will need a good education even if they underscore it. We attempted to apply the concepts of the epistemic community, the ethical community, and the community of practice to the phenomenon of ethics committees. It offers certain concepts, perhaps visions, which could become a functional basis for a discussion about the role of the ethics committees in the near future.

## 5. Conclusions

Medical ethics is a Cinderella among other medical disciplines, but in a synergy with other forces (EU legislation, international contacts, development of components of civic society) it has some impact on the development in the Czech Republic. As a discipline, medical ethics suffers from lack of experts, insufficient amount of research projects, public presentation, periodicals, and publications. Medical ethicists are not considered to be relevant stakeholders in health policy making or in discussions on the shape of the Czech health care system. Positively, it has been established at each medical faculty and now it is an obligatory

part of health care providers' education. Some research was done and interested persons meet at conferences and seminars. In our survey we presented some results of ten years' research.

Informed consent was in the Czech Republic implemented from above (EU legislation) and without previous discussions among stakeholders. For this reason it is often understood as a mere formal instrument. Due to historical reasons everyday democratic negotiation is not well developed, and therefore, shared decision making is not an issue in discussions about the implementations of informed consent in the Czech health care. In this specific context the call for a reliable and trustworthy physician is better visible.

Rationing in the Czech Republic has its specific features thanks to a more prominent lack of resources and thanks to the transition from a paternalistic state health care system to democratic insurance based system. It took some time to understand the need for implementation of regulative measures in the system. Only gradually did all the stakeholders learn the need for negotiations. Official co-payments of patients were unusual and their acceptance in public was quite difficult. Public debate was too much emotive and lacked sound arguments. We could also notice how the slowing down of high expensive technology development could help to overcome deficiencies in resources.

Ethics committees in the Czech Republic represent a special institute of secular ethics in the country, where ethics is underscored both in academia and in everyday communication. We propose to use concepts of ethical community, epistemic community, and community of practice, to better understand the role and mission of ethics committees.

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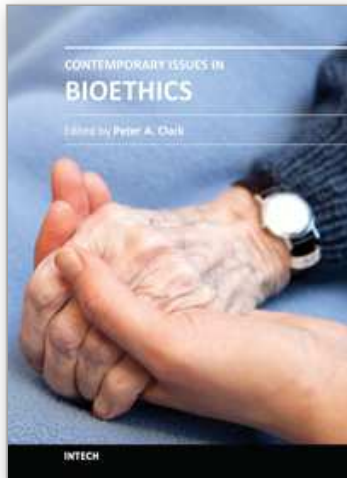
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