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ABSTRACTS

Pandemic uncertainty - the ethics of mass vaccination

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During spring 2009, an increasing number of cases of a new and potentially fatal influenza were reported from Mexico and the US. The impact was enormous. Media reported about a deadly plague spreading around the world. Late in the summer, WHO declared that the highest step, 6, on the epidemic scale was reached – a pandemic was declared. This activated the agreements that several countries had with the drug companies, and the production of vaccine started.

However, it was soon clear that the situation was difficult to judge. From the Southern hemisphere, there were reports that the infection was mild. But there were also reports of young persons with very serious courses of the new influenza. In short, experts were not in full agreement – and on top of this, there were hesitations about the vaccine, its potential side effects and also its capacity to induce immunity.

The health authorities in different countries chose different strategies. The most common was to restrict vaccination to risk groups, meaning that between 5-10% of the population were vaccinated, predominantly older persons (in spite of the possibility that this virus was more dangerous for those under 30). Sweden, however, the authorities under heavy pressure from media and from the political sphere, chose a line of massvaccination. 5,3 million persons were vaccinated from mid October to mid December 2009 to the total cost of around 500 million euro. By then, however, it was clear that the infection was not the world wide new plague – rather an influenza variant with lower virulence than the ordinary seasonal outbursts. About a year later, the first reports on the appearance of clusters of new cases of the neurological disease narcolepsia came. Most cases were reported from Sweden, Finland and Norway, of which the two latter had chosen a mass vaccination line. Around 160 young persons are estimated to have fallen ill with narcolepsia as a side effect of the vaccination, though the number is uncertain and causality can in some instances be questioned.

The tragic outcome raises a number of central ethical questions, related to action under medical uncertainty. Among these questions are:

- On what evidence may decisions of massvaccination be taken?
- Which conditions for agreements with drug companies are acceptable?
- How should potentially serious side-effects be weighed against the unknown risk for wide spread serious disease with many fatal outcomes?
- To what extent is the acceptance of an offer to be vaccinated really to be seen as informed consent?
- Who is responsible for compensating those who got narcolepsia?

I will argue that any retrospective analysis of the step to mass vaccinate must depart from an analysis of the decision-making situation at the time – how much time there was for expectancy, what sources of information were used, how the reliability of this information should be judged and how inevitable uncertainty ought to be judged. It is concluded that the chances to obtain a reasonable degree of informed consent were small, that the invocations to solidarity through vaccination were largely misguided. Finally it is argued that the health authorities, when recommending vaccination of the whole population, were in fact redistributing suffering from those who would have fallen ill, and did not do that due to the vaccination, to those who had the side effects of the vaccination, which are not likely to be the same persons.

Changing technologies, changing responsibilities?

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The notion of individual responsibility is given considerable attention in current bioethical debates. Especially in the context of health care distribution and justice, the concept of individual responsibility is central to the debates and much depends on how much an individual is thought to have control over her own life. Alternative approaches have different views of this control.

Even though views and arguments are diverse, majority of the literature admits the limits of individual responsibility in a person's possibility to control her health and well-being. Placing most of responsibility for health to the individual is not straightforward because the influence of cultural, societal and socioeconomic factors to people's lifestyle and choices is remarkable. Apart from the influence of socioeconomic and cultural issues, the role of the environment is an important determinant of health also at a molecular level. Epigenetic modifications altering gene expression are dependent on the environment in the broadest sense of the term, including prenatal conditions and physical, chemical and social environments. Thus, the control that a person has about her life is decreased by environmental factors of both molecular and societal mechanisms, and the preconditions for full personal responsibility – informed, voluntary and uncoerced choices– are diminished.

However, when the discussion about health care and well-being in the future is compared to the present one, a major difference can be noted: the issues concerning health and well-being seem to be reduced to genetics and choices about genetics, as if the present environmental effects through epigenetics and societal issues did not exist. It seems that the notions of health and well-being are very differently constructed when it comes to future technologies, as it is assumed that a person's characteristics could be straightforwardly influenced through genetic interventions. Suddenly the comprehensive responsibility for a person's health and well-being is directed only to the person herself: by choosing the right genetic traits for her or for her progeny and being able to use these good genetic traits by turning them into success and happiness.

This notion is a fallacy because despite new genetic technologies, the environment will continue to affect a person's life both at a molecular and societal level. The fact that the discussion about the future's health and well-being concentrates on remarkably limited issues is questionable because it leads the discussion about personal responsibility to a fallacious direction. If personal responsibility for one's health and well-being is overemphasized, we run a risk of missing more attainable and possibly more efficient means of improving the health of the population. Although the development of new biomedical technologies is crucial, it is a mistake to think that the most important actions concerning health and well-being of population lie in genetic technology.

Technological innovation and the precautionary principle: friends or foes?

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The precautionary principle (PP) becomes increasingly relevant in our technological societies. This standard urges policy-makers to make decisions about new products or technologies when there are good reasons to believe that they may have a negative impact on the public health or the environment, even if there is not definitive evidence of the risk yet. In other words, this new principle intends to anticipate problems before they arise or before

scientific proof of harm is established. Ultimately, the PP is no more than a call to caution addressed to policy-makers about uncertain risks posed by new technologies. Inspired on this principle, the wisdom of policy-makers consists in finding an adequate balance between two extreme positions: on the one hand, an irrational fear of new technologies for the sole reason that they are new, and, on the other hand, an irresponsible, passive attitude towards products or activities that could really be harmful.

The overall scope of this presentation is to argue that, far from being antithetical to science or to technological innovation, the PP aims to promote alternative modes of development (safer and cleaner technologies) in order to ensure a good quality of life for present and future generations. After having summarized the conditions for a reasonable use of the precautionary principle, this presentation will briefly highlight recent developments in the recourse to the PP.

Are “undue inducements” a problem for benefit sharing?

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When medical research is conducted in resource-poor countries, the results are often primarily for the benefit of health care systems to which the research participants have little or no access. In such cases the research participants carry the burdens of participating in the research, while patients in developed countries enjoy the benefits. To correct this injustice, various benefit sharing frameworks have been proposed. One of the main problems for benefit sharing is how to avoid the problem of undue inducements. If people in resource-poor countries are offered significant payments or health care services which they would otherwise not have access to, the fear is that they might be “unduly induced” to participate in the research. Such undue inducement is prohibited by most international research ethics guidelines. In this paper I discuss the meaning of “undue inducement” and in what ways inducement may be perceived to be ethically problematic. I argue that the problem of undue inducements is insignificant and should not be used as an argument against benefit sharing frameworks.

Responsible Return: Consent for Feedback from Biobanks Research

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When population database research started, it was intended to provide basic general knowledge and not to reveal information about individuals. This has shaped the policies and ethical frameworks for population database research. Recently, much attention has been focussed on return of unexpected findings that could be of great relevance for individual contributors. In this paper, I deal with the question how this information could be returned to individuals in a responsible way. First, I consider this in the case of participants who never expected return of individual findings. I evaluate three main options for this task. I argue that participants only have strong autonomy claims for not knowing results while they have weak autonomy for obtaining information. It is weak autonomy in the sense that it should be limited by professional responsibility of health care professionals and researchers. In order to secure that, I argue that return of individual findings should only take place in a context of genetic counselling. Conducted in the form of dialogue, counselling provides the proper conditions for autonomy in this context. I then address the task of designing an appropriate

consent for return of unexpected findings about individuals. In this context I ask how useful the ideas of restricted informed consent, open consent and wide authorization for conditions of use of samples in biobank research are for the challenge of managing feedback of research results to individual contributors. I argue that the most fitting way is to formulate an authorization for conditions that need to be met. In all cases, regardless of whether participants have consented to receiving individual results or not, researchers have perfect duties only to respect the right of those who prefer not to know. In the task of returning results, they have imperfect duties that require contextual judgment limited by a sensible framework for conveying the results in a trustworthy and caring way.

Genetic enhancement in humans: between the good, the useful, and the prevention of risks

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During the last decades, genetics has been at the center of discussions in ethics, science, religion, politics, law and public opinion. On the one hand, there are fantastic ideas of a perfect human being with determined characteristics, the possibility of eradicating terrible diseases and to revive extinct species of animals and plants, and the dream of becoming the co-creator of evolution – all this is not just bold projects of the far-away future, but real goals set by genetics. But, on the other hand, beyond the great promises of science and the economic profit of genetic technologies, there is the potential danger of a total control over future generations, the possibility that human beings become a sort of artifacts and lose their intrinsic value, and the emergence of new social inequalities.

The way out of this dilemma is not to ban genetic research and technologies; their benefits are clear and attractive to humankind. But we must appeal to ethical principles to find an adequate balance between, first, the *good* as a particular kind of spiritual benefit in the sphere of human behavior; second, the *useful*, understood as the result of the focused and rapid improvement of the environment and the human body, and, third, the prevention of serious *risks* resulting from genetic experiments.

Do the achievements of genetics really increase the amount of the good in modern world? This question is crucial in our search for some ethical imperatives that could harmonize the long-term perspectives of human technologies with the interests of future generations.

A just framework for managing drug shortages and hoarding

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Record numbers of drug shortages, including generic injectable drugs, (e.g. Methotrexate, used to treat adults and children for osteosarcoma, acute lymphoid leukemia treatment, and lung cancer, among other conditions) have been reported since 2010. There are several reasons for shortages such as natural disasters, the rise of new medical evidence, which may instigate a change in demand for products, stringent DEA regulations, manufacturing quality problems, shortages of raw and bulk materials, recalls of affected or related products, and company business decisions to stop drug production due to mergers, funding issues, or problems with internal oversight and quality control, for example (Jensen et al. 2002; Fox et al. 2009).

There are several negative effects of drug shortages including, but not limited to, an increase in health system costs and work burden, patient and provider frustration directed at pharmacies and pharmacists, the inability of providers to effectively care for patients, unexpected delays or termination of research studies, and unanticipated interruptions in therapies, e.g., chemotherapy, which affects the continuity of care. Furthermore, drug shortages can emotionally impact patients and families who are counting on treatments and last chance therapies to cure life-threatening diseases, e.g., February 2012, Methotrexate, used to treat leukemia in children, became unavailable.

Related to the numerous effects of drug shortages are practices that may be unethical, or perceived as unethical, among clinicians and pharmacists, including the hoarding of limited drugs, purchasing drugs from the grey market, or secondary wholesalers, unjust allocation and decision-making, and a general lack of full disclosure and truth-telling whereby patients and providers may not know why the shortage has occurred.

To circumvent many of the negative effects of drug shortages, efforts have been made at institutional, state, and federal levels. For example, January 2012, the federal government implemented an interim rule that requires pharmaceutical companies to give the Food and Drug Administration (FDA) a 6-month advance notice of potential disruption of supply of critical FDA-approved drug products; failure to report may result in the withdrawal of new drug applications whereby companies may no longer market their drug products. Institutions are responding by developing and implementing policies requiring that patients and families be notified of drug shortages in a timely manner, or requiring providers to purchase drugs directly from companies and reputable wholesalers, and not from the grey market. However, on an institutional level, many hospitals and clinics are struggling with the fair distribution of limited drugs, many of which may be available for only a short time.

In this paper presentation, an ethical framework of justice is presented that addresses and aims to resolve some of these problems associated with national drug shortages. Specific cases surrounding the unjust distribution of drugs and the lack of adequate access and availability will be presented. Through this framework, which builds upon existing perspectives of priority setting and Martha Nussbaum's capabilities approach, future policies may be developed within clinical institutions to prepare for and resolve ethical dilemmas pertaining to drug shortages.

Fairness instead of altruism: post-mortem organ donation and the moral duty of cooperation

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Transplantation medicine belongs to one of the most important and well established field in modern medicine. Due to the enormous improvement of and innovation in organ transplantation the life of many seriously ill patients has been saved. In organ transplantation medicine there is still (despite all its technological innovations) an enormous gap between available organs and demand. In transplantation medicine altruism has played a central role throughout the history of the field. Even today, altruism is considered to be an essential moral concept in the field of organ transplantation. A large number of medical associations and organ procurement institutions (the United Network for Organ Sharing (Unos), the American Society of Transplantation (AST), The World Medical Association (WMA) etc.) emphasize altruism as a morally suitable basis for choosing to donate an organ. However the model of altruistic giving has not yet led to an increase in the willingness to donate. In addition, the possibility to actually develop a technology to produce genetically tailored solid organs still

remains a utopian idea. In this talk I will argue that not only technological innovations, but especially new ethical principles guiding innovation in public health in organ transplantation medicine are requested.

For this purpose, I will first examine to what extent altruism arguments are likely to increase the willingness to donate organs. The working hypothesis is that altruism arguments are unsuitable for this purpose. In order to demonstrate this, I will first deal with the concept of "altruism." Despite all the different meanings of the term, altruism is always related to a free action, which is defined by either self-abandonment or self-sacrifice for the benefit of another person's well-being. In a second step, I will be concerned with the voluntary nature of altruistic actions and present this as a problem for the control of organ shortage. Since altruistic actions are selfless or self-sacrificing, they cannot be forced upon an individual. Altruistic actions are therefore often referred to as an "act of giving." Due to the ethical and political challenge to tackle organ shortage – and that means to make the survival of seriously ill patients possible or to improve their quality of life – we urgently need binding measures. For that purpose, only a moral obligation to donate is suitable, not altruism arguments.

In a third step, I will suggest that not altruism but mutualism, or better, justice (as fairness) is the key word in promoting organ donation. Mutualism implies a cooperative action in which there is a reciprocal relationship with mutual benefit. Cooperative actions permit a balanced ratio between the care of oneself and the wellbeing of a community. Organ donation should therefore be understood as a form of social cooperation. The hypothesis here is: the argument "to help others, also helps me" could be more effective in combating organ shortage than altruism arguments. Finally, I would like to draw attention to the meaning of justice for the success of cooperative actions. Only when fairness is assured will cooperation persist.

Big pharma: innovation and the common good

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Many human resources are held *in common*, including areas of common land, public buildings and some natural and intellectual assets to which people have certain traditional rights of access. By contrast, other tracts of land, and some buildings constitute private property, and written works, audio or video recordings often enjoy a period of copyright, and qualifying inventions such as novel therapeutic drugs can be safeguarded by patent protection. Patents which must demonstrate novelty, non-obviousness and feasibility provide their holders with a limited period of monopolistic control in exchange for full disclosure. So-called *property rights* ensure that those who have "mixed their labour, and joined to it something that is their own", thereby make it *their property*. Public access to these latter privately owned *properties* requires consent or purchase from their legitimate owners.

A major portion of public health funding is devoted to treatment of a wide spectrum of common and less common diseases and illness. The healthcare professions, and more importantly patients are highly dependent on research-based pharmaceutical companies (Big Pharma) for a continuing supply of new, safer and more effective medicinal drugs. These organisations are an important part of the Western capitalistic economy and wholly reliant on the monopolistic patent system. The industry is highly competitive and tends to concentrate on researching the financially lucrative therapeutic domains that predominate in the West, and because of the high costs of R & D, and long development time-scales, new drugs and vaccines are almost inevitably more expensive than their predecessors. Product availability differs markedly across the world for reasons of regional disease spectrum and above all, affordability. Developing countries are largely dependent on older off-patent generic

equivalents or occasionally may manufacture under licence. Many diseases are neglected by Western research because of low incidence or potentially low return on investment in financially poorer markets.

There has been continuing criticism of Big Pharma over many years because of its perceived profiteering and highly selective approach. Even in the West, patients suffering from some serious life-threatening or terminal diseases do not have sufficient access to expensive novel medications. Western governmental health departments are frequently under pressure to provide additional funding, to better control market prices and to properly address questions of distributive justice in health care. Even initiatives such as that of the Trade Related Intellectual Property Rights Agreement (TRIPS) which are intended to tackle the problems in developing countries are criticised as making access to new medicines even more difficult.

Is there a potential solution that will satisfy all parties, which would provide equitable universal access to new drugs without stifling innovation? It is doubtful, but the paper will summarise and evaluate the major criticisms and examine some suggested approaches toward resolution such as “open-access drug companies”, and alternative systems of rewarding patents. In particular, the crucial importance of an increasingly greater awareness of Big Pharma’s societal responsibility beyond the “financial bottom line” that takes account of the common good will be explored.

Child well-being and circumcision

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Male circumcision has, contrary to female circumcision, for long been seen as a rather harmless medical procedure. However, nowadays circumcision comes more and more in the focus of law and morals. In a recent, highly contested verdict the judges of the Cologne county court in Germany argued that the circumcision of a four year old boy was medically not necessary. Hence, according to the Cologne judges, the boy’s right to physical integrity was violated. As a consequence, Jewish and Muslim communities in Germany feel threatened in their cultural identities, as the parental autonomy – the right of the parents to determine what is in the best interest of their offspring – of Jewish and Muslim parents could be confined. What we find in this situation is a deep-seated moral conflict between parental autonomy and children’s right to physical integrity that is the well-being of children. I will offer an analysis of this moral conflict: The main question is whether, in the case of (male) circumcision the state should interfere with parental autonomy. This question will be addressed by firstly clarifying the notion of parental autonomy and by secondly explaining which rights children have. After getting at clues with the notion of children’s rights, we can go on asking if circumcision endangers those rights.

Medicalization, public health and postmodern culture

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There is a Janus-faced relationship between the growing tendency of medicalization and the public health movement. On the one hand medicalization has ‘disenchanted’ consequences for it seems that more and more health problems are coming to the surface of Western societies (worried well) despite the efforts public health has made in the last decades, on the other hand the public health movement can be part of medicalization processes by way of

propagating – therefore accepting - new diseases which were partly outcomes of medicalizing tendencies.

As heuristic tools, the lecture will propose four categories creating a kind of frame of reference for situating medicalization in the post-modern culture.

On the one hand there is an internalizing discourse which emphasizes the bodily distress together with marginalizing the environment of the body in the creation and foundation of diseases. In contrast with this decontextualizing attitude the externalizing discourse counts with familial, social, cultural aspects of the disease phenomenon. (M.Lock- V.Nguyen)

On the other hand, the agential way of thought uses a kind of humanistic approach in which health-illness issues are formed in a meaningful and idiosyncratic person-centred narrative, while in the pathological approach the health problems are expressed in a causal way which means that things happen 'at the back of 'the person, outside his/her existential life, but in his/her biological life. (David H. Jacobs, David Cohen)

Two pairs of categories can be created from these above mentioned four ones:

- externalizing – agential
- internalizing – pathological

The first pair describes the so called CAM practices, while the second pair can show some basic qualities of our mainstream medicine.

The first attitude makes a 'clear' medicalization almost impossible, because beside biological ones, other aspects of human life are always present – from personal to cultural – in the ideologies which surround ill-health.

The second attitude is the proper one for medicalization, because by way of closing health and ill-health phenomenon in the body and disconnecting it from broader existential components, it makes a deep and thorough translation of these latter issues into biological ones.

The disease labels can change the moral confusions of the post-modern culture into something meaningful in the reductionistic categories of biomedicine. The border between health and disease has been fading away and the disease can be a more or less essential part of the contemporary identity.

If people feel that they are not able to control their lives, then they try to avoid responsibility by way of 'getting a disease' which is by definition outside their capacity of control; pushing these onto the field of medicine can raise the hope that they can be cured with technological means.

The constructed new identity of being ill can provide some security and order in an insecure and disordered life. An anorectic patient's claim seems to support this for she says that 'everything is in order' when she practises her vomiting ritual. Thus the patient can find some *order* in the phenomenon which the physician considers to be a *dis-order*.

Ethical "live surgery"

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Medical teaching to either students or peers is one of the inherent obligations of every physician and is part of the moral heritage of the medical profession throughout the ages. The Hippocratic Oath obliges the physician to teach the practice of medicine to his sons and to his teacher's sons and to all those who wish to be taught and take the Oath.

One of the mostly used methods of acquiring the art of medicine and especially the practice of surgery is by observation. Medical records both in writings and in graphical arts, throughout the ages provide abundant evidence for the presence of spectators watching

physicians and surgeons performing their work. The term "Operating Theater" is a sound indicator of this phenomenon.

Technical advances and breakthroughs in the field of television broadcasting, information technology and the miniaturization of electronic and optical devices especially since the second half of the 20th century have made real-time broadcasting of surgical and other invasive procedures possible. This is achieved with a quality and acuity surpassing that can be attained by watching the procedure directly. Moreover, these technical advances allow demonstration of medical procedures to an unlimited number of observers in real time without their physical presence in the operating room and practically with no limit on the distance between the observers and the site where the operation is being performed.

In recent years live surgery sessions have become the highlight and major attraction of many professional meetings especially those of surgeons, cardiologists and other physicians who perform a variety of procedures. Live surgery however, raises moral questions as to preserving patients' rights and the assurance of quality of care given to them. Several professional societies have questioned its real contribution to the teaching and training process and pointed to its potential harms. Some of those societies issued formal regulations limiting its use or even banned the practice from their meetings.

The talk will focus on the advantages, disadvantages and ethical implications of live-surgery and suggest ways to limit its potential perils.

Altruism, altruistic punishment and giving priority to organ card holders on a waiting list for transplantation

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In 2008 Israel enacted a transplantation law which grants priority to donor card holders who become needy of an organ transplant. This meant to create and incentive to donate, and to prevent a "free rider" situation, in which non-donors compete equally over organs when they need them. In this presentation I will argue that despite its intuitive appeal to fairness, the prioritization scheme is immoral and apparently self-defeating as well. I will argue that the scheme of rewarding is also a scheme of punishment; that it is incompatible with the universally accepted values of basic and public healthcare and even incompatible with its own internal logic of reward. The source of the moral error lies in the use of allocation of positional goods in a problem of absolute goods, even if scarce and in the human tendency to place fairness above self-interest, an attitude known as "altruistic punishment". Moreover, the prioritization scheme legitimizes refusal of donation on the very grounds on which it stands – personal risk and benefit calculation.

Evidence-based practice, therapeutic expertise, and music therapy in America and Europe

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Establishing the scope of medical and allied practices requires a critical examination of the nature of medical expertise and the concept of therapy (and therapeutic expertise). This presentation will look at some aspects of these concepts and some of the questions surrounding medical expertise and therapy as they relate to medical practice—and attempts to limit that practice—and especially to the application of the concepts to the expressive therapy

field of music therapy. The presentation will begin with establishing the theoretical framework of evidence-based therapeutic practice (EBTP). The presentation will explore linkages between this framework and 19th and 20th century debates (including the Flexner Report) surrounding medical expertise and therapy, leading to current debates and medico-political struggles. Given the theoretical framework and historical background and with contemporary music therapy (as a therapeutic discipline) grounded in a research-based set of practices and qualifying certifications, there is a reasonable case for the claims of therapeutic expertise and effectiveness in contemporary music therapy. The presentation concludes with an examination of the challenges to the recognition of that expertise in America and within the European Union, including challenges to the European Music Therapy Confederation's aim "to promote the further development of professional practice in Europe."

Rethinking the promise of technology in an age of austerity

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In the last century major advances took place in health care. The emphasis in health care shifted from the focus on a medicine as a healing art to medicine as an endeavor shaped increasingly by technology and science. The power, controls and priorities that dominate health care today moved from community based and clinically oriented practices to institutional medicine which too often emphasized research, technology and cure at the expense of human well-being.

Major discoveries brought welcome changes. Death from childhood infection is markedly diminished. We witnessed major advances in the treatment of heart disease and cancer.

Significant demographic changes are taking place worldwide, including an aging population, smaller families, greater mobility and a decline in the number of working age adults. In certain countries sex selection is complicating the picture.

There have been major discoveries linked to advances in basic science and technology. As we approached this millennium it was expected that significant advances and innovations in technology would occur in health care.

We continue to link a better future to innovations and technological advances. However, in many countries the current expenditure for disease prevention and health care is approaching the limit that those societies can allocate. There are, other basic human needs that must be met including a safe, sustainable and nutritious food supply, clean water, adequate housing and basic education.

It is anticipated that there will be discoveries related to genetic research with increased ability to modify gene structure and to provide treatments targeted for individuals based on their natural or modified genetic structure. Other areas in which we can anticipate major research efforts are those involving better understanding of brain functioning and the neural pathways. This is appropriate considering the ageing population and the incidence of mental illness autism, and Alzheimer's and mental illnesses.

Appropriate therapeutic modalities may be expensive to develop, costly to produce and may involve unforeseen vulnerabilities or increased risk. Although genetic discoveries and innovations may solve some problems, new unanticipated problems may occur as the result of genetic interventions. Basic research is clearly needed to better understand disease markers in the human genome, the relationships of stem cells to cancer and the neural pathways in the brain. The funds allocated to such projects may limit the funds available for other needs. Diagnostic and therapeutic interventions have been increasingly the preserve of entrepreneurial individuals and entities. Will the innovations coming from basic and clinical research benefit

the many or only benefits a few? Will the results be significant improvements and advances or only changes that are simply modifications?

There is no evidence that technology has made us a peaceful, safer world or that it will make us a healthier world. The appropriate measure of success from innovation and technology will be in its application. While celebrating medical advances this presentation explores the dark side of research and balancing other needs. It calls for moral reflection and societal dialogue.

Oh, Yeah! Male Contraception (At Last!)

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Women of reproductive age have a lavish smorgasbord of forms of contraception available to them—foams, gels, female condoms, pills, patches, rings, injectables, subdermal implants, IUDs, scheduled abstinence, tubal ligation, and chemical sterilization. Males, in contrast, have just three: withdrawal, the condom, and vasectomy. That’s all, guys.

However, extensive research in modern male methods is underway in many countries; these include hormonal methods, heat-based and ultrasound methods, vas occlusion, native-plant preparations, and more. While none is actually on the market yet, several are on the horizon.

Objections to new male contraceptives can be expected from certain religious groups, from those concerned about side effects and failure rates; or those foreseeing threats to male pride. Particularly important is the objection from some feminist quarters, that the move to male contraception would leave females more vulnerable. They warn: “Could you really trust a man who says, *don’t worry, I’m on the pill?*”

This talk employs a thought experiment, *M’s Conjecture*, to expose the faulty assumption here, that one’s enough, either female or male contraception, but not both. “Double coverage,” the use of highly effective long-acting reversible contraception by *both* male and female in sexual intercourse, on the contrary both reduces the failure rate and enhances reproductive rights for men as well as women, since both parties now can expect to have only the children they actively wish to have. With double coverage, the default in human reproduction is reversed, so that procreation requires active, positive choice. Would this mean that childbearing could no longer be left to chance, or that one partner could trump the other’s procreative desires? This talk considers whether these would be losses or gains.

The title of this talk, *Oh, Yeah! Male Contraception (At Last!)*, may suggest that these male methods are already available. They aren’t, quite. But what is here right now, as we prepare for the entry of male methods into the market, is a critical choice-point in how we think about them. Are they to be marketed as alternatives to female contraception, the likely way, or as complements? Should health insurance cover both male and female contraception for a single couple? What should physicians recommend in counseling individual patients, or couples? In general, how can we conceptualize the new methods of male contraception to avoid the unwarranted assumption that *one’s enough*? We need to do this now, before these new methods actually arrive.

Inequality income indices: critical analyses for public health considerations

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The traditional home of inequality measures is economics, but they have found applications in some instantiations of social justice. In particular, the Atkinson index, derived for

inequality of income distributions, has been described as a “member of the generalized entropy family of indicators, explicitly incorporating normative judgments about social welfare” (Atkinson, 1970; Yitzhaki, 1983; Donaldson and Weymark, 1980; Levy, Chemerynski, Tuchmann 2006). Atkinson Index (AI) is defined by:

$$AI = 1 - \frac{\left(\sum_{i=1}^N \left(\frac{x_i}{\mu} \right)^{1-\epsilon} \right)^{\frac{1}{1-\epsilon}}}{n}$$

Broadly and more recently, the univariate Atkinson Index has been utilized to guide healthcare resource distribution and risk management and reduction through population-based analyses. The original univariate approach, along with Atkinson’s multivariate distributions (Atkinson, 1982), have been criticized by Amartya Sen (1979) and others who question whether inequality can be assessed in terms of its implications for social welfare.

However, both historical and contemporary critiques often avoid or fail to address some of the more subtle questions and problems surrounding not just Atkinson’s measurement in general, but all univariate and multivariate indices within public health and welfare. In this presentation, we examine these indices and emphasize some important concerns surrounding their application to public health issues, including the misrepresentation or lack of normative features of individuals and populations (e.g., how health is or is not valued), the bias present among policy makers and those persons utilizing these indices, and the lack of scientific certainty when applying indices to risk-benefit analyses. Furthermore, the inequality aversion parameter of the Atkinson index introduces a mathematical subtlety that begs the question: how unfair is unfair?

We, a mathematician and an ethicist, will address these issues from our disciplinary perspectives, and ultimately, we will present some remedies when univariate and multivariate indices are used particularly for purposes of public health evaluation, risk management and distribution of resources, as well as some alternatives to such an economic approach.

Ethical paradigms for the evaluation of neurotechnologies in human enhancement

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Knowledge's improvement in neurosciences and large number of neurotechnological application, big part of them over human beings, should be well understood and evaluate to void serial ethical implications. These experiments, often characterized by low invasiveness, are aimed to better understand brain functioning and its relationship with the thought and behavior. These trials have given a significant contribution to the debate in the cognitive field, stimulated a philosophical debate about free will-responsibility and attracted interest from the public. In this context we show how ethics and bioethics should try to analyze how neurosciences and neurotechnologies, with their progress, require to be understood and analyzed mainly in relation to their impact on society to answer with effective governance. In our lecture we would like to draft an outlook of this new frontier and let emerge how and why governance of neurotechnology and enhancement drugs is urgently required. We will summarize ongoing ethical paradigm that are now used to evaluate those phenomena (“Fear for uncertain”, “Equality and pursuit for happiness”, and “Policy) and we will propose a new paradigm based on recent acquisition of philosophy of technology that we call “empiric turn”.

New priority setting in Italy: the revision of primary care

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Recently, 2013, the Italian law on “Urgent dispositions to promote the Country development through a higher protection of health”, called the Balduzzi law, sees the introduction of new and important provisions for the entire Italian healthcare sector. Among others, it requires that family physicians should provide 24-hour services to reduce inappropriate attendance in Emergency Rooms. With more treatment occurring in primary care, there is likely to be more pressure on GPs to serve a gatekeeper function and make rationing decisions. Until now, Italian GPs have, most commonly, made implicit rationing decisions. Decentralization of services to primary care could lead to a shift from implicit to explicit rationing. However, many issues remain. This reform could be really useful in terms of rationing if the homogeneous benefit package to citizens is adequately revised, (taking the real needs of people into account. In fact, as reported by Carelli (Br J Gen Pract. 2010), Italian GPs are often “extremely frustrated” and feel “pulled and pushed by politicians and technologists with large and unrealistic decisions in the form of diktat”. The 1978 Italian health care reform has been the focus of intense public debate for many years. Probably, the current period of scarce resources will require even higher awareness of the dilemmas physicians face with micro allocative choices, but should also provide impetus for the development of new shared priority setting guidance from central and regional authorities.

Innovations in health care: accountable care organizations from an ethical perspective

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Accountable care organizations (ACOs) are coordinated groups of health care providers that agree to be accountable for the quality and cost of patient care. ACOs are a key element in the U.S. Affordable Care Act and expected to play an important role in the attempt to increase the cost-efficiency of health care delivery while maintaining or improving patient care and population health. Performance measures and incentives are used as managerial tools to move towards these aims. The presentation will explore how these tools can be used in an ethically acceptable way, and outline framework conditions for an "ethical ACO". These findings are of interest as well to other health care organizations that struggle with integrating the requirements of cost-efficiency, quality and equity.

Assessment of ethical aspects within health technology assessment – theory versus practice

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History of including ethical issues assessment into health technology assessment (HTA) reports worldwide is still fresh and it pertains also to Poland and other Central and Eastern European countries. The popularity of HTA is growing and it is being increasingly used as a decision-making tool in health care. The goal of this study was to evaluate the position, which ethics has in HTA, according to the current status of knowledge and everyday practice of selected national HTA agencies. The available guidelines, directing researchers how to perform HTA analyses and how to incorporate ethical considerations into HTA reports, as

well as the existing procedures and practice of functioning of HTA agencies were identified and analyzed. The differentiated approaches to ethical analysis within HTA were compared and summarized and the real-life practice was assessed and described in this study. Some case studies were also brought in order to examine differing approaches to the same health technology in various countries.

Biomarkers as translators: ontological and epistemological issues

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Since the completion of the Human Genome Project, the hope that genetic markers would enable a predictive and preventive medicine, geared towards one's genetic constitution, has gradually been proven vain. The actual results harvested from genetic and genomic research have been disappointing compared to the promises and expectations raised. This has not discouraged biomedical researchers and policy makers, however, to keep pursuing the ideal of predictive, preventive and personalized (PPP-) medicine. Their focus of attention has shifted, and now 'biomarkers' seem to have replaced 'genes' as the hope for the future of PPP-medicine.

This rise of interest in 'biomarkers' indicates a conceptual shift in biomedicine that is philosophically interesting for more than one reason. The most commonly used definition of a biomarker is "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention" (1). Thus, a biomarker is a technologically and scientifically constituted entity that is interpreted as a sign of real time bodily processes. A biomarker is, then, a translator, opening up the domain of the body for discussion (and intervention). This is not a new phenomenon in medicine: cholesterol, blood pressure or PSA-levels are just some of the biomarkers 'avant la lettre' that have been around for quite some time. What is new, however, is that biomarkers are now sought for mainly on the molecular level (RNA, proteins), as well as the sheer increase in number of proposed biomarkers (2).

In addition, even though the phenomenon in itself may not be new, both the status of biomarkers and their role as a translator are problematic. First: What exactly is a biomarker? How can it be recognized? How does technology constitute this phenomenon and how does that determine the way it opens up the body for investigation and intervention? And secondly: How do biomarkers distinguish between 'normal' and 'abnormal' biological processes? Which concept of normality/abnormality is presupposed? And which concept of disease does it reinforce? And, taking the answers to the afore mentioned questions into account, how plausible is it that biomarkers will help establish PPP-medicine and if so, what would it look like?

In this presentation, I will first offer a brief overview of the way the search for biomarkers now informs biomedical research and research policy. Subsequently, I will go into the ontological and epistemological issues raised by the concept, using (among others) the work of Canguilhem (3) to reflect on the concept of (ab-)normality implied in most biomarker research. In conclusion, I will indicate how the philosophical questions and doubts raised by biomarkers may impact the plausibility of the PPP-vision of the future of medicine.

References:

- Biomarkers Definition Working Group (2001), Biomarkers as Surrogate Endpoints: referred definitions and conceptual framework. *Clin. Pharmacol. Ther.* 69 (3), 89-95.
- Metzler, I. (2010), Biomarkers and their consequences for the biomedical profession: a social science perspective. *Personalized Medicine* 7(4), 407-420.

Canguilhem, G. (1991), *The normal and the pathological*. New York: Zone Books.

Ethics of innovative research biobanks: from theory to practice

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Sometimes, doing bioethics means finding solutions to important theoretical issues related to clinical and biomedical activity and research but, sometimes, we do not have the opportunity to implement them on the organisation of the real clinical and biomedical activity and research. Sometimes, it happens that the bioethicists have the opportunity to really implement their solutions.

In 2011 we thought how to organize an innovative cancer research biobank at the European Institute of Oncology (IEO, Milano), one of the most advanced comprehensive cancer hospital in Europe. During those days and confronting us with the relevant literature on the ethical aspects involving innovative research biobanks, we arrived at proposing what we called ‘trusted consent’ characterized by an alliance between the researchers and the oncological patients, now thought of as co-participants to the research. On the basis of this alliance we suggested a consent in which we proposed a solution to the problem concerning the fact that neither the patients nor the researchers may know in advance which kind of researches could be done on the stored specimens in 5, 10 or more years. Those considerations were, then, proposed to the international bioethical community in paper published in 2012 (G. Boniolo, P.P. Di Fiore, S. Pece, ‘Trusted Consent and Research Biobanks. Towards a “new alliance” between researchers and donors’, in *Bioethics*, 26(2012), 93-100).

Over these last months, that theoretical analysis and the suggestions implied have had the possibility of being implemented in a real consent that is submitted to the patients and in a real new organisation of the innovative research biobank realized at the IEO, which is strongly permeated by those ethical considerations and by the idea of a new alliance.

In the talk, after recalling the main aspects of the proposal, I will show how it has been really implemented and which have been the difficulties encountered.

What will be presented should not be intended only as a local attempt to apply bioethical theorisations, but as a sort of case study from which we could learn which are the difficulties that could be met any time we try to move from the sky of the theory to the earth of application, even if this is innovative.

The (tragic) case against the given human enhancement as a condemnation to be free

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According to Michael Sandel, if the human enhancement enterprise is not categorically resisted, parents will be increasingly held responsible for not selecting good traits for their offspring, athletes for not injecting performance-enhancers, etc. All persons whose naturally given state has become amenable for intervention will face similar responsibility ascriptions, resulting in a society-wide ‘explosion of responsibility’. Although I subscribe to this pessimistic prognosis, beyond this initial agreement I will develop a diametrically opposed argument about the question whether this responsibility explosion can – in good faith – be evaded. When an effective alteration of some naturally given aspect of one’s existence is made available, this strips one of the comfort of exculpation: to accept some affliction or

insufficiency as a given fate – as a predetermined and immutable nature that must be accepted as-is – relieves one of responsibility and hence of potential self-blame, shame, indecision, regret, etc. In his *Case Against Perfection*, Sandel states that seeing oneself as a creature of nature, God, or fortune holds the blessing of not being wholly responsible for who one is. I argue that such a case against enhancement is based on an appreciation of one's given human nature as at once a responsibility-relieving *excuse* and a purpose-providing *gift*. A self-conception with such conspicuous benefits can strike an existentialist as a case of bad faith: by outsourcing one's individual responsibility to other (imagined) entities and by following their cues (developing one's talents or remaining true to one's 'given' identity) to experience meaningfulness, one denies the extent to which a human being finds herself 'foundationlessly free and ruthlessly responsible'. Though the discourse of Sandel and like minds is often steeped in the language of dignity, within an existentialist-humanist ethic human dignity lies in the uncompromising acceptance of this god- and nature-forsaken condition, and indignity lies in its denial – at least when based in self-deception. I argue that enhancement should at heart be understood as an ultimate verification of this nature-less liberty which defines humanity. *As such* – that is: as self-creation – the enhancement enterprise should be explicitly embraced. However, I argue that underneath the myriad bodily traits and abilities it improves according to certain (possibly suspect) norms, above all it 'enhances' two major existential burdens: it explodes our responsibility over ourselves to an unseen breadth, and it deepens our rootlessness to an unseen depth. However, human(ist) dignity compels us to stay true to *this* 'nature-less human nature'. Though tempting, 'seeing ourselves as a creature of nature, God, or fortune' is inauthentic. If my argument holds, it is doubly ironic. First, the *no-tech* mental self-revision proposed by Sandel may be no less of an undignified self-manipulation than the unwise usage of high-tech, physical means of self-manipulation he denounces. Second, for all the health, ability, beauty and welfare it may bring, with increasingly profound possibilities for self-creation we may be enhancing ourselves into an ever-expanding existential void. If the enhancement enterprise ultimately is such a tragedy, the question then becomes how to bear this total loss of given meaning.

Biobanks - developments and ethical issues in the Republic of Croatia

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Various types of biobanks (biological samples plus related databases) are now present all over the Europe. In recent years more than 160 articles have been published in relation to ethical issues and biobanks. In the European Union, Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) project has been initiated with the idea of enabling better networking and information exchange that could foster collaborative research. In transitional countries Estonia and Latvia have created a joint population biobank while Hungary, Poland and Slovenia are preparing to implement some form of structure regarding their biobanking facilities. Croatia has several important biobanks with legal requirements that do not truly cover all their activities. This paper will give an overview of the situation regarding biobanks in Croatia (types, functions, legal requirements). Possible problems and ethical issues will be discussed as well as the recommendations for the improvement of the current situation.

Ethical concerns about deep brain stimulation in medical ethics

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Deep brain stimulation is an invasive treatment for neurological and psychiatric disorders. It involves the implantation of electrodes in the brain, and it is an example of a neuromodulation therapy. Depending on the stimulation site in the brain, it causes psychiatric side effects, such as suicidality, affective and manic symptoms, cognitive changes, and speech problems. Consequently, the ethical issues of deep brain stimulation include the following: 1. *Autonomy and agency*: Patients need to give their informed consent to the treatment. How can they be adequately informed about potential psychiatric side effects in advance in order to make their own decisions? 2. *Changes in preferences*: Conflicts may ensue between patients' preferences before and during the treatment because of psychiatric side effects. What is the role of advance directives, particularly so-called odysseus directives, in this situation? Insights into the ethical difficulties of deep brain stimulation may inform ethics debates about both autonomy in health care and future neurotechnology in general.

Neuroethics and non-human animals

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Since its emergence Neuroethics has adopted a very humanistic view of mind: to have a mind is to have thoughts, beliefs and other “higher-level” psychological states, and these states are generally accessible only in a privileged first-person way. We are interested in neuroimaging because it can, in principle, reveal a person’s conscious inner mental life, that is to say, it can access mental intentions, and other, mental contents that we previously thought to be private. We find cognitive enhancement problematic because it is seen to pose a threat to “authenticity” – a normative notion of first-person psychological integration. Neuroethics has had little interest in nonhuman animals because we generally believe that they lack such a sophisticated conscious mental life: we may be willing to accept that nonhuman animals are sentient, that they have preferences, and that there is a rich variety of animal cognition; but we are skeptical that they have thoughts and beliefs. This skepticism is aided by a fear of uncritical anthropomorphism.

One of the core questions that Neuroethics asks is, “What are the implications that advances in neuroscience have for the law and morality?” This question is, obviously, dependent on the initial belief that we are, for the most part, intentional agents capable of moral decision-making and acting responsibly. Our initial belief about nonhuman animals, however, is that it is inappropriate to view them in this light: the behavior of nonhuman animals is judged to be predominantly instinctive or hardwired, rather than intentional and voluntary. This is not to deny that some animals, for example, chimps, have complex social and group behaviors and are capable of morally questionable actions like deception, but even in these cases we are reluctant to conceive of these animals as agents.

Although there may be no agreement as to the specific relationship between mind and brain, within Neuroethics there is general agreement that this relationship is robust, if not even necessary. Accordingly, we seek to identify the neural processes that underlie psychological states and these processes are viewed as evidence of what is “really going on.” For conceptual and practical reasons, however, a different approach has been adopted in regard to animal cognition. One of the influential approaches to the study of animal mind, cognitive ethology, supports the “comparative, evolutionary and ecological study of animal thought

processes.” In order to understand the animal mind we should take fully into account the place and nature of the animal within its natural environment and evolutionary history, in addition to focusing on the underlying neurophysical states.

In light of the above reasons it may seem that Neuroethics’ humanistic focus is inevitable and that animals are of interest only indirectly as a means to study human cognition. In this paper I will attempt to broaden the humanistic focus and identify a number of areas in which discussion of non-human animals is long overdue.

Is whole genome sequencing questioning the status of genetic information in health care and society?

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While genomic science is advancing tremendously, medical, ethical, legal, and social questions are arising regarding genetic information. Ethical aspects of genetic testing related to the use of high throughput techniques pose the problems of status of large scale genetic information regarding privacy and confidentiality, clinically useful information and the duties attached, health related information where no immediate clinical measure exists. Although most of the traditional ethical/legal frames that have developed over years for genetic research and applications (see for example the Eurogentest website: www.eurogentest.org) continue to apply, some aspects challenge this existing framework. For example

1. The necessity of sharing in data bases sequence data generated both in health care and in research
2. The type of consent that may cope with such developments
3. The privacy issues (sensitivity of data; data access; anonymity that cannot always be guaranteed)
4. The communication of results of different significance and uncertainty.

While in the move toward clinical applications the massive amount of sequence data generated already leads to unexpected findings and complicates our understanding of clinical utility and patient benefit. As with any new clinical test, analysis of clinical utility has to be undertaken and clear standards and guidelines are being prepared while massively parallel sequencing starts to be routinely offered. The availability of the offer of sequencing directly to consumers also poses questions about the use of such data, relations between commercial sector, health sector, clinical care and research are being more merged than previously.

The focus of the talk will be on initiatives and examples of governance in several European projects and contexts. The contexts addressed will use recent guidelines and the controversies they generate regarding unsolicited findings, conditions to prescribe whole genome/exome sequencing and the challenge of anonymity.

Questions raised by large scale genetic technologies applications are:

- Can the same type of regulation apply to targeted tests and to genome-wide sequencing?
- Does sequencing require a different level or kind of consent than other genetic tests or medical assessments?
- Should whole-genome sequencing method be performed for children or incompetent adults?
- How to communicate results when their interpretation remains uncertain?
- Should patients be informed of incidental findings that unequivocally predict serious disease that can be prevented or ameliorated by early detection? What if the disease cannot be prevented or ameliorated?

- How will healthcare providers manage cases in the face of such a rapidly changing knowledge base?
- How to regulate sequencing services offered directly to consumers?

To ensure fair and reasonable translation of sequencing technologies, the issue of prioritization needs to be addressed explicitly by collaborative efforts of geneticists, ethicists, health economists, patient representatives and decision makers. However the status of genetic information remains a challenge in itself.

References:

- ANASTASOVA V., et al.. Genomic incidental findings: reducing the burden to be fair. *Am J Bioethics*, 2013 Feb;13(2):52-4
- ANASTASOVA V., et al. Communication of results and disclosure of incidental findings in longitudinal paediatric research. *Pediatr Allergy Immunol* 2013, 24 389–394
- HOWARD H. C. et al. The ethical introduction of genome-based information and technologies into public health. *Public health genomics*, 2013, 16(3):100-9
- BLASIMME A et al. Disclosing results to genomic research participants: differences that matter. *Am J Bioethics*, 2012, 12:10, 20-22
- VAN EL CG et al. Whole-genome sequencing in health care. *Eur J Hum Genet.* 2013 Jun;21(6):580-4

Innovation, Human Subjects Research, and Ethics: Conceptual and Practical Issues Along the Boundaries of the Common Rule

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Innovation—the creation of a new process, product, policy, plan or proposal—is essential if a society is to survive and flourish in the face of scarce resources, changing circumstances, and unmet needs and aspirations. In health care and the life sciences, innovation ranges from departures from existing practice, either in responding to immediate need in an individual situation (as, for example, by experimenting when standard treatment has not produced the desired result) or in conducting a formal research project to test a hypothesis about a new preventive, diagnostic or therapeutic intervention. Are the activities involved—from standard care through examination of the outcomes of variations in existing care through individual experiments to controlled clinical trials—points along a continuous spectrum or are the activities different in ethically significant ways? In the early years after the Nuremberg Code, the formulation of standards and rules for research proceeded on the premise that lines could and should be drawn to separate activities in various ways. For example, lines were drawn by the Declaration of Helsinki (1964) between research involving patients as part of medical care and research with normal volunteers, and by the Belmont Report (1978) between the practice of accepted therapy and activities designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge. The groups drawing such lines did so in part because they believed that the relationship of the participants in the activities differed in important ways but also in part because they wished to protect medical practitioners from the obligations and oversight that were being established for research involving human beings. Today, the characterization of activities that lie at either end of the spectrum (at one pole, care that adheres strictly to an evidence-based standard and, at the other, a randomized controlled trial of a new drug) remains unproblematic. But a range of activities along the boundary between practice and research have generated controversies between practitioners and regulators, as can be seen in the United States where the Office of Human Research Protections (OHRP) has informed professionals who thought they were acting to improve health care that their activities amounted to research subject to the so-called

“Common Rule,” the regulations that govern all research supported by agencies of the federal government. This paper examines this problem from a conceptual viewpoint (what characteristics of an activity are relevant in assigning it to the category of “research,” and why?). Further, it argues that rather than categorizing an activity as research in order to ensure that it receives ethical oversight, other means of oversight can be developed that offer practical strategies for ethical review appropriate to the risks involved. Particular attention is given to such areas along the border between research and practice as activities in quality improvement and public health and to innovative therapy.

Big Data in Medicine: Should health data be considered a public good?

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The data generated in the process of medical care has historically not just been under-utilized, it has been wasted. This was due in part to the difficulty of accessing, organizing and utilizing data entered on paper charts, but notable variability in clinical documentation methods and quality made the problem even more challenging. In the absence of a practical way to systematically capture, analyse and integrate the information contained in the massive amount of data generated during patient care, medicine has remained a highly empirical process in which the disconnected application of individual experiences and subjective preferences continues to thwart continuous improvement and consistent delivery of best practices to all patients.

In 2006, IMS Health earned \$2 billion by selling data obtained from pharmacies about doctor prescription patterns to pharmaceutical companies who used the data to fine-tune their marketing strategies. It is estimated that there is another \$300 billion yet to be made in the US alone over the next 10 years from health data. Highlighting a similar premise, researchers surmised that the adverse effects of the now-withdrawn drug Vioxx could have been noticed earlier, and that 27,000 deaths could have been avoided just by analysing clinical databases. There is no question that health data is useful and valuable. The question is, “Who owns it, how should we use it, and who can profit from it?”

In 2010, health ministers from OECD countries called for more and effective use of health data that has already been collected to deliver better quality of care, reduce medical errors and streamline administration. This requires balancing of individual rights to privacy with the collective rights to a high performing health system. Although it is unethical to endanger patient privacy, this presentation will argue that it is also unethical to continue endangering patient lives by failing to improve healthcare. Medicine should long ago adopted a data-driven approach but unfortunately, for technical (including privacy and security), financial (including data ownership), and cultural reasons, this has not yet occurred. Work of this nature has the potential to identify and scale best practice, and generate huge dividends in human health and the rational use of healthcare resources.

How should we think about epigenetics?

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As scientific knowledge about gene-environment interactions and the role of epigenetic factors in gene expression grows, this appears to open up new possibilities for personalized medicine but also raises questions about how we think about the philosophical and ethical

issues. In particular, the associations that have been demonstrated between epigenetic markers and certain diseases lead to questions about our understanding of causation and responsibility in this field, and the relationship between biomedical and environmental ethics. New ethical challenges arise, due to unique characteristics of how epigenetic effects regulate gene expression, how such effects are established and how they may change over the course of a person's life.

Contextualizing the ethical perspectives on NIPD

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There is commonly held belief that NIPD will have significant impact on fetal medicine and will give rise to new ethical concerns. A concern was raised that the limited number of genetic counselors available may not be sufficient to answer the growing need for their services. It is also argued that the lower risks associated with NIPD may induce pregnant women to feel that they 'should' seek a diagnosis which in turn may undermine the voluntariness of their consent. Further, the introduction of NPID is expected to induce a greater number of pregnancy terminations. In my statement I will argue that NIPD does not give rise to new ethical questions and concerns but simply reiterates existing debates on prenatal diagnosis.

Ethical arguments regarding non-invasive prenatal diagnosis – the critical appraisal

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In the past fifteen years, the isolation and analysis of free fetal DNA or whole fetal cells in maternal blood has been made. As a result new methods for testing during pregnancy were established. These technologies aim to offer non-invasive prenatal diagnosis (NIPD) to provide definitive molecular or chromosomal information about the health of a fetus. Not posing a risk to the pregnancy, they are expected to become routine methods for prenatal testing in the near future.

There is commonly held belief that NIPD will have significant impact on fetal medicine and will give rise to new ethical concerns. One of the most debated issues concerning the introduction of NIPD is the provision of pretest genetic counseling and the process of obtaining consent from women considering the test. Adequate counseling and consent based on in-depth information about the clinical significance of a positive test, pregnancy termination options, and other important issues are perceived as necessary elements of patient autonomy and reproductive decision-making. A concern was raised that the limited number of genetic counselors available may not be sufficient to answer the growing need for their services. It is also argued that the lower risks associated with NIPD may induce pregnant women to feel that they 'should' seek a diagnosis which in turn may undermine the voluntariness of their consent.

The introduction of NPID is expected to result in the discovery of a greater number of fetuses affected with genetic anomalies. This will likely induce a greater number of pregnancy terminations. There is concern that new trends in prenatal screening and diagnosis are likely to lead to the decline in the number of children born with disabilities and undermine the worth of disabled people.

The aim of this presentation is to provide clarification and critical evaluation of arguments used in the debates concerning non-invasive prenatal diagnosis. The question of whether NIPD gives rise to new ethical questions and concerns or simply reiterates existing debates in prenatal diagnosis will be addressed.

Viewpoint discrimination and the publication of scholarly research from Africa and other Developing Countries

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Viewpoint discrimination maybe described as any regulation or practices that attack a particular individual or group's message, as opposed to the mode in which such message is conveyed. According to Jackson J, "Progress generally begins in scepticism about accepted truths", yet when scepticism cannot be expressed, re-examination of established ideas and consideration of new ones will probably never occur, under such circumstances intellectual contestation is fundamentally unfair and impairs the competition of ideas on merits (Walker H, *FCC Law J* 2000). Viewpoint discrimination may be unconscious or conscious, direct or indirect. It is considered unconstitutional by American legal authorities since it represents an egregious violation of free speech. Legal scholars therefore advocate that any such unavoidable abrogation of free speech must remain viewpoint-neutral.

Since we live in an information age, it could be argued that free exchange of information and knowledge systems between developed and developing countries is essential for the improvement of global human development index (HDI). Arguably, free exchange of biomedical research information would be of enormous benefit in bridging the 10/90 gap-where 90% of global research funding is directed towards finding a cure for diseases affecting 10% of global population. Scientometric analysis of worldwide publications from 2000-2004, revealed that African researchers produced only 1.8% of global publications, while India and Latin America produced 2.4% and 3.5% respectively. By contrast researchers from the European Union and USA produced 38.8% and 33.6% of worldwide publications respectively (Pouris & Pouris, *Scientometrics* 2009). This skewed publication data has been ascribed not only to infrastructural constraints in developing countries, but other factors such as 'institutionalized racism' by leading international journals published in developed countries. Some journal editors interviewed regarding these observations take exception to 'racism' as a cause of this observed imbalance, ascribing it instead to elitism, bias, insularity, and regionalism (Horton R, *The Lancet* 2003). Evidence of discriminatory practices include lack of representation of scientists/researchers from developing countries on the editorial/advisory boards of leading biomedical journals; bias against publication of research relating to diseases of the poor. For example only 5.1% of the editorial/advisory board members from 12 leading journals on tropical diseases were from countries with low HDI while, 70.8% were from countries with high HDI (Keiser J et al, *BMJ* 2004). The overall impact of such actions is the development of a 'viewpoint discrimination' against knowledge generated in Africa and other developing countries.

Therefore, to minimize viewpoint discrimination, leading international journals and scientific publications from developed countries may require affirmative action such improving diversity of editorial/advisory board membership, more north-south collaborations, and arguably a conscious effort to allocate about 5-10% of publication space in leading scientific journals to reporting on scientific knowledge generated or diseases prevalent in countries with low HDI. This will go a long way towards global dissemination of knowledge, closing the information gap and improving HDI in developing countries.

Prevention, Treatment and Priority Setting in the Use of ARVs

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Antiretrovirals (ARVs) are unusual. Normally, in debates about rationing we might argue about priorities in relation to different services or different drugs. Here the same drug can be used in different ways. The focus of use of ARVs has, on the whole, been on treatment (T) not prevention (P) (except for mother/child or vertical transmission). However, evidence is now emerging that two new preventive methods are effective: PrEP (pre-exposure prophylaxis) and TasP (treatment as prevention). How should national governments set priorities for ARV use? Macklin & Cowan (2012) have argued that T should be preferred to P. They suggest this is justified through an appeal to a utilitarian goal, 'tempered' by three other principles: (a) the rule of rescue; (b) urgent need; and (c) a prioritarian focus on those currently sick. In this paper I argue that their reasons for supporting these principles are problematic and that in at least some situations we should prioritise P over T. A justified policy of ARV use should not just be focused on individuals, but should take population factors into account, and PrEP and TasP allow this to occur. My positive argument employ public health ethics concepts that Macklin & Cowan do not discuss, such as solidarity and common goods. A focus on prevention of transmission does not "merely" prevent many individual tragedies, but benefits us all.

Proactivity of the community in biobanks: a Sardinian outlook

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The region of Sardinia, in Italy, represents a very stimulating case for genetic research. With a unique genetic pool, an interesting epidemiological history, geographical location, environmental and behavioral factors, altogether could contribute to the peculiarity of Sardinian population. In this perspective, several studies and projects, mainly focused on the aging process, have been developed in collaboration within national and international institutions. One of the main objective of these projects was the Sardinian genes coding, which has been deemed useful to a better understand the ageing process of Sardinians who often enjoy a very long and healthy life. Moreover, the data and samples collected during the last decade form an important source of information for further epidemiological research. Even though Sardinian population has a basic knowledge about bio-banks and their scope, there is at least one example of a sustainable model of bio-bank, where the community is proactive in the research process. The bio-bank of Sarroch, a small town located in south Sardinia, which is also one of the biggest refineries of Europe, collects and keeps biological tissues and samples of the local population characterized by a high frequency of some diseases. The high exposure to pollution, in this area increases health risks of the inhabitants, making a personal health problem of each citizen a concern for the community and a big question for public health. The purpose of this paper is to illustrate how a community concerned in finding a solution, approaches the context and the utility of a bio-bank not as the chance of profit for pharmaceutical industries, or an answer for individual needs, but a place where values like responsibility, participation, civic behaviors as important tools to reach the real benefit of collectivity wellbeing. Education of population according to this perspective will make this bio-banking approach a more sustainable one, in harmony with the environment which could influence in health of present and the future generations.

Furthermore, this would provide useful data to the governments in matter of public health, environment, and industrial policies.

Electronic patient records and their legal and ethical implications – a Swiss perspective

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With the ambitious goals to improve the quality of treatment processes, to increase patient safety and to enhance the efficiency of the health system, a new draft on the Electronic Patient Record Law has been elaborated in Switzerland and recently referred to Parliament. The promotion of electronic health services ("e-health"), and in particular electronic patient records, is an essential element of the strategy "Gesundheit2020" of the Swiss Federal Council.

This draft law defines the legal conditions under which medical data contained in the electronic patient record can be edited and accessed irrespective of place and time by all those involved in treatment. However, health professionals are only enabled to access medical data relevant to the treatment of their patients if they have been granted appropriate access rights from their patients. Thus, the draft law enables the patients to decide freely whether they want an electronic patient record being created and if so, to manage the allocation of access rights by themselves and to access own medical data as well. The conference talk focuses on the legal and ethical implications this draft law may have for patients, health professionals and health institutions.

Donors should be informed about possible forensic use of their biological samples

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In many countries legal regulations leave a possibility open to use for forensic purposes (e.g. criminal or paternity identification) human biological samples collected for diagnostics, scientific research and other non-forensic purposes. Should donors be informed about this possibility during the consent procedure? There are reasons to say no: this information is not directly connected to the primary purpose of the removal of the materials, the possibility of forensic use is very remote and consent forms are already too long. Of course, it is not realistic to communicate to the donor all information on possible uses of their samples. My suggestion is that at least they should be informed of what I call relevant considerations. (The notion of relevant considerations is taken from Goodin and Eriksson 2009.) By relevant considerations is meant information that is likely to change choice in the following way: if someone chooses A from a set [A; B] when information x is not revealed to that person and B from set [A; B] when that information is revealed, then x can be called a relevant consideration. Is possibility of forensic use a relevant consideration? There are good reasons to think it is. Let me provide just one example: according to 2005 Eurobarometer survey, more than a third of Europeans disagree that the police should have access to people's genetic information. Information to the effect that their samples may be made available to the police would likely be a relevant consideration for that portion of population. There may be fears that disclosing the possibility of forensic use during the consent procedure would result in negative consequences on research. In particular, it would become more difficult to collect and retain samples, especially when samples are intended for long-term storage. One way to avoid this worry is to prohibit forensic access to research collections (e.g. as provided in the

Estonian Human Genes Research Act). If forensic access cannot be ruled out by legislative means, the possibility of forensic use must be communicated to the donors. UK Biobank took a lead by stating in the donor information leaflet that if forced by courts, it will grant access to the police to the individual's information, samples or test results, but absolute majority of other collections still do not explicitly mention the possibility of forensic use in their consent forms.

Interpreting and manipulating ageing – a conflict of interpretation between biogerontology and social gerontology

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Biogerontology has recently created the prospect to develop interventions against age-associated diseases based on successful experiments with laboratory organisms. This promise has gained the attention of policy makers some of whom see this field of research as a future key science and technology. With an increasing importance of biogerontology biological concepts of the ageing process and of old age are likely to become more influential in science and in society. This has raised concerns of some social gerontologist, who fear that the main achievements of their field, results of its fight against age discrimination will be endangered by exclusively negative images of old age transported by the success of biogerontology. They accuse their opponents of a negative and ageist attitude which they integrate uncritical into their picture of ageing as a starting point of their production of knowledge. This is countered by a positive outlook on old age based on its positive sense in the life course. These two perspectives on old age create a conflict of interpretations. While one may expect the biological and the sociological perspective as merely descriptive, both have a strong normative orientation. However, the normative claims raised by the opponents in this conflict remain unquestioned, most importantly those which refer to the basic problem: Is there a positive sense of ageing and if so, how can it be justified?

The normative goals and elements of biogerontologists and social gerontologists will be clarified. Conflicts but also common ground will be sketched. Finally, the limitations of both perspectives on the sense of ageing will be outlined. A simple naturalistic approach can't claim to explain all aspects of ageing. Also, the conclusion from "dysfunctional" to "bad for" can't easily be drawn. However, the negative aspects of ageing have to be taken seriously. Denial can lead to overly positive images of ageing and to a too optimistic view of physical ageing. Not every loss is compensated and not every aspect of human life may make sense from an ethical perspective. A look at the philosophical tradition shows that ageing was often considered to be a form of evil. It will be examined whether these views can still be fruitful or whether they also should be considered to be negative stereotypes. The result should be a differentiated view of positive and negative aspects of ageing, and a justification for manipulating ageing processes without promoting ageism.

Life scientists' views and perspectives on dual-use research

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Recent studies altering the host range of the H5N1 flu virus from birds to mammals have refuelled intense debates over the misuse potential of academic life science research. The debate was first initiated in the US in the aftermaths of the 9/11 anthrax attacks. In the light

of the recent bird flu studies and the central involvement of European researchers, Europe has finally turned an eye on the topic: the EU, local governments and the scientific community have started to discuss potential measures to prevent deliberate misuse of life science research results. However, opinions are divided on how immanent the threat of misuse actually is and on what measures may be effective in preventing misuse while preserving the benefits of research.

To facilitate an evidence-based debate of the dual-use topic and potential preventive measures, I have started an interview study in Switzerland. For the study, I exclusively interviewed life scientists working with pathogens as the most prominent dual-use cases in the life sciences involved research with pathogens. Previous studies investigating the views and perspectives of the scientific community were predominantly conducted in the UK and involved life scientists from various fields. In contrast to these previous studies, which reported a limited awareness of life scientists towards dual-use research, my preliminary results indicate that most scientists working with pathogens are aware of the dual-use topic. The interviews also show that especially those scientists working with influenza and other human pathogens have reflected on their responsibility in regard to the dual-use potential of the results and techniques of their work.

Diffusion of knowledge through a natural resource model

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In order to constitute progress, innovation necessarily involves sharing newly discovered knowledge. In many European and other countries, the impact of innovation is siphoned into society through mechanisms such as patents and licenses linked to utilization through a market model. This is especially prevalent in direct-to-consumer advertising for products involving genetic testing, genomic medicine, and enhancements to human fertility.

Thus, new knowledge and products are regarded (at least in legal domains) as “intellectual property.” The very classification of knowledge as private property has deep implications for epistemology. This presentation would examine ethical implications of the status quo and would introduce an alternative model.

My hypothesis is that curiosity, creativity, intelligence, and intellectual energy are innate to the human species, and innovation is part of human telos. Accordingly, innovation and *the* knowledge it generates can be regarded as natural resources. Like water, they can be viewed as an intellectual wellspring and a common good. If this is the case, a natural resource model for sharing innovation and progress can be constructed, and there are many implications for solidarity, autonomy, justice, and other ethical principles.

There are also many lessons from myths and religions. At what point does innovation become hubris? Will we be able to plant a Garden of Eden, where knowledge and innovation are no longer a poison apple, or are we doomed to the fate of Icarus? Further consideration would be given to ethical implications and precedents for developing a natural resource model for sharing innovation.

Citizens' preferences concerning non-invasive molecular genetic prenatal diagnostic testing of trisomies 13, 18 and 21

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Objectives: Established prenatal screening methods necessitate invasive procedures to confirm a positive test result. These invasive procedures are fraught with risk for the unborn. Since about half a year a new non-invasive molecular genetic test is available in Germany (PraenaTest® - LifeCodexx AG). This test analyses fetal DNA fragments in a pregnant woman's blood. Even this method requires invasive procedures to confirm a positive result. The method's substantial advantage is being able to avoid the risk of invasive procedures. This is possible in case of a negative PraenaTest® result after noticeable findings of other screening methods. Criticism relates to the argument that the test does not suit therapeutic targets, but the decision on abortion. There are fears that social pressure could make parents feel obliged to use the test and to have only healthy babies. At the moment, the discussion has to proceed without information regarding citizens' preferences and expectations. Our goal is to counteract this lack of information.

Methods: Therefore we developed a structured questionnaire, which initially collects information about the knowledge of different prenatal diagnostic procedures (including PraenaTest®) as well as of trisomies 13, 18 and 21. Furthermore we evaluated the knowledge about the terms Patau, Edwards and Down Syndrome. Subsequently the questionnaire informs about prenatal diagnostic, the PraenaTest®, trisomies 13, 18, 21 (respectively associated syndromes) and abortion in case of trisomie 21. Following questions involve preferences and opinions about reasonableness, legal status, reimbursement, personal recommendation and consequences of test results in regard to PraenaTest®. In addition the questionnaire is concerned with further potential tests. To date preliminary results of a pretest are available.

Preliminary Results

State of knowledge: PraenaTest® seems to be clearly less known than other prenatal diagnostic methods such as amniocentesis or control of growth by ultrasound. Knowledge about trisomie 21 appears to be greater than about trisomies 13 and 18 as well as knowledge about Down syndrome appears to be greater than about Patau and Edwards syndrome.

Preferences: Majority of interviewees rates the usage of PraenaTest® to test for trisomies 13, 18 and 21 as reasonable and holds the opinion that statutory health insurance should reimburse costs (at least above at a certain age). The decision whether to recommend or to advise against using PraenaTest® seems to depend on the pregnant woman's age in some cases. Testing of genetic characteristics, that are not related with diseases respectively health problems, is mostly rejected.

Discussion: After validation of preliminary results citizens' preferences could be taken into consideration to increase acceptance and strengthen the legitimacy of decisions concerning application and reimbursement of PraenaTest®. Furthermore this study might be able to elucidate the importance of information in regard to prenatal diagnostics. Valid, objective and balanced information becomes even more necessary as an increasing number of sophisticated genetic tests will be available in near future.

The price of innovation: placebo control in clinical trials

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The controversies related to the use of placebo control in clinical trials continue to fuel heated ethical debate at both policy making circles as well as academia. For example, a recent 2008 draft of the Helsinki Declaration (HD) was unanimously approved by the General Assembly of the World Medical Association with the exception of the Paragraph 32 (dealing with placebo controlled trials), which met a strong opposition from the Brazilian Medical Association representing the views of developing countries. The reason behind this protest was the inclusion of the second clause of the proviso allowing placebo control in case of “compelling and scientifically sound methodological reasons” even when “current proven intervention exists”. The incentive to use placebo is first of all based on the claim that study design that includes placebo arm is in some cases methodologically superior to the active control study design and therefore is a very important feature of innovation and progress in the field of health care. However, as has been the case in the HD debate, it raises the issue of exploitation by exporting placebo controlled trials to the regions where “current proven interventions” are simply not available due to the scarcity of health care resources. What is of no less importance, the use of placebo in clinical research still stimulates a methodological debate on the justification of particular types of study design. The paper aims at exploring the relationship between these two types of placebo related debates concentrating in particular on the use of placebo control in clinical research conducted in resource poor health care setting.

The emperor’s new clothes? ADHD and methylphenidate in adults

- An example for the necessity of complex cooperation of methods in medical research

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Attention Deficit and Hyperactivity Disorder, ADHD, is an exploding diagnosis – be it because there is a sort of “epidemic” of the disease by environmental factors, be it that it was always there and not recognised, be it that it is for different reasons a fashionable sort of diagnosis that embraces all kinds of conditions.

Children with the diagnosis ADHD have big problems in school with their deficits in attention and concentration, their distractibility and their problems with sitting still and not disturbing the lessons. Before ADHD as a diagnosis was known, such children were often regarded as naughty, badly educated and/or stupid. Nowadays, ADHD is regarded as a neuropsychiatric hereditary and chronic condition that implies many functional problems in life. While until the 1970s it was supposed that it is self-limited and vanishes in adult age, newer estimations claim that at least in one third of the cases it proceeds also in adults, though often with a modified symptomatic and a considerable comorbidity with addiction and depression, and also an elevated risk for criminal behaviour.

The history of ADHD unites interesting and also some exceptional aspects that may be worth having a look at them:

- ADHD is mainly characterised by functional problems, individual suffering is mostly secondary to reactions of the surrounding and diminished perspectives in society. As function is a relational term between individual and society, it is not clear which part is mainly responsible for the mismatch.

- ADHD is sometimes criticised for being a “clinical diagnosis” with no reliable objective measurements for it.

- Though there seems to be a strong hereditary influence, the aetiology and the reason for the increased incidence is by no way clear: ADHD is a fruitful battlefield for a complex re-enactment of the old nature-nurture debate.

- Pharmacologically, ADHD is often treated with the psychostimulant methylphenidate, which is also used by addicts and by healthy people who want to enhance their ability and endurance to learn. Drawing the line between therapy, misuse and enhancement/doping can be difficult.

- As an absolute exception, ADHD is a disease in which medication has been first tested and widely applied in children (though long-term studies are still missing). Now it is more and more used in adults, though it is not approved in this indication and the evidence base for this is still poor. Usually, it is the other way round, and children are prescribed medications that are only tested in adults.

In this paper, I want to focus on the last point and to discuss the extension of a still somewhat controversial diagnosis and therapy from children to adults, and the possible reasons and justifications for it. Mentioning the fairy tale of the Danish author Hans Christian Andersen could imply that I take for granted that the diagnosis or at least the extension of it weren't justified. That is not the case (as I try to indicate by the question-mark). There is a discrepancy between the still unclear state of the diagnosis and the status of its therapy on the one hand and the wide use of it on the other that should be critically evaluated. As the data are so far insufficient, a judgment about the justification would be premature. A medical philosopher like me could easily lay back and pretend it were all an empirical question that could be left to sociologists and epidemiologists.

Hans Christian Andersen's fairy tale of the naked emperor can tell us this: Don't get seduced by big selling strategies and big empty words. Be critical and see hidden motives and their dynamics. But do not take, naively as an innocent child, all complex or simple theories for empty words either – if one wants to evaluate new concepts, diagnoses and therapies, it requires *epidemiology*, well-constructed and independent *clinical trials* as well as *careful conceptual analyses* of the competing ideas and strategies and their impacts. Unfortunately, the latter that requires rather philosophical and analytical than biostatistical and epidemiologic methods seems less en vogue, in philosophy of medicine, in medical ethics as well as in medical research. The example of ADHD can illustrate that meaningful research is in urgent need of all of these methods in order to create and evaluate new findings and developments in a fruitful way.

The interrelation of needs and autonomy in priority setting

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One commonly considered plausible way to allocate scarce resources in health care is according to people's needs. There are several ambiguities regarding how such a principle should be best understood. In this talk I focus on a particular problem, that is how the principle of need ought to relate to a principle of autonomy in the context of priority setting in health care. On the one hand it seems plausible to allocate resources according to need and on the other it seems reasonable to give at least some weight to patient autonomy.

One possible position here (call this position (A)) is that the principle of need should rank different interventions and then patients are offered health care on the basis of this ranking. If patient (1) rationally declines the given intervention his or her decision ought to be respected (on the basis of the principle of autonomy) and the intervention then goes to patient (2).

However, the principle of need, autonomy and the practice of priority setting seem to have a more complex relation if one really wants to give weight to patient autonomy.

Consider next position (B), the nature of a patient's need and hence the appropriate intervention to satisfy this given need may be directly influenced by a person's preferences. For example, a patient with a certain heart condition may want to reduce the intake of diuretic medicine in order to avoid constant visits to the bathroom. Even though it comes with an increased risk for future complications he or she may be rationally willing to take the risk of reducing his or her intake of medicine.

Moving from A to B involves a greater weight to patient preferences. This move, however, may affect how one interprets the need of the patient. That is, based on an analysis of needs in terms of a subject *x* needing some object *y* in order to achieve some goal *z* (position B seems to open up for a change regarding the goal *z* (and hence also regarding *y*)). Turning next to priority setting in health care, how to best understand a situation when a patient is allowed to modify how a need is interpreted in this manner? If a person wants to introduce other aspects into his or her need for health care than strictly medical aspects, for example avoiding constant visits to the bathroom, and hence reduce the intake of diuretics – what are the implications on the given need in terms of greatness and ranking in a priority setting?

Humanism as a transcendental basis for intellectual-disability policies and studies

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In societies that are ideologically and politically committed to the notion of equality it is necessary to choose a criterion for the kind of beings who merit equal respect or equal treatment. Historically, men, citizens, those with economic means, those with defined religious views, and those with defined physiological features have been included in the community of equals, while others have been excluded. Enlightenment philosophers extended the sphere of equality to all rational beings and to all sentient beings; and their critics have used membership in the human species as the measure of dignity and moral worth.

One group whose inclusion in the community of equals has not traditionally been self-evident but has gained momentum during the last decades is constituted by human beings with intellectual disabilities. On what grounds can they be included? On what grounds can they be excluded? Answers to these questions are crucial for policy decisions concerning the treatment of people with intellectual disabilities and informing popular attitudes towards them.

This paper studies answers to the question of including people with intellectual disabilities into the sphere of equal moral consideration and respect. The question will be approached by philosophically examining the views presented by Jeff McMahan and Eva Feder Kittay in an exchange of views during the last decade. McMahan and Kittay represent the opposite poles of the debate, and it is therefore instructive to see how their arguments and counterarguments proceed.

The conclusion will be that the only way to grant people with intellectual disabilities an entitlement to equal consideration and respect in policy making and legislation is to assume that humanity as a transcendental principle is the only, or at least the most important, yardstick of moral status.

Experts' opinions on prioritizing ethical issues in research with minors: a delphi approach¹

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Background: The necessity of conducting health preventive research is shown by the WHO being motivated by the alarming growth rate of risk-taking behaviors in teens². Research with minors creates specific challenges for research ethics, such as concerns regarding the treatment of personal information provided by minors in general. Minors are held as being vulnerable, especially regarding their incomplete, but dynamic capacity of decision-making and giving assent/consent to research participation. Ethical issues such as confidentiality and minors' competency to assent or consent to participate in research were addressed at an international, multidisciplinary workshop held in Basel 2012. A preliminary "Needs' List" of researcher was formulated used as a starting point for engaging experts in a Delphi process identifying needs and preparing consensus.

Research Question: Which topics are ethically most relevant for those doing research with minors?

Approach: We conducted an online Delphi process with experts in health research with minors.

2012

1. Workshop – preliminary Needs' List of researchers

2. Delphi round 1:

- invitation of 60 addressees: approve of the preliminary Needs' List, modify or add new needs
- panel 1

2013

3. Delphi round 2:

- feedback to all 60 addressees of Delphi round 1 and invitation to reply: rating the Needs (agree or disagree)
- invitation of additional experts (7)
- panel 2

4. Delivery of results to addressees

- feedback: finalizing Needs' List

Based on the preliminary Needs' List, the 1st round questionnaire was designed and distributed. Addressees were asked to review the proposed 'Needs' List'. The answers were analyzed within a panel session. Based on these results the 2nd round questionnaire was developed and distributed, followed by feedback about which Needs had reached consensus.

Results: 22 researchers replied in Delphi round 1. They prioritized the following ethical issues regarding minors' participation in research: 1) informed consent (20/22), 2) confidentiality (17/22), 3) risk of harm (15/22). The preliminary Needs' List was approved by 91%. Some comments were subjected to further discussion; also, clarification of the preliminary Needs' list was requested. The previous needs were defined more clearly and refined; new needs, after obtaining expert-consensus of Panel 1, were added. Two criteria were proposed to be added to the Needs' List, i.e. criteria for sufficiency of a minor's consent, both personal and situational aspects. Delphi round 2 led to three categories:

- a majority of accepted Needs (more than 70% of the respondents' votes),

¹ This work is supported by the Botnar Foundation, Basel.

² <http://www.euro.who.int/en/what-we-do/health-topics/Life-stages/child-and-adolescent-health/adolescent-health>.

- a small number of clearly rejected Needs (less than 30% of the respondents' votes),
- ambiguous cases (more than 30%, but less than 70% of the respondents' votes).

The ambiguous needs will be put to discussion within Panel 2 for clarifications or changes.

Conclusions: The project responds to the lack of specific recommendations shown in previous studies regarding the participating of minors in health preventive research on sensitive topics. Ethical issues such as informed consent, confidentiality, and risk of harm should be better addressed and tailored to the requirements of the research with minors. The "Researchers' Needs' List" is suggested to offer ethical guidance for research with minors.

Changing notions of consent and confidentiality in genomics: recent developments in the UK

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The following paper discusses some recent developments in UK government policy with respect to Genomics, placing special attention on their implications for consent and confidentiality, and makes the wider claim that while these changes impact upon human values, they were not instituted by the public. I begin by describing these changes, making a case for their importance, firstly, in terms of their implications for privacy and confidentiality, and secondly, that the wider significance of this case for bioethical discussion lies in the democratic deficit by which such developments took place. I then conclude that not only do these changes lack legitimacy, but the risks they imply might well have been mitigated through greater public involvement.

At present, in the UK, the fundamental principles of information protection and sharing are being adjusted to suit the requirements of genomics. This will result in changes to the NHS constitution, thus removing the requirement to seek informed consent for medical research. Patient data will be automatically used for research by third parties unless one specifically chooses to opt out. At the beginning of the last decade, a private-public partnership put into place a major legislative programme to create a national genetic database. Major infrastructural changes were made, the most prominent of which, a set of interconnected databases that hold personal medical records, was established in 2011, on an opt-out, rather than opt-in, basis. In August, evidence was obtained that the Government are to go ahead with a national genetic database in the autumn of 2013. This too, will be on an opt-out basis. It will contain a person's entire genome, stored on a file, attached to personal medical records and made available to private organisations.

No doubt, there is potential in 50 million sequenced genomes connected to relevant phenotypic data, but changes of this magnitude also bring new dangers. As we know, a genome cannot be anonymised. Furthermore, genomic information is stored over long periods of time; with an *open* or *general* model of consent, data can be used for purposes that are not defined at the outset, and thus, carry risks that are very difficult to legislate against. Discarding informed consent gives the public less control, not more. This could result in free-reign for researchers, but the public and medical good may, in time, become blurred.

I argue that it may seem like a straightforward exchange: less informational autonomy for the public good of genomics – but as there are risks, greater public involvement could potentially offset narrower, sectional interests and provide the right balance. I conclude that if we cannot have informed consent, then we need an *informed public*. And for this, we need an open, public dialogue, about the benefits and the risks of genomics and advanced biotechnology. This, however, might require a step change in technological innovation and development, as often, the direction it takes is in line with commercial interests, and the promise of economic

growth results in favourable regulation. As such, it seems fair that if the old model of consent was 'inadequate,' this model, too, falls short.

Moral Status, Justice, and the Common Morality: Challenges for the Principlist Account of Moral Change

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The theory of principlism elaborated by Beauchamp and Childress in *Principles of Biomedical Ethics* has become extremely influential in bioethics. The theory employs the idea of the common morality as a foundation for the principles of autonomy, beneficence, non-maleficence, and justice. According to this account, the content of the common morality is universal and constant, while variability in morals is due to the fact that the issue of who is included within the scope of moral status evolves over time. This suggests that issues of moral status are not part of the common morality at all, and this presents a conundrum: questions of moral status seem central to any substantive account of justice, and any conception of the common morality that excludes moral status therefore seems inadequate for supporting a robust principle of justice. We argue that proponents of common morality theory are left with four options: making moral status a part of the objective common morality and ignoring evidence that views about moral status do seem to vary over time and place; excluding justice from the substantive content of the common morality; taking common morality to be an imperfect approximation of an independently justified and universal foundationalist ethic against which the common morality is judged; or weakening claims about the universality of common morality, thereby allowing the common morality to support a variety of principles of justice applicable only within particular communities that have specified the scope of moral status. We suspect that proponents of common morality theory will not view any of these options favorably, which raises questions about the ultimate contribution of this account.

Disease prototypes

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The concept of disease has fuelled long and partly heated debates. The concept poses profound ontological, epistemological, and ethical challenges, yet not settled. Accordingly, defining disease has turned out to be demanding. In the philosophy of language concepts have been considered to be prototypes (or stereotypes). One can therefore ask whether the concept of disease is a candidate for being a prototype. To address this question, 150 health care professionals have been asked to range various diseases according to how (proto)typical they consider them to be. The results are used to discuss whether the concept of disease can be a prototype, and whether prototypes are useful to the philosophy of medicine. Moreover, the results also shed light on the hierarchy of prestige that health care professionals' attribute to various diseases. Empirical studies have shown that health care professionals consistently rank diseases according to prestige. The explanation for this their ranking may as well be due to how (proto)typical the diseases are.

Should there be a right to ‘absenteeism’ for health care workers?

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This paper will discuss whether we can justify a right to be absent from work when ill in the specific case of health care workers.

In the first part it will outline two current public debates. 1) a debate about ‘absenteeism’ in health care, i.e. the perceived problem that health care workers have too much absence due to illness; and 2) the public and academic debate about the obligations of health care workers in relation to epidemics of infectious diseases, e.g. obligations to have vaccinations, or obligations to turn up to work even if there is a risk of becoming infected.

These two debates occur in isolation and the second part of the paper will try to bring them together. It will be shown that the justifications given for the obligations of health care workers also justify an obligation not to turn to work when ill. It will further be argued that if health care workers fulfil their other obligations, they are more likely to become ill than the average worker, and that it is therefore not strange if they are more likely to be absent; and that considerations of reciprocity provide an independent justification for a right to be absent from work when ill.

In a coda, it will be argued that the concept of ‘absenteeism’ misrepresents the issue and that the term should be erased from the English language.

Which are the new ethical issues posed in NIPD, and which of the “old” questions reappear in new robes?

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In discussions about prenatal diagnosis we have so far operated with a distinction between screening procedures and diagnostic procedures, based on perceived differences in the technological possibilities and societal organisation. NIPD potentially de-stabilises this distinction and may force us to rethink some of our ‘stock’ arguments in relation to PD and prenatal screening. In this presentation I will discuss two sets of arguments in relation to NIPD: 1) the ‘expressivist objection’ arguments, and 2) arguments relating to reproductive choice and reproductive obligations.

Perceptions, practices and ethics of cognitive enhancement drugs. A case study among academic youth in Amsterdam

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The perceptions, practices and ethics of academic youth using cognitive enhancement drugs (CEDs) is a novel area of research in the field of medical anthropology and sociology, especially in the Netherlands. It touches upon recent academic developments on both the anthropology of pharmaceuticals (Van der Geest et al. 1996; Whyte et al. 2002) and the anthropology of ethics (Zigon 2007; 2008). The sociological concepts of (bio)medicalization and pharmaceuticalisation (Abraham 2010; Williams et al. 2011; Coveney et al. 2011; Bell & Figert 2012) can be used as analytical tools to give more insight to the discussion about neuroenhancement of “healthy” people through the use of pharmaceuticals. The data for this master’s thesis will be collected by using semi-structured interviews of “users”, “providers”

and “peers” among university students in Amsterdam. The thesis will be submitted on the 28th of June and it is part of the master’s programme of Medical Anthropology and Sociology at the Graduate School of Social Sciences of the University of Amsterdam.

Neuroenhancement through the use of pharmaceuticals is a topic that has not yet received much attention from a medical anthropological and sociological perspective. There has been a number of studies showing the prevalence of non-prescription use of CEDs specially among college and university students on campuses across the United States (see for example Arria & Wish 2006; Arria et al. 2011; DeSantis et al. 2008; McCabe & Teter 2007; Rozenbroek & Rothstein 2011; Sussman et al. 2006). Although the estimates of their use vary, these studies give the impression that the use of CEDs, such as methylphenidate (Ritalin) by “healthy” people is something that is already happening (Coveney et al. 2011), at least in the USA. In the Netherlands the incidence of ADHD medicine increased 6.5-fold from 2001 until 2006 (Van den Ban et al. 2010). The main focus of this master’s thesis is on students who use pharmaceutical cognitive enhancers to have an effect on their studying. A national survey on the use of illicit and licit drugs in the Netherlands in 2001 shows that the use of “smart drugs” was highest among 20-24 year olds (12,6 %) and especially high in the same age cohort in Amsterdam (21,5 %) compared to, for example, the same age cohort in Rotterdam (6,3 %) (Abraham et al. 2002: 218).

How do users of cognitive enhancement drugs perceive the use of these substances? Do they see it as morally acceptable? How do they legitimize their use? These questions require empirical investigation about the different practices and perceptions that are involved around the use of CEDs in the context of academic youth in Amsterdam. A qualitative study on user perceptions, practices and ethics can give more insights on the variety of ethical issues that rise from the use of cognitive enhancement drugs, offer a thicker description of the different practices involved and add valuable arguments to the on-going ethical debate.

Innovation culture and Mertonian norms: tensions in the ethics of scientific publication

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The presentation attempts to analyze some ethical challenges posed by the newly emerged innovation culture in science. As an interpretative framework I use Ziman’s CUDOS principles of the scientific ethos and its transformation to new norms of post-academic science. The current emphasis on innovation in the biomedical sciences and its policy incentives create and sustain new norms of scientific conduct that I attempt to briefly describe. I use some examples from the ethics of publication and scientific integrity where the effects of innovation culture can be analyzed from an ethical perspective.

A Child Born to be an Orphan – Psychological factors

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Sperm preservation techniques allow men who might die to freeze sperm that would be used after their death. So far, there have been a handful of children who were thus conceived. Until direct information about these children’s wellbeing is obtained, I explore analogous situations of fatherless birth as background to the ethical study of the problem of planned post-humus paternity.

The analogous cases discussed are: orphans (children born after their father's death), and loss of a parent at a very early age. Among the issues explored are the circumstances of mourning and bereavement surrounding the child's birth, the possible projection of roles on the child, such as replacement or memorial to a dead person and the state of existence owing itself to fulfillment of a promise to a dead and dear person.

A second comparative perspective would be births by means of an unknown father and anonymous sperm donation. Despite significant criticism, these modes of progeny have been accepted by liberal societies and are actually quite common.

Lastly, in this presentation, I reflect on a likely hybridization of the two critical perspectives: the conscientious choice by women seeking sperm donation to have a child to a non-anonymous man who willed the preservation of his sperm after his death.

Population based genetics in public health perspective

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A new decade of the 21st century brings to the ethicists a significant number of challenges. Electronic databases, population - based biobanks, development of the technologies are not perfectly analyzed and it is not clear from what we should protect our communities and individuals. Electronical databases pose number of question about confidentiality and data security, new technologies pose issues of privacy. But the most challenging event is population- based biobanks and their influence to community and individuals. Taking into account aspects of public health we should focus discuss those problems from three ethical principles of public health – utilitarianism, communitarianism and liberalism.

Regenerative Medicine and the “New Normal”

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There has been much discussion of anti-aging research, enhancement, and transhumanism in bioethics, and the goal of increasing the human lifespan has been widely debated. Less attention has been paid, however, to the incremental changes potentially introduced by organ and tissue regeneration.

This presentation examines the implications of regenerative medicine for the concepts of *treatment*, *prevention*, *enhancement*, and *normal function*. Research is underway to investigate the safety and efficacy of regenerative technologies to improve organ function and offer alternatives to allotransplantation. They include in situ regeneration (mediated by inserted genes or mesenchymal stem cells), targeted stem cell transplantation, surgical implantation of immunoisolated cellular wafers into failing organs, and autologous transplantation of complete or partial organs.

All these regenerative technologies share the potential to alter the determination that an organ's function is abnormal and in need of treatment. The appropriateness of allotransplantation is determined not only by the supply of organs but also by balancing benefits and harms. Major surgery, life-long immunosuppression, and all their complications are not undertaken until organ function has fallen below a threshold determined by professional consensus and policy guidelines. If the surgery required to restore function is minor – an injection of a cell-based intervention, the small incision required to insert a wafer of healthy cells into an organ, or a minimally invasive surgery to implant a functioning partial

organ – then there is less need to postpone intervention until organ function has fallen to a low level. And if immunosuppression is not required because the implanted material is autologous or immunoisolated, there is similarly less need to wait for poor organ function. Thus, it is easy to imagine that with the advent of less invasive, less harmful regenerative medicine technologies, the threshold of need for treatment could rise, and the distinction between “normal” and “abnormal” function could shift, labeling better function as below normal.

At the same time, the use of partially regenerative technologies could result in a different adjustment to the concept of “normal.” Restoration of function to a normal level is a successful treatment. Like the need for treatment, functional normality is determined by professional consensus and policy guidelines. Normality can be demonstrated when an organ is functioning at less than 100% capacity. Partially restorative regenerative medicine interventions thus could be successful even when they do not restore full capacity. This could lower the threshold for successful treatment, by labeling worse function as normal after treatment.

The combination could result in a paradoxically narrow “normal” and an increased area of disputable, medicalized territory in which what might have been labeled prevention, or enhancement, may soon be regarded as treatment. Within this newly liminal zone, providers and patients may continue to disagree about what is normal and what is abnormal, but the potential cumulative effect is likely to be a gradual and subtle shift toward the belief that organs need never fail. How these small accumulated changes affect – and should affect -- our collective sense of mortality is something to consider sooner rather than later.

Do psychiatry journals support the unbiased translation of clinical research? A structured analysis of editorial policies.

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Introduction: The successful translation of findings from clinical trials into health care practice, guidelines and patient information depends on the timely, accurate and unbiased reporting of trial methodology and results. Reporting guidelines (e.g. CONSORT) have been developed as tools to improve quality and reduce bias in reporting research findings. Trial registration has been recommended for countering selective publication. The International Committee of Medical Journal Editors (ICMJE) encourages the implementation of reporting guidelines and trial registration as uniform requirements (URM). For the last two decades, however, biased reporting and insufficient registration of clinical trials has been identified in several literature reviews and other investigations. Among these findings were many high profile cases in the field of psychiatry. No study has so far investigated the extent to which author instructions in psychiatry journals encourage following reporting guidelines and trial registration.

Method: Psychiatry Journals were identified from the 2011 Journal Citation Report. Further, the top seven general medicine journals (NEJM, LANCET, JAMA, PLOS Med, BMJ, CMAJ, and BMC Med) were included. Information given in the author instructions and during the submission procedure of all journals was assessed on whether major reporting guidelines, trial registration and the ICMJE’s URM in general were mentioned and adherence recommended.

Results: We included 123 psychiatry journals (English and German language) in our analysis. A minority recommend or require 1) following the URM (21%), 2) adherence to reporting guidelines such as CONSORT, PRISMA, STROBE (23%, 7%, 4%), or 3)

registration of clinical trials (34%). In contrast, all top-7 general medicine journals recommend or require adherence to ICMJE's URM. We present more details about the wording and discuss the binding character of the information given to authors.

Discussion: For the field of psychiatry, which addresses an immense patient population with one of the world's highest burdens of disease, major improvements have to be made with respect to how journals inform and require their authors to adhere to a high quality of reporting and adequate trial registration. From an ethical viewpoint, the core principles of medicine (including the Ethics Codex of the American Psychiatric Association) all point towards greater efforts by journal editors to improve the quality of reporting and trial registration. Such improvements, which are quickly and easily achieved by revising authors' instructions and information given during the submission procedure, support the unbiased translation of research findings into clinical practice, guidelines and patient information. Further research is needed to assess how editorial policies address reporting standards for ethical review, informed consent of trial participants, or conflict of interests.

Medical brain drain as *structural* human rights violation

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The ethical-political debate about international *medical brain drain* is dominated by the human rights language. It is widely thought that affluent nations, by actively engaging in the recruitment of health professionals from world regions with critical health worker shortages are violating the human right to health of vulnerable populations. It is also argued that developing countries that fail to retain their health workforce are violating the right to health of their own citizens. Moreover, there are those who think that the migrating doctors and nurses are implicated in the harm through the compound effect of their personal choice to emigrate. The aim of this paper is to understand *in what sense* is medical brain drain a human rights violation.

Existing accounts, as this paper argues, suffer from two types of conceptual biases. First, they are locked into a statist paradigm that limits the root causes of medical brain drain to domestic societies and bad government choices. Second, by focusing on the agents (migrants and national governments), they omit the essential role played by structural constraints; namely, international institutions and the background condition of global socio-economic inequality that together significantly limit the range of options available to individual and collective agents.

This paper argues that there is a need to move beyond this *agent-centered* framework of moral assessment towards a *structural* conception of human rights (and its violation), that takes into account both the *agents* and the *structure* that shapes their actions. The 'political-institutional turn' in the human rights debate provides innovative conceptual tools in this direction, in particular, by taking human rights as international standards of legitimate political standing and action, the content of which may be specified through a critical analysis of the international doctrine. What remains unclear is the appropriate *judicandum* of such a conception: whether the legitimacy of states, international institutions or the global order should be the object of normative assessment. This paper aims to contribute to the debate by specifying this theoretical stake in a concrete international political context. It argues that medical brain drain is a *structural* violation of the human right to health, resulting from a complex interplay between individual and collective actions, framed by international institutions in the context of excessive global socio-economic inequalities.

The legal principles of reproductive technologies: the European court of human rights evaluating the margin of appreciation doctrine.

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Reproductive technologies as a new subset of the human rights protection system are considered to be one of the most problematic areas of the social development, both from the ethical and legal standpoint. An individual's right to benefit from the most effective and advanced medical treatments, especially those related to assisted reproduction technologies and reproductive genetic engineering, entails an efficient legal system that provides fundamental judicial guarantees. The task of developing and maintaining such a system seems to be particularly difficult to achieve in the European legal culture, because of the cultural, philosophical and political differences between the European nations.

Answering the demands of biomedical development the European Court of Human Rights (ECHR) has recognized the individual's right to use medically assisted procreation and reproductive techniques, stating that it is protected under Article 8 (Right to respect for private and family life) of the European Convention for the Protection of Human Rights and Fundamental Freedoms. Additionally, in one of the most recent and final judgements the Court stated that the pre-implantation genetic diagnosis should be considered a human right that is indirectly guaranteed by the Convention. The ECHR, however, did not settle *expressis verbis* whether assisted reproduction should also be considered a human right. The cases concerning reproductive technologies brought before the ECHR can also constitute an *actio popularis*, which means, that the applicants are trying to directly challenge the domestic law *in abstracto* of a violation of the Convention. It is important to underline that the European Court of Human Rights and its judiciary system should be of the subsidiary character and so the State's authorities have the right to benefit from the margin of appreciation doctrine. It means that States, at the national level, are allowed to enjoy certain freedom extending to "its decision to intervene in the area and, once having intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests" (*S.H. v. Austria*, Ap. 57813/00, 3 November 2011). The recent judgment in the *Costa and Pavan v. Italy* case radically limits the State's margin of appreciation, giving precedence to the rights of the individual.

This paper aims to provide the analysis of the European Court of Human Rights jurisprudence underlining the variety of relevant normative aspects. The fundamental legal principles of reproductive technologies seem to be especially important now, when we know that the ECHR is able and ready to control national legislation of the State Parties in accordance to broad interpretation of the norms of the Conventions, and to directly question domestic law without proving applicants quality of a victim nor submitting the case to the domestic courts.

Age, self-responsibility, and evidence-based health care as basis for priority setting – a participatory approach

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Objectives: Citizen's participation must be enhanced to increase acceptance and strengthen the legitimacy of priority setting in medicine. Therefore our preceding project analyzed different stakeholders' preferences concerning certain prioritization criteria. We identified

age, self-responsibility, and EBM to be important for further investigations. The current project evaluates citizen's arguments for/against these criteria. Furthermore we investigate if affected persons' differ from not affected persons' preferences and if laymen's differ from experts' preferences. Additionally we analyze whether preferences are context-sensitive. Therefore, the criteria are explored in context of organ transplantation and dental care.

Methods: We conducted twelve focus groups as qualitative, deliberative method: Two expert groups (economics, philosophy, law, medicine) and ten laymen groups. Experts discussed all three criteria against the background of the two contexts. Laymen discussions were limited to a single criterion. Besides laymen groups differed in characteristics regarding the criteria: E.g. participants aged 18-63 and elder discussed the age criterion separately. The interviews are currently analyzed (content analysis with MAXQDA 10).

Preliminary Results

Age: General arguments for the age criterion refer to its simplicity and objectiveness. Counterarguments are high follow-up costs in case of non-treatment and that chronologic age does not reflect medical condition. In the context of organ allocation age is accepted on the basis of less remaining life years and lower quality of life and rejected with the argument of an equal value of life and that it is impossible to determine an age limit.

In dental care a pro argument is that premium dentures should be limited to younger persons. A second argument is to use age inversed (prioritizing elders). Counterarguments are that mastication function is elementary and basic care must be provided irrespective of age.

Self-responsibility: General counterarguments refer to the uncertain causal relationship between an unhealthy lifestyle and diseases and to problems of measurability.

In context of organ allocation pro arguments are that withdrawal before transplantation is necessary and the medical situation might be caused by an actual fault. Drastic consequences and uncertain personal influence are counterarguments.

In contrast minor consequences and the incentive for prevention are pro arguments in dental care. Counterarguments are that self-responsibility is not verifiable and influence on dental health is limited.

Ebm: Generally the body of evidence and the consideration of case-by-case decisions are elementary in focus group discussions. In the context of organ allocation the use of EBM for deduction/identification of prioritization criteria is important. Medical urgency and the prospects of success are major subjects. In dental care benefit/costs and regulation for subgroups/exceptions are important.

Affected - not affected: There is no evidence for a consistent difference between affected and not affected persons. Many patterns of argument are equal.

Laymen – experts: Experts' preferences are more differentiated. Experts tend to weigh up more arguments. Some arguments only experts took into consideration.

Context sensitivity: Preferences are context-sensitive. Main reasons identified are different consequences and different reasons for prioritization.

Innovations in Health Care: Employment of carers in health care organizations

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In health care the availability of sufficient qualified personnel is a basic requirement for a functional health care system. With health care in Switzerland in mind, the demographic, epidemiological and social developments indicate that the shift from inpatient to outpatient care, the increasing demand for long-term care in old age and the lack of specialists, which has become apparent for quite some time, have significant ramifications, namely an

additional demand for qualified personnel. The new hospital funding regulations, which came into effect on 1st January 2009, and the new SwissDRG tariff system are similarly of great importance for the future development of the Swiss health care. They strengthen the price and quality competition between the hospitals, forcing the service providers to adapt their business expenditure and investments to the income from the fee-for-service-based flat rates. With the new tariff system of the fee-for-service-based flat rates per case in mind, the hospitals will increase their focus on the business management in order to succeed. Improved process quality and better interface management lead to faster discharge of patients from acute care; therefore, the aftercare providers (rehabilitation clinics, general practitioners, Spitex organisations (hospital external care providers), homes and relatives) have to respond faster. This puts greater demands, in particular, on the relatives who take over the home health care of these patients, requiring an (even) greater time commitment from them. In Switzerland there are more than 100,000 people who look after or care for another adult. Bearing the existing bottlenecks with regard to nursing staff in the Swiss health care system in mind, it is on the one hand crucial to know how and with which measures the personnel can be retained for these establishments whilst on the other hand innovative approaches to opening up new professional prospects - in particular for family carers - are of great significance. The focus is on the question how the state and the private health sector for the population can work together towards a common goal. In this context the reconcilability of employment and caring for relatives poses one of the great social and economic challenges we have to face today. Up-to-date findings of studies indicate that approximately half of all family carers do not work or have given up their employment or reduced their workload. As a result, the family carers suffer a loss of income and disadvantages with regard to their own retirement provision. During discussions concerning the support of family carers, financial recompense, professional assistance and respite offers are frequently demanded. There is, however, the possibility of new, innovative approaches, such as funding new ways of a relative-friendly home care system, for instance by employing family carers in health organizations.

Why we need a change in the placebo terminology

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It is not news that there is a lot of confusion in the terminology about placebos and placebo effects/responses. The problem does not concern lay media or general medical literature only, but even the placebo research community uses the terminology in inconsistent and misleading ways.

I shall argue in my presentation that the placebo research community should pay more attention to the prevailing conceptual confusion for the following reasons: 1) 'Placebo effect' is a contradictory term in itself, since a placebo has by definition no effect as such. 2) The negative and pejorative connotations related to 'placebo' ('inert', 'sham', 'noise', 'bias', 'only') are necessarily carried further on to the other terms (placebo effect/response), however much the researchers explain the nature of the phenomena. 3) Talking about placebo effects/responses maintain the false impression that giving a placebo is a necessary condition of the effect/response. What is called placebo effect or response has been well demonstrated without any placebos also in the research context. 4) What is now referred to as placebo effects/responses represent, in fact, a wide spectrum of phenomena related to human communication in general and the prefix 'placebo' prevents the medical community from seeing and understanding this.

Philosophers and ethicists out there: What can we learn from each other and how to improve our work?

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Quite a few of us are working outside the academia in professional settings, where we often are the sole philosopher or ethicist. This may often require different capabilities than those required and valued within the academia. However, there seem to be hardly any research and knowledge about being a 'philosophical/ethical professional'. The ESPMH conference provides an excellent opportunity to discuss what it is to be in such a position, to learn from each other, and to reflect conceptually upon this kind of work. Some of the relevant questions are: What kinds of positions do we have, what works in that position, how and why? What does 'working' mean here, when would we call it good work and when and why not? What can be learned from each other, what are good practices, why is an action or a way of being present deemed good and in what kind of practice? And what are the goals we strive after, driven by which motives and sources? To get a clearer picture, first a survey will be sent in May to all registered participants of the conference with items focusing on such questions. Second, responses will be collected and preliminary processing will be done in advance of the conference. Third, during the conference the results will be presented with a first interpretation, inspired by insights of eg. Schön - Reflective Practitioner, Sennett's Craftsmanship, Novotny's mode 1 and 2 of knowledge production, together with mode 3 from Kunneman and his ideas on normative professionalisation. Reflecting together on our experiences, goals and ways of doing, we will learn from each other and discover new possibilities improving our work at our own positions. This way this presentation contributes to the ongoing professionalisation of and innovation in the everyday practice of many ESPMH-members and registrees.

What is a public health measure: screening or testing?

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In Wales there has been a public health green paper issued for consultation in 2013 asking what measures the Welsh Assembly government should and could take to improve public health. They state that public health has been defined as "the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society."

The existing public health measures include screening programmes for breast and bowel cancer for example. However, the government introduced a testing programme, jointly funded by the British Heart Foundation, in 2009 for Familial Hypercholesterolaemia (FH) which uses a cascade method to identify family members with FH. This was not seen as a public health measure but rather a clinical genetic service.

FH is an inherited condition that leads to raised cholesterol. It is common among western populations and there are an estimated 5 000 people with FH in Wales, the majority of whom do not know about the disease. If untreated, FH leads to coronary artery disease in 50% of males by the age of 55 and 30% of females by 65. It can also cause sudden death or cardiac arrest before the age of 40. It can be effectively treated through the use of statins. Lifestyle changes are also encouraged but these by themselves will not prevent symptoms developing.

The comprehensive testing programme in Wales includes specialist clinics, specialist nurses, genetic counsellors and a coordinated database of test results. It is based on a NICE clinical guideline CG71 'Cascade family testing for Familial Hypercholesterolaemia' of August 2008.

This programme was not classed as a public health measure by either NICE or the Welsh Assembly government but will identify a significant number of the Welsh population at risk of coronary heart disease which is a significant health problem in Wales. What then differentiates a screening programme that is a public health measure from a testing system aiming to identify people at risk of disease?

Rethinking the ethical principle of human dignity?

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This paper aims at discussing the principle of human dignity using empirical material as a starting-point.

In my research I have carried out a narrative analysis of interviews with doctors in neonatal care, doctors in palliative care and hospital chaplains. One recurring topic, with regard to neonatal care, is that parents' relationship to their child in some cases has a direct influence on the medical treatment of the child. One narrative concerns a newborn girl where the diagnosis is not yet settled, but it is clear she suffers from severe illnesses. For her survival she is in need of a respirator and the estimated length of her life is about four to five months. The child's mother pleads with the physician to let this child die since she is afraid that if she has to take care of this severely sick child, her husband would leave her and the rest of the family. This influences the physician's decision and the child is never put on a respirator, and as a result of this she dies. The physician explicitly states that if the child had had parents who wanted the child to live, he would have acted differently.

The idea of human dignity has been understood as a value that a person has, regardless of one's recognition of it; it is a value that cannot be lost and a value that is equal. Many would agree with Immanuel Kant in his description: "Act so that you use humanity, as much in your own person as in the person of every other, always at the same time as end and never merely as means."³ Another way of discussing human dignity comes from Ted Peters, Professor of Systematic Theology at the Pacific Lutheran Theological Seminary in the USA. Peters suggests that human dignity has a phenomenological source and he claims that dignity is not connected to biology; rather dignity depends on the relationship to God and other human beings. Dignity is not understood as intrinsic but follows a process of first being conferred (by God and other humans), then grasped and claimed.

It could be argued that the treatment of the newborn girl is morally wrong since the child should be treated as an end in herself and receive medical treatment regardless of the wishes the parents might have. However, could an understanding of the ethical principle of human dignity as relational give another answer and could an understanding of human dignity as relational contribute to medical ethics in some way?

³ Kant, Immanuel. *Groundwork for the Metaphysics of Morals*. Edited and translated by Allen W. Wood, New Haven, Yale University Press, 2002, p 46-47.

How to deal with personality changes caused by deep brain stimulation which make the patient dangerous?

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Some neurosurgical interventions cause changes in personality or behavior of the patients. By way of example, after pallidotomy for the treatment of Parkinsonism, hypersexuality has occurred in a few cases. Following deep brain stimulation (DBS), on the one hand depression and apathy, on the other hand (hypo-)mania and hypersexuality occur in a small fraction of Parkinsonian patients. Whereas lesional interventions are generally irreversible, the effects of DBS are mostly reversible, and their extent and quality can be modified by postsurgical adaptations. Iatrogenic personality changes raise difficult ethical and legal questions, particularly when these changes can be modified by technical means.

Although the principle of respect for the patient's autonomy and the nonmaleficence principle forbid interventions which could cause personality changes that are either unwanted by or harmful for the patient, these principles do not forbid interventions that cause personality changes, which are appreciated by and beneficial for the patient but potentially harmful for third persons. Paradigms are interventions which cause or strengthen a person's disposition for immoral or criminal behavior, for example by reducing her capabilities for empathy, moral judgment, impulse control or self-reflection, or by causing hypersexuality, recklessness or aggressiveness. Indeed Beauchamp and Childress acknowledge that patient's decisions which potentially harm others might be overridden by competing moral considerations – one man's freedom ends where another man's freedom begins. But although the principle of nonmaleficence is not explicitly restricted to evil or harm for the patient, it is noticeable that Beauchamp and Childress have developed it exclusively with respect to the patient concerned. Dilemmas resulting from therapies, which are demanded by and beneficial for the patient, but harmful for other persons, reveal conceptual limits of Beauchamp and Childress' ethics. Altogether, the principles do not provide strong arguments to ban interventions which cause personality changes that imply a high risks for other persons.

I will discuss this thesis using the example of a pedophilic Parkinsonian patient who could profit from DBS from a neurological point of view, but for whom a significant risk exists that DBS will make him hypersexual and/or will reduce his ability of self-control so that his risk of sexual offenses against children would increase significantly.

The discussion will provide three conclusions: First, a principle-based risk-benefit assessment requires a broader perspective that includes all foreseeable consequences of the treatment both for patients and third persons, particularly consequences which might result from therapy-related personality changes. Second, the ethical evaluation of therapies with might cause personality changes, an ethical valuation of personality changes is required, since neither the conservative general condemnation of technically caused personality changes nor the libertarian abstinence in valuating personality is helpful. Third, a legal investigation is necessary in how far negative consequences of intervention-related personality changes have to be accounted for by the patient, the physicians or the manufactures of the responsible drugs or devices.

Ethical challenges regarding ambient assisted living technologies for the elderly – A closer look at self-determination

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The current demographic trends require rethinking health care and home care solutions. Rapid development of information and communication technologies that can be applied to technically equip private homes seems to be socially valuable for more than just economic reasons. As increased life expectancy comes along with increased rates of limited mobility, chronic disease, and multimorbidity, there are great hopes that new assistive health technologies allow an independent and self-determined life into old age through physical safety. A crucial assumption is that these technologies increase self-determination of those who use the technologies. Maintaining self-determination can be understood as a main motivation for developing and employing assistive technologies. Elderly people usually wish to keep the authorship of their life until the end. Independence, with its longest possible preservation, is the central normative legitimating background for the introduction of technologies in the home environment. We discuss the ethical ambivalence reflecting conflicts regarding the application of these technologies. On the one hand elderly people wish to keep the authorship of their life until the end. This desire often meets the creative potential of self-determined lifestyles. Furthermore, there is an ethical imperative of allowing social participation by enhancing physical potential (“capabilities”). The allocation of assistive technologies can be an imperative of social responsibility and mutual solidarity. On the other hand ethical problems arise when rights of protection of personality, privacy, and confidentiality collide with property rights of body and life. Here, classical bioethical conflicts between autonomy and beneficence emerge. The installation of technical surveillance systems impinges on privacy and requires careful consideration of relevant rights and duties. Determining whether informed consent can be provided is complicated in situations of physical dependency and potential cognitive impairment: Can one speak of an autonomous ability to consent under the conditions of physical dependence of those in need of care? What should happen if cognitive impairments are added? How intensively may monitoring be carried out, even *against* someone’s will, if there are possible advantages for them associated with it? We argue for a careful analysis of how the relation to technology changes individual self-perception. While technologies become more and more part of the lifeworld, they also become part of bodies and thus influence self-perception. Assistive technologies, in particular those that have sensors on the body, are likely to change self-perception. Consequently, one cannot assume the distanced judgmental perspective on attitudes and moral relations that is usually claimed for external artifacts, when one considers artifacts with which the person is functionally immersed. We investigate the influences this has on the potential for self-determined decisions regarding AAL technologies (Nagel & Remmers 2012). Further ethical conflicts arise from risks in data security, when the actual usage of information depends on many different persons (relatives, nursing staff, physicians, insurances, etc.). Moreover, it can be controversially debated whether public goods - like health science and development of health care services, which use vast and technically never fully secure databases - should be valued higher than the protection of personality rights.

Polio eradication as a national mission - Exploring structure and some ethical issues through a case study in Odisha, India

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As part of a broader project to study the 'Ethics, Policy and Practice of Poliomyelitis Vaccination in Orissa: A case study in community, professional and governmental attitudes to mass public health programmes in Orissa, India', the paper modestly seeks to present some broad and tentative initial findings on the structure of the polio eradication campaign as carried out in one of its eastern states of India in the last decade or so based on a case study involving both preliminary archival research and field work. While doing this, the underlying objective is to focus on the features of Global Polio Eradication Initiative (GPEI) and also to dwell on how the nature of the polio campaign has assumed the form of a national mission in India. This aspect is intended to be examined along with the attempt to map the general and overall response of people, public health activists, and the state to polio eradication campaign. The other significant dimension which the paper hopes to explore is to assess the nature of polio eradication drive by weaving together the arguments advocated by 'Indian dissenters' those who have expressed their discontents with the ways the polio campaign has been forced upon the developing countries like India undermining some of the critical areas of ethical considerations. The paper would try to address some of the issues namely effect of massive dosing of OPV on millions of children without taking into consideration the individual health profile, prevailing nature of general public health system in localities, the ethics underlying resistance to polio vaccination as located in certain pockets and communities, and the ethical dilemma between the conception of 'global good' vs 'Indian good'. The possible justification and relevance of these 'dissenting' ideas along with their associated ethical concerns are sought to be examined in the light of some of the findings from the field study and beyond.

Facilitating social innovation: exploring the roots of paternalism in post-Soviet health care

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Social innovation, as a way of introducing new and better practices, is one of the important drivers of ethical progress. Being a country in transition, Latvia is undergoing change in all of its social institutions, including that of health care. As it has been noted, "The rise of western standards in medical and research ethics was simultaneously contradicted by tradition of hierarchical paternalism, inherited from Soviet medicine, and pragmatic selfishness of the newly introduced free market economy." (Silis, 2010, 58-59)

Soviet health care system was notoriously paternalistic; patients usually were poorly informed and restricted in their choices. As an attempt to evaluate the social innovation and ethical progress in the field of health care, in 2012 we performed a qualitative enquiry into truth-telling practices and attitudes of Latvian physicians and medical students. The results of this study are described in the paper "Truth-telling and the asymmetry of the attitude to truth-telling to dying patients in Latvia" (to be published in a special issue of *Studia Philosophica Estonica*).

One of the most important results of this study was that after more than 20 years the old paternalistic practices are still found in Latvian health care. To shed some light on the origin of these standards and to evaluate the level of achieved innovation as well as to set the goals

for the future, we set to perform a literature survey of relevant Soviet-era publications on medical ethics during the first half of 2013. It will be one of the first attempts to address this largely unexplored field which could prove interesting and relevant to a number of Eastern European countries having a similar heritage.

At the conference we intend to present the main findings of a content analysis of Soviet medical ethics, or as it was called back then – deontology. We will summarize ethical principles and give analysis of the arguments that were used train soviet health care specialists. We will also attempt to envisage strategies for social innovation and change.

Innovations and Public Opinion. Teaching Ethics Expertise in Regenerative Medicine

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Funded by the German Ministry of Education and Research, an “Ethics University” on moral issues of regenerative medicine has been performed by the authors in 2012/13. The programme was called “Ethics Literacy in Young Adults (ELYA)”. About 200 pupils (from health related educations and grammar schools, mostly 17-19 years old) attended the courses, covering four half days. Teaching methods included lectures, role-plays, small-group discussions and specific “learning stations”, a concept developed previously by the Patient University, an educational institution to raise health literacy in patients and users of the health care system. The programme’s core content will be described in detail.

Teaching aims included “ethics literacy” in this innovative field of medical research. The concept of “ethics literacy” will be developed and defined in this presentation, comparing it to similar concepts such as “health literacy” and “ethical competence”. Ethics literacy comprises three domains: information, interaction, and deliberation/reflection. Examples will be given from the curriculum, which teaching methods could support which of the domains of ethics literacy. As a special feature, medical students acted as tutors. After being trained themselves they, for instance, supported the pupils performing ethics exercises such as a role-plays or small group discussions. The tutors were supervised by the academic team over the whole process. Thus, performing an ethics university likewise contributes to ethics literacy among medical students and didactic tools could be applied to the medical curriculum as well. Data from the evaluation indicate that the programme was successful to support ethics literacy in the field of regenerative medicine.

Finally, the impact of ethics literacy and expertise of the public in fields of future technologies will be discussed. Public responsibility in matters of bioethics needs well informed and ethically trained subjects. As part of health technology assessment, public opinion could be integrated if it is founded in comprehensive information and sound judgement. Even research funding, which governs research orientation and directions of development, could improve from ethics expertise of lay-people. Data from the evaluation are presented to prove participants’ appreciation of the programme and a growth in self-confidence and ethics expertise in moral judgements concerning regenerative medicine as an innovative field of biomedical research.

Privacy by design in personal health monitoring: possibilities and limitations

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The concept of privacy by design is becoming increasingly popular among regulators of information and communications technologies. For example, it is incorporated in the recent proposal for a “General Data Protection Regulation” from the European Commission to the European Parliament. The concept has important implications for personal health monitoring, that is, the surveillance of patients’ health status by means of technical devices in patients’ homes, worn by patients or implanted in patients. A key component of the concept is minimisation of the amount of data to be collected from patients and transmitted to health care professionals. A question to be asked in each particular case is: What information is really needed? However, privacy includes more than embedded data protection. Examples of privacy issues that cannot be solved by the approach of privacy by design are the handling of the information by health care professionals, decisions on what to do on the basis of the information, and the issue of who shall have access to the information. The concept of privacy by design has potential but also certain limitations.

Ambient intelligence for people with dementia

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Ambient assisted living (AAL) technologies can provide assistance and support to vulnerable persons, including those who suffer from dementia. They might allow these persons the possibility of living at home for longer whilst still maintaining their comfort, safety and security. However, the development, introduction and use of AAL technologies also trigger serious ethical issues. This talk will provide an overview of the ongoing scholarly debate about these issues. More specifically, we address the question of what ethical issues are involved in the various stages of research and development, clinical experimentation, and clinical application of AAL technologies for people with dementia and other related stakeholders? The talk will focus specifically on the value of the goals of AAL for persons with dementia.

Bioethical considerations on the legislation concerning pre-implantation genetic diagnosis in Portugal

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Until 2006 there was no legislation in Portugal concerning any aspect of Assisted Reproduction Techniques (ART) or pre-implantation genetic diagnosis (PGD) and there was a relative absence of juridical precepts applicable to the new challenges facing Bioethics. This may have been due to the very rapid scientific expansion of these subjects in relation to ethical considerations.

Although PGD does not hold a separate legislation, in the current Law 32/2006 (duly approved in 2008, by its proper Regulatory Decree 5/2008), which is divided into eight chapters, Chapter V addresses Pre-Implantation Genetic diagnosis. This Law is fully comprehensive of other aspects related with associated medical conduct in ART, such as

informed consent, confidentiality, etc., and dedicates Chapter IV (articles 24-27) to In Vitro Fertilisation (IVF), which must be performed previous to any PGD techniques.

The first chapter of Law 32/2006 comprises the general dispositions on Assisted Reproduction Techniques. In general, and because PGD can only be considered if there has been success in the method of ART chosen, certain aspects more directly linked to Bioethics, such as informed consent and confidentiality, which are fundamental in any genetic test, have been included in the Law (Chapter II, Article 14 – Consent; Article 15 – Confidentiality). Fully aware of the sensitivity around possible fates of embryos, the legislators have discriminated 5 different possibilities in Chapter IV, Article 25.

Chapter V of Law 32/2006, exclusively dedicated to PGD, is divided into Article 28 – Aneuploidy screening and PGD and Article 29 – Applications of PGD. In full agreement with the legislation in other countries, Law 32/2006 dedicates a whole chapter, with one article only (Article 30), to the regulating body for the sector designated “National Council for Assisted Reproduction Techniques” (CNPMA).

The existence in Portugal of legislation in ART and PGD since 2006 and its normalization as Law in 2008 demonstrates an important evolution of the Portuguese society, both in terms of new technologies and in the inherent ethical problems, as is proved by the detail with which the legislators have dealt with the various preoccupations described above while following rigorous and precise clinical criteria. It is hoped that in Portugal, as occurs in other countries where similar legislation exists, the practice of PGD will be greatly facilitated by the correct interpretation of the current law and, perhaps even more importantly, its periodic revisions will favour both the patient’s rights and needs and the practitioner’s conducts.

The double face of innovation: merits & demerits

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Innovation pertains to the appearance of something new in our conceptual and physical universe. However, so do discoveries, inventions, and improvements although not all of them to the same degree but in a different ways and varying extent each. We have come to value new things, whether discovered or invented, and we appreciate new methods and procedures which make our lives longer, fuller, richer.

This idyllic picture of humanity discovering, inventing, innovating beneficial methods and techniques, in the course of its long history is not really that accurate. Some discoveries have been really lethal to a large number of individuals. Inventors have created the light bulb but they also have made the atom bomb. General Kalashnikov’s innovativeness allowed every criminal -in Europe, at least- to possess an armory of Kalashnikovs, these excellent weapons. Taylorism, another landmark of innovation in industrial management, at the end of the 19th century, is depicted magnificently in Charlie Chaplin’s film *Modern Times* in all the magnitude of its alienating results.

However, the question, at this point, is not whether or not to cease all attempts to modify, to enrich and improve the quality of human life but, rather, how to minimize the undesirable out comes of each intervention, of each practice.

I think that there are criteria on the basis of which specific guidelines can be set so that undesirable or even catastrophic consequences can be avoided. I consider the specification of the need which the proposed intervention aims at satisfying as such a primary criterion. Research activity is often generated by human arrogance or human narcissism, both sources of human misery. The other two criteria are, first, who pays –directly or indirectly- for the

given research and, who benefits. The employment of these criteria will allow us to set our research priorities in a more reasonable way and with a greater sense of justice.

Who should set priorities in medicine?

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The wide ranging international research project "The Goals of Medicine" (1993-1996) run by Daniel Callahan from The Hastings Center came across the problem of who is to make a decision about priorities in medicine and health care at large. Although there are other goods that require distribution and that cannot be produced by bare financial sources (experts, transplants) the majority of commodities depend on invested money. The tough question is now who should make the choice about allocation of the budget. There are actually various groups in every society which pursue various interests and there are naturally conflicts between them. Therefore we need also criteria according to which these clashes should be resolved and again we must ask who is to fix them.

Indeed we can simply refer to the modern democratic structures but these structures are wobbling now when the transnational monopolies exert a strong impact on national parliaments as well as on the general public itself: the calculated advertisement and likely also corruption twists natural motivation of people wherefore people are prone to wish things that they actually do not wish. This domination of obscure forces over the whole states raises doubt about whether these states can rely on mere election as a sacrosanct pillar of the democratic society. Ergo many political critics suggest that democracy itself must go through a thorough transformation.

Accordingly we must put into doubt also the former notions of health care priorities that have been severely skewed due to manipulations by the technically-pharmacological complex and its power of money. Some political philosophers have proposed how this monster could be tamed and harnessed on the background of conversion of democracy from the old to the new version while these suggestions can be employed for the solution of the question how to obtain criteria of health care priorities and how to apply them. The presentation based on these hints will sketch direction of development towards the distinct priority and will attempt to draft it.

Mass media, oncology, ethics - The experience of an Ethics Committee

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Given the complexity and problematic nature underlying the perception and the personal experience of the cancer disease by the general population, it is easier to have a too high expectations and misunderstanding of the medical progress.

The need to identify the criteria and procedures to provide more effective and correct information to patients and to the general population on this issue is urgent and relevant.

One area of concern is the skill enhancement of physicians and healthcare professionals in regards to communicating information regarding diagnosis, treatment, rehabilitation, clinical trials and palliative care in a more realistic and aware manner.

Based on these considerations, the Ethics Committee of the Oncology Institute of Veneto in Padua has decided to start a shared debate on the Ethics of Information in Oncology, involving health professionals, communication experts and representatives of oncological

volunteering organizations. This interaction raised several considerations, among them: the need for greater transparency in media communications operated by physicians (avoiding personal interest or conflict of interest, while promoting accurate information to patients and the general public); it is important to stimulate journalists on how to correctly manage medical and healthcare communication. Both physicians and journalists are called to improve their own specific professional ethics and elaborate mutual cooperation with the common goal of adequate, correct and complete information to the public opinion. It has also been proposed to create a training course managed by the Hospital Ethics Committee on the Ethics of information for health care professionals in order to improve their capacity to appropriately relate with the media.

Technology has reconfigured medicine: a more wide technology assessment

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Surely the evaluation of technologies employed in the health care is very useful, it has also allowed a better understanding of the technologies themselves. However, an exclusive focus on the process of health technology assessment (HTA) has delayed a broader evaluation of the influences that technology had in medical practice. We need a systematic reflection on the kind of changes introduced in clinical practice.

Undoubtedly, physicians and philosophers have done some analysis: for example, they have studied how innovative technologies have impacted on the patient-physician relationship, they have also assessed the ethical issues inherent in many technological innovations used in medicine.

In order to study how technologies have changed the medical practice, we need a more extensive evaluation of the several ones used currently. Innovative technologies have introduced new professional in the clinical setting, they have urged to reconsider the social values over individual ones, etc..

In fact, technology has changed the way in which physicians make a diagnosis, it has changed their treatment and rehabilitation approaches. Technology has also had a strong impact on some specialties and specialists who practice them. An example is surgery that has completely changed its nature with the introduction of robots.

Surely all these innovative technologies have improved both the diagnostic model and the therapeutic-rehabilitative approach, and they have also reconfigured the clinical setting. Technique has imposed its own criteria of rationality, functionality and efficiency, as well it has put before its needs to the human being ones (in the case of the physicians and the patients). Moreover, there is a symbiotic relationship between man and machine. Man and machine coexist and this association can not be overlooked or avoided. Today it is necessary to understand and properly manage this relationship especially in health care.

Virtual reality in medicine

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Access to telematic networks has had a fundamental role into modifying the relationship between people and the healthcare system (HCS).

The possibility to access the net has even transformed the concept of health and has rapidly introduced new ways to supply and to consume goods, instruments and sanitary resources.

The Bupa Health Pulse 2011 International Healthcare Survey states that in the 12 Nations where the survey took place: 83% 'often' or 'sometimes' search the Internet for information and advice about their health, medicines or medical conditions. A quarter of the respondents (23%) use social networking websites to find out about health.

The Virtual Reality (VR) first applications in HCS started in '90s by the need of medical staff to visualize complex medical data, particularly during surgery and for surgery planning. These factors are evident in the extensive material published in both scientific and popular press, and in the unrealistic expectations on the part of the healthcare professionals.

Less than 20% of VR healthcare applications are actually using any immersive equipment.

Rubino, McCloy and Székely, in their reviews share the same vision of VR: "a collection of technologies that allow people to interact efficiently with 3D computerized databases in real time using their natural senses and skills". VR is also described in terms of human experience as "a real or simulated environment in which a perceiver experiences telepresence", where telepresence can be described as the "experience of 'Presence' in an environment by means of a communication medium". For Heim, VR is "an immersive, interactive system based on computable information... an experience that describes many life activities in the information age". He describes the VR experience around its "three I's": Immersion, Interactivity & Information intensity. According to Riva's definition on "VE in Medicine" we think that the VR medicine application may be divided in 4 great areas:

1. Communication Interface: Presence and Avatar; HealthInfo Island in Second Life, integration in Virtual World of chat, video-call (Skype), etc.

2. Medical Educational: training; apart from anatomical training, VR has been used for teaching the skill of performing different tasks like a 12-lead ECG or The PIVOTE system of St. George's University of London or the European DISTance TRaining Interactive and Collaborative Tools for the Civil Protection (Disaster's Medicine). In all these cases, VR simulators allowed the acquisition of necessary technical skills required for the procedure.

3. Surgical Simulation: a) Neuro (Surgery), b) Laparoscopic & Endoscopic, c) Simulators, d) Other. VR simulators provide explanations of the tasks to be practised and objective assessment of the performance; however they lack realistic haptic feedback. AR simulators retain realistic haptic feedback and provide objective assessment of the performance of the trainee (some laparoscopic AR simulators are: ProMIS, CELTS, LTS3-e and Blue DRAGON).

4. Psychotherapy: a) Phobias, PTSD, Anxiety disorders, etc., b) Rehabilitation, c) Clinical & Pain Management. VR was verified in the treatment of acrophobia, spider phobia, panic disorders with agoraphobia, body image disturbances, binge eating disorders and fear of flying.

Broad and Specific Consent to Biobanking: Lessons from Switzerland

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As storages of both human samples and corresponding data, biobanks are becoming increasingly significant for both clinical and research purposes. Biobanks normally focus on a certain type of samples (blood, tissue, DNA etc.) or specific diseases such as cancer. This means that networking and the exchange of information and material are an essential part of biobank stakeholders' work. Various barriers hinder the process of data and sample sharing, and a particular problem arises for biobanking in Switzerland as a result of the large variety of specific and broad patient consents that are obtained together with the samples and variation between the attitudes of ethics committees in different cantons. While some patients

sign a consent form permitting a broad spectrum of unspecified research on their sample, others are restricted to a particular institute, study or diagnostic purpose. In these cases, the samples cannot be made available for sharing partners without reconsenting the patient. However, the new Humanforschungsgesetz (2011), a Swiss law regulating research on human material, aims to facilitate research when there is no signed consent form for a stored sample. Under the condition that it is impractical to re consent, that the patient has not refused research using his sample, and that the research purpose outweighs the patient's interest, a sample might be used without the patients consent.

We present the findings of a qualitative study: 36 semi-structured interviews were conducted with stakeholders in Swiss biobanks and biobank networks. The results provide valuable insights regarding the extent to which the absence or presence of broad and specific consent have been obstacles for national and international data and material sharing between biobanks and between biobanks and other research institutes. Interviewees mentioned different strategies of dealing with a lack of consent, from not using affected samples at all to successfully obtaining new consent for formerly taken samples. Depending on their perspectives as clinicians, researchers, managers or ethicists, different stakeholders described consent forms as a necessary means of respecting patients' rights or as time-consuming bureaucratic obstacles that obstruct research. A national or even worldwide standardised version of consent was suggested by several interviewees.

These results provide a useful overview of attitudes towards biobanking consent in Switzerland as well as the first reactions of biobank stakeholders to the new regulations in the Humanforschungsgesetz. The finding that many stakeholders see consent as a potential obstacle to data and sample sharing in Switzerland is likely to be generalizable to the international context. Greater engagement with stakeholders may be necessary to stress the importance of consent in biobanking.

Innovative drugs and vulnerability of children

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Research on children is strictly limited to mainly two cases: when it is thought to bring a direct benefit to a child or when it is burdened with minimal risk and may be beneficial to the whole population. These limitations may hinder research on innovative drugs. The current studies in EU show that non-therapeutic research on minors is an ethically problematic issue (Lenk, C., et al. (2004). "Non-therapeutic research with minors: how do chairpersons of German research ethics committees decide?" Westra, A. E., et al. (2010). "Acceptable risks and burdens for children in research without direct benefit: a systematic analysis of the decisions made by the Dutch Central Committee."). Therefore some new regulations are suggested to be considered. The article sees through proposals of possible future regulations, trying to find such a solution that will allow for developing innovative drugs and at the same time properly protecting children as vulnerable population.

Pushing Too Hard for Innovation? Accessing Tissue Samples and Private Information in Planning Research

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Background and Central Ethical Problem: Data about tissue samples and private information are easily available to clinicians and absolutely vital to fulfill their mission. But when the same clinicians use their privileges to collect patients names, medical record numbers, diagnosis, lab tests results, outcomes of treatment with the intention of writing a protocol and looking at the feasibility of a research project, what are they really doing? Quality improvement? Research? Are they not crossing the ethical frontier between clinical and research activities? Many do not see, in such a situation, any problem at all or are not aware of the issue.

Arguments: Using the rather vague definition in the US Federal Regulations to make their point ("Research means a systematic investigation designed to develop or contribute to generalizable knowledge" 45 CFR 46.102e), some argue that planning for research is a different phase separate from the research itself. In most cases the collected data does not identify an individual and, in that case, the clinician could play the role of an honest broker, using a code before transmitting the basic information. Finally, some do believe that research is part of their professional activities in an institution committed to research. Every patient should sign a blanket consent at admission to allow the use of tissues and private information.

At the other end of the spectrum some will put forward the difference between care and research and ask for a specific consent from the patient. If deemed unfeasible, some will say that the institution should require at least the authorization of the Institutional Review Board or the Privacy Officer. Others will stress the fact that the identity of the subject is known, or may readily be ascertained by, the investigator or associated with the information in such cases. Not only names and social security numbers are identifiers, but also date of birth, sex, ethnicity, diagnosis, and course of treatments.

Conclusion: Reports of such dubious practices should be systematically documented, described and quantified using anonymous surveys to have a better idea of the problem. Partnerships between IRBs, researchers and clinicians should be supported and realistic solutions considered so that privacy and development of research find their dues.

On the notion of the experimental in the field of reproductive medicine: a conceptual framework based on three categories of treatment

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In the rapidly evolving field of reproductive medicine, the introduction of new technologies or treatments is common practice. Ideally, this introduction is preceded by scientific research into the efficacy and the safety of the intervention. During this research phase any clinical application of the technique would be considered experimental, meaning that it should only be offered in a research setting and with approval of a medical-ethical review board. However, the precise delineation of this research phase is a recurrent subject of debate. When is the evidence base firm enough to decide that a new technology or treatment no longer needs to be regarded as 'experimental'?

Traditionally, guidelines from medical societies depart from a dichotomy between experimental treatment and established treatment. However, in the field of reproductive

medicine, there are several problems with a dichotomous framework. First, it does not offer an adequate account of the reality in the clinic. Many fertility centers offer treatments to patients that are neither considered established medical treatment, nor regarded as experimental. Second, this view may bring about several negative effects for the patient. On the one hand, considering all procedures that are not yet established, as experimental treatment, would incline that these procedures can only be performed with the specific review of an Institutional Review Board. This could leave many patients waiting for a treatment they could benefit from, as most of them do not have the time to wait until the procedure is considered an established medical procedure. On the other hand, also the opposite may be the case: techniques being considered established too early, sometimes implying risks unknown to patients. A further drawback related to the dichotomy is that if a technique is no longer considered experimental, centers offering the technique may no longer consider it useful to gather and critically examine (follow up) data.

Two special interests groups (on 'Ethics & Law' and on 'Safety & Quality in Assisted Reproductive Technology') of the European Society of Human Reproduction and Embryology have considered the notion of 'experimental'. We propose a conceptual framework that distinguishes between three instead of two types of treatment and describe a continuum from experimental over innovative to established treatment. With the introduction of the category 'innovative treatment', we want to provide an answer to the problematic dichotomy between the two extreme points of the continuum: experimental treatment and established treatment. In our proposal, whether a procedure is to be viewed experimental, innovative, or established can be judged according to four criteria: efficacy (proof of principle), safety, efficiency, and procedural transparency/certainty. We also provide a tool to facilitate the discussion and reach an agreement about the classification of treatments in the field of infertility. Finally, we have formulated recommendations regarding the role and responsibilities of centers offering specific treatments with regard to: the informed consent of the patient; the collection of data that allow continued and long-term evaluation; the publication of these data, regardless of treatment success; the need for specific or general approval of local ethics committees, etc.

Projecting futures of NIPD

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Which futures of NIPD are desirable, reasonable, or realistic? And which would be morally objectionable, or unlikely? I will develop a rather descriptive analysis of relevant governance parameters that influence future developments of NIPD practice, based on knowledge from the history of medical genetics and science and technology studies on genetic medicine. With regard to ethics I will argue that NIPD, while perhaps not raising fundamentally new ethical issues, will still reshuffle prenatal diagnosis, open new markets for test providers, change the lived practice of reproduction and put more women/couples into a dilemma. It will be more difficult to resist these offers, and test possibilities might become as comprehensive as technically feasible.

How can we improve treatment decision-making for incapacitated patients? Patients' priorities

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Background: Treatment decision-making for incapacitated patients poses a significant challenge. Most patients do not document their treatment preferences, and it is often unclear which treatment best promotes their clinical interests. Current practice, in these cases, is to rely on surrogates to make treatment decisions in consultation with the patients' clinicians. This is intended to promote several important ethical goals, including 1) providing treatment consistent with patients' considered preferences and values, 2) respecting the patients' preferences for how treatment decisions are made, and 3) respecting and helping the patients' families and loved ones. Unfortunately, empirical data find that surrogates often do not know the patients' preferences and values, and that helping to make decisions places substantial stress and burden on many surrogates. Furthermore, most patients want their loved ones to help make decisions, but they also want to minimize the burden on them. Patients also believe their loved ones know which treatments they want (or do not want). Any proposals for how to improve this situation need to be evaluated in light of patients' priorities.

Methods: Quantitative survey of patients' priorities regarding treatment decision-making at a large tertiary care center in Washington, D.C. (United States).

Results: The vast majority of 1135 patients rated all self-and family-related goals for treatment decision-making as extremely or moderately important: getting the treatments they want / avoiding the treatments they do not want (95% / 89%); getting the treatments the family thinks they want (81%); having the family make treatment decisions (88%); minimizing stress on the family (87%); not being a financial burden on the family (85%). When asked which of these goals they prioritize, 25% responded that no goal was most important. Of those who prioritized one of the goals, 37% indicated that getting the treatments they want was most important, followed by minimizing stress on the family (17%) and avoiding the treatments they do not want (15%). Most respondents (96%) were unsure of these priorities. When informed about surrogates' inaccuracy and their stress from helping to make treatment decisions, 60% said their family should make decisions after discussing treatment options with their doctors. 29% wanted their doctors to make the final decision. – The response rate was 60%.

Discussion: Patients do not have clear priorities for how treatment decisions should be made during periods of decisional incapacity. Many patients want their family and loved ones to make decisions for them, but they also prioritize goals that are difficult to square with family involvement – notably getting the treatments they want and minimizing stress on patients' loved ones.

Conclusion: Empirical data on patients' priorities are necessary for improving treatment decision-making for incapacitated patients. The present study suggests, however, that patients' priorities are often unclear. This finding underscores the challenges for responsible innovation in this area.

Should biomedical innovation be denied to athletes?

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It is by now axiomatic that the discovery or application of biomedical interventions that retard or arrest neuromuscular deterioration, or improve cardiovascular efficiency, almost inevitably raise alarms within the sports ethics (i.e., anti-doping) community concerning their availability to athletes.

It perhaps goes without saying that any technology that will increase muscle mass, or rebuild muscle tissue, is naturally of great interest to athletes. What is less obvious, however, and is one of the fundamental questions this paper raises, is why athletes should be denied the benefits of biomedical innovation, when society as a whole is encouraged to not only eagerly anticipate innovation but to advance it, to whatever extent their own participation (as research subjects, financial support of research, etc.) will permit.

This is a much more complex issue than it might at first appear. And the therapy-enhancement dichotomy is a less than satisfactory line of inquiry, not least because enhancement is the condition to which all athletes obviously aspire.

The most compelling argument against biomedical enhancement in sport highlights matters of safety. But the overwhelming majority of sports are inherently dangerous. In fact, it is arguable that danger is a defining characteristic of sport, such that absent the risk of physical harm an activity is more properly defined as simply a 'game.' Further, Alice Dreger has argued that in the United States at least, sport's governing bodies' concern for the safety and well-being of athletes is so poorly evidenced that perhaps American athletes need a safety/anti-exploitation advocacy organization similar to PETA (People for the Ethical Treatment of Animals). Although there are those who warn of the dangers of enhancement-oriented use of, for example, HGH or testosterone, it is most often the case that sanctions against athletes who are found to have used such substances are based upon a stated desire to protect the sport, not the athlete.

This begs the question whether in the name of hero worship (at best) or quasi-religious standards of athletic/moral purity (at worst), we have created a carefully constructed and highly selective underclass of individuals whose greatest transgression is to behave in ways that are perfectly acceptable in society as a whole. Eric Juengst posits for instance that this type of reasoning is tantamount to a peculiar kind of modern-day eugenics, which places athletes with a genetic predisposition toward a sport in a special category, one that is judged to be ethically unattainable by those who seek to cancel or mitigate a putative genetic shortfall by biomedical recalibration. Likewise, Andy Miah contends, most recently as quoted in a January 2013 New York Times article, that the behavior we call doping derives essentially from a need to surreptitiously advance the science of human performance against arbitrary (if not capricious) standards of moral rectitude, unreasonably divorced from everyday reality.

To simply call this a double standard would be to ignore the broader social justice — and therefore, ethical — implications of explicitly denying to a select group the benefits of biomedical innovation that others enjoy.

Bioenhancing moral virtues

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In a recent series of articles and books J. Savulescu and I. Persson have argued for the urgent need of morally enhancing humans by biomedical means. They claim that there are two central moral dispositions: *altruism*, involving empathy and sympathy, and *a sense of justice*. Both of them have a biological/genetic basis, therefore, biomedical manipulation of those traits is possible and strongly needed. A morally bioenhanced person would be more willing to sacrifice own interests for the benefit of others, and that would be a moral enhancement, on any account of morality [The Monist 2012, 95(3)]. Savulescu and Persson further claim that J. Harris' worries that moral enhancement would "make the freedom to do immoral things impossible" and "without the freedom to fall, good cannot be a choice; and freedom disappears and along with it virtue [Bioethics 2011, (25)2] are groundless. In their opinion the morally enhanced persons would not be deprived of their freedom to do wrong. In fact, they "would act for the same reasons as those of us who are most moral today, and the sense in which it is "impossible" that they do what they regard as immoral will be the same for the morally enhanced as for the garden-variety virtuous person: it is psychologically and motivationally out of the questions" [2012, 95(3):409].

The aim of my presentation is to discuss whether bioenhancement of natural dispositions, in particular altruism and justice, would indeed constitute moral enhancement; whether it would make us more moral/virtuous persons. Firstly, I will discuss the traditional concept of moral virtues and its relations to natural dispositions. Secondly, I will argue that moral virtue is not just a natural tendency to act in a virtuous way, that might be medically induced or improved. Virtue requires rational choice based on the recognition of the value of virtue and the understating that a given action is the right one in a given circumstances. The virtuous individual acts out of the right reasons, not because she is naturally or biomedically inclined to do so. Therefore, I will argue, contrary to Savulescu and Persson, that a man who would take a drug which makes him more like a woman in respect of empathy and aggression would not 'automatically' become more moral or virtuous. As N. Athanassoulis puts it: "true virtue requires conscious choice, understanding, and knowledge" [IEP, 2010], and the development of those mental phenomena requires time, afford, education and life experience.

Moral Enhancement

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Following recent empirical findings in the science of morality, there appears to be the slight but intriguing possibility that at some point in the future we may be able to develop a series of biomedical interventions (genetic or otherwise) that may be able to 'enhance' our 'moral dispositions'; for example, by attenuating our so-called 'counter-moral' emotions (Douglas, 2008). The prospect of this possibility has subsequently given rise to a series of papers by prominent ethicists seeking to address the ethical implications of such imagined technologies. For example, Ingmar Persson and Julian Savulescu (2008, 2011, 2012, 2013) have recently argued that we should prioritise the development of technologies aimed at moral enhancement in order to avert future catastrophe, with Tom Douglas (2008, 2013) making the more modest claim that, under certain conditions, the use of such technologies would be morally permissible. In this paper, I argue that for one to use such a technology, while not being necessarily morally *impermissible*, would at the same time be to fail to understand the

project of humanity, and what we mean when we say we want to be a better person. As I explain, what advocates of moral enhancement technologies appear to have ignored is that, in the path of our moral lives, our aim is not just to *be* a better person (or someone with better ‘dispositions’), but more precisely to *become* a better person, and to do so in ways that are themselves morally worthwhile and satisfying. In seeking to circumvent or dramatically compress this process of ‘becoming’, therefore – as well as in attempting to distil it into a pill, or some sort of intervention in our genetic code – the use of imagined morally-enhancing technologies would not only rob us of the *work* of morality but perhaps also its ultimate reward. I finish by offering a series of responses to anticipated counter-arguments, as well as addressing Persson and Savulescu’s ‘burning platform’ argument, which may, under one reading, suggest the prioritisation of ‘being’ good over ‘becoming’ good.

References:

- Douglas, T., (2008) ‘Moral Enhancement’, *J Appl Philos*, 25(3): 228–245.
- Douglas, T., (2013) ‘Moral Enhancement via direct emotion modulation: a reply to John Harris’ *Bioethics* 27(3): 160–168
- Persson, I and Savulescu, J., (2008) ‘The Perils of Cognitive Enhancement and the Urgent Imperative to Enhance the Moral Character of Humanity’, *Journal of Applied Philosophy*, 25(3):162–177.
- Persson, I and Savulescu, J., (2011) ‘The Turn for Ultimate Harm: A Reply to Fenton’, *Journal of Medical Ethics*; 37:441–444.
- Savulescu, J. and Persson, I., (2012) ‘Moral Enhancement, Freedom and the God Machine’ *Monist*, 95(3): 399–421.
- Persson, I. And Savulescu, J., (2013) ‘Getting Moral Enhancement Right: The desirability of moral bioenhancement’ *Bioethics*, 27(3): 124–131

On ambivalence and morals: a draft law on banning commercial assistance with suicide in Germany

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In Germany suicide is not an illegal act (as it is in some other countries). While active euthanasia is punishable as *homicide on demand* to assist with suicide is not illegal with respect to the systematic of rights. The latter precludes to bar assistance with suicide as assistance with an act that is not illegal cannot be prohibited by law.

Nevertheless, the German Medical Council holds assistance with suicide of patients as opposed to medical ethics. A respective statement has been laid down in a code of conduct (“It is forbidden to kill patients on their demand. They [physicians, addendum by the author] are not allowed to assist with suicide”). Yet, this code of conduct is not binding as it has to be adopted by the Medical Councils of each single state in Germany.

Prompted by various cases and initiatives that intend to increase the acceptance of physician assisted suicide, e.g. the German branches of originally Swiss based organizations such as Dignitas, the ethics as well as legal ruling of organized offer to assist with suicide had been discussed for years. In the end of 2012 the government has presented a draft law to ban commercial suicide assistance. The draft had been criticized as it is said to privilege organizations that offer suicide assistance if there is no intention to realize financial profit.

In this paper the ethical conception behind physicians’ rejection of assistance with suicide is outlined. The argument is presented against the background of recent findings in empirical research that show a high level of ambivalence of patients that utter wishes to receive assistance with suicide. In addition the importance of establishing a net of relations for persons at risk to suicide had been proven in empirical studies. Considering the ambivalence

of patients' asking for assistance and the particularity of organized offer the German Medical Council's position is found to be justified and, hence, the draft law insufficient.

How to decide who decides? From the investigation of the existence of bioethical expertise to its authority in public decision-making.

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Specialization – according to which having some knowledge in one field equals to deepen in one or few issues of a certain discipline and to investigate them in every aspect – it is the other side of the coin of the expertise – to possess an exclusionary knowledge or skill in a precise domain. Indeed in a specialized world, where knowledge has increasingly become a collective enterprise, nobody can master all fields, thus provoking the birth of a myriad of experts, each specialized in a precise domain or subdomain (Rasmussen 2005). Given this framework, it is not surprising at all that people with a training in ethics and/or bioethics are often referred to as 'ethics experts' and/or 'bioethics experts'.

Traditionally, the issue of bioethical expertise (BE) has been mainly addressed from two different perspectives, that we can define as the "metaethical perspective" and "the political theory perspective".

The metaethical framework investigates the issue of BE wondering whether there is something like an expertise in a field such as that of ethics/bioethics and, in case of a positive answer, whether moral philosophers are the best equipped to be moral experts or whether moral philosophers are not and should not be moral experts at all.

The political theory framework addresses the issue of BE analyzing it with regard to two different categories of political questions: the "deliberation questions" and the "authority questions". Whether deliberation questions are those investigating the relation between expertise and democracy – and, more precisely, the compatibility of the ethical expertise with the deliberative democracy turn – the authority questions examine what political weight should be granted to bioethical experts in public decision-making.

My purpose is to provide a systematic review of the contemporary literature on the issue of BE, analysing it especially from the metaethical perspective. In particular, we take into account all the objections which have been posed towards the concept of BE, distinguishing them as follows: i) skeptical reactions towards the concept of BE as such; ii) actual objections towards the concept of BE as such; iii) objections towards the idea that moral philosophers can be moral experts. Once examined this debate and showed that none of these objections seems to be a definitive one, it will be eventually suggested that the relevant question does not seem that of asking whether bioethics expertise actually exists. Indeed, the lack of a unique way of defining what BE actually is, seems to make impossible to provide a definitive answer to the problem. In conclusion, it will be argued that the investigation of BE should take another direction, by analysing the problem through the gaze of political theory. Therefore, trying to provide an answer to the authority questions and the deliberative questions seems to be the most valuable strategy to deal with a flourishing debate on BE.

Nano Tech, Mega Risks? Ethical uncertainties in first-in-human trials of nanotechnology

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Medical applications of nanotechnology have tremendous potential for targeted drug delivery to diseased organs and consequent improvement in the quality-of-life of patients suffering from chronic diseases. This technology can also facilitate more accurate and affordable diagnostic methods and medical record storage facilities such as nanochips which could improve the patient-health care interface. But like every new technology, nanomedicine poses questions regarding safety. This paper looks at three main ethical issues surrounding medical applications of nanotechnology.

First, we discuss whether nanomedicine raises any novel ethical concerns. In the debate on this issue, it is often difficult to separate the 'nano' nature of particles, objects and interfaces from other fields that use nanoapplications and nanoprocesses, such as stem cell research, gene therapy, human enhancement, and tissue engineering. Our focus here is on toxicity due to modified and hence often unpredictable physical and chemical properties of nanostructures and nanoparticles within tissues, organs and the environment. Owing to their nanosize, these particles significantly enhance surface area available for chemical reactions and also have potential to reach deeper into tissue spaces than larger molecules. Though these properties might benefit drug development processes to achieve better drug concentration in deeper tissue spaces which are otherwise not accessible with traditional drugs, it also poses threat of accumulation of such particles in these tissue spaces and subsequent toxicity. At present, we have limited data on the toxicity and long-term safety of nanoparticles and products containing them. We conclude that, if there is anything about nanotechnology and nanomedicine that is ethically novel, it has to do with ambiguous and uncertain risks and harms that cannot be adequately predicted and hence cannot be prevented. These risks are not limited to the patients alone but extend to people involved in production of these drugs and eventually wider population through release of these particles into the environment and their entry into ecosystem.

Second, we systematically review the risks, uncertainties and ambiguities involved in First-in-Human (FIH) trials in nanomedicine, focusing upon philosophical discussions about risk. Risk assessment and risk management go beyond medicine and we can draw valuable insights from other fields such as the aviation industry, the nuclear energy sector and global climate change. Our discussion will focus on the medical applications of nanotechnology, and attempt to answer the following questions: Which risks are worth taking? Who should take these risks - patients or healthy volunteers? When are these risks justified? How does the risk-benefit balance tilt when the prospective benefits are not clear and convincing and the risks are unknown and uncertain?

Finally, we provide an overview of existing guidelines for assessing ethical issues of new technologies and assess whether they provide adequate governance for the ethical review process of FIH nanomedicine trials and what issues remain unaddressed.

Licensed to 'Treat': The Importance of Enhancement in Medicine

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Julian Savulescu will explore the difficulties that arise in a world where there are professional and/or societal reasons for attaching a diagnosis and providing treatment to persons with

behaviours or conditions that in earlier times could have been accepted as falling within the range of normal. He will discuss the concerns about overdiagnosis and/or overtreatment of conditions as diverse as ADHD, premenstrual syndromes, and poor impulse control in toddlers.

Re-Focusing the Ethical Discourse on Personalized Medicine

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Background: In recent years, personalized medicine (PM) has become a highly regarded line of development in medicine. Yet, it is still a relatively new field. As a consequence, the discussion of its future developments, in particular of its ethical implications, in most cases can only be anticipative. Such anticipative discussions, however, pose several challenges. Nevertheless, they play a crucial role for shaping PM's further developments. Therefore, it is vital to understand how the ethical discourse on PM is conducted, i.e. on what – empirical and normative – assumptions ethical arguments are based regarding PM's current and future developments.

Methods: To gather this information, I conducted a qualitative interview study with stakeholders in the German health care system. My purposive sample included 17 representatives of basic research, clinical research, health economics, regulatory authorities, reimbursement institutions, pharmaceutical industry, patient organizations, as well as clinicians and legal experts involved in PM developments or policy making. I used an interview guide with open-ended questions and analyzed transcriptions of the interviews by means of qualitative content analysis.

Results: In my talk, I will present a multitude of concerns in the context of research on as well as application of individualized preventive and therapeutic measures addressed by the respondents both on the individual and on the societal level. Interestingly, regarding future developments of PM the ethical evaluation seemed to follow the rule: the less likely its application, the more problematic a PM measure is assessed. The more likely its application, on the other hand, the less problematic it is evaluated.

Conclusions: The results of my study suggest re-focusing the ethical discourse on PM in Germany towards a *constructive* ethical monitoring which ensures to include *only*, nevertheless *all* of the actual and/or potential concerns that are *ethically relevant* in order to allow balancing them against the actual and potential ethically relevant benefits of PM measures. In my presentation, I will therefore propose an adequate strategy for evaluating ethical concerns in the context of PM.

Priority setting in humanitarian emergencies: what are the ethical issues?

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Médecins Sans Frontières (MSF) is probably the world largest medical humanitarian organisation, delivering emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters. While MSF provides medical care to individuals, it is also organises health care for entire population groups, implementing disease control programmes and setting priorities in its projects. In doing so MSF is confronted with competing needs. This potentially creates tension and dilemmas in three distinct areas:

(1) Health professionals may be torn between medical ethics and organisational constraints. Examples of such dilemmas are:

- Treating the most “urgent” diseases and leaving others for later or never (e.g. HIV, TB)
- Limiting access to care (some services are provided, others not)
- Rationing care (some get a certain service, others not)
- Closing a programme (for security reasons; to allocate resources elsewhere)

(2) Direct patient care objectives and public health goals may also clash during an emergency. For example, not providing TB treatment for fear of resistance or treating cholera patients without implementing preventive activities.

(3) MSF sets operational priorities at many different levels. In the field, doctors and other health professionals make implicit or explicit choices about how resources ought to be allocated almost on a daily basis. These decisions are also made in country coordination teams (e.g. closing one project, opening a new one) and in headquarters (e.g. high proportion of MSF’s resources spent on ARV treatment). MSF does so in emergency situations, as well as in longer term programmes. What underpins these decisions? What are MSF’s organizational responsibilities towards populations it assists? How do these responsibilities evolve when lack of security becomes a major threat to MSF teams, but also to the population it serves?

These operational choices should be ethically sound, acknowledging that MSF’s responsibilities as a medical humanitarian organisation have limits (“we are not the only one”). MSF has to decide where to set the limits and how to set them accepting that often the decision made is not ideal, but the “least worst” option.

It may be difficult to apply ethical principles under complex operational circumstances in humanitarian emergencies. However, MSF should acknowledge that operational decisions must not be arbitrary and that they can be questioned on ethical grounds. The organisation has to be selective and because of that is imperfect. This is justifiable as long as those making decisions are conscious of the principles that underlie these decisions, evaluate their consequences and communicate the reasons for making such decisions to those concerned. I will argue that the process of decision making is paramount and that *Accountability for reasonableness* could be one way to engage a more transparent decision making process.

As MSF and other medical humanitarian organisations will face global pandemics, the consequences of more severe natural disasters due to climate change and environmental degradation, an increase in the prevalence of chronic diseases and increased antibiotic/drug resistance, setting priorities in an ethical manner will become ever more important.

Innovation and progress in health care

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Innovation is supposed to generate beneficial effects, i.e. it is intended not merely to cause change but to provide real progress. These general statements obviously also apply to health care innovation. It seems, however, that progress in health care requires at least some rough idea of goals that innovation is supposed to fulfil. Otherwise it is hard to see how innovation could claim to be beneficial, since it is, by itself, not a goal but a means to certain goals. Can innovation be directed through the idea of goals of health care? Are there any such goals?

There have been several attempts within philosophy of medicine to identify goals of health care and medicine. My contribution will scrutinize some of these approaches. I will also draw a distinction between internal and external goals of health care. In conclusion, I will be

sceptical about the reasonableness of the idea of internal goals of health care, but also critical of using external goals, such as cost effectiveness, for claiming progress in health care.

How will NIPD affect generative relationships and natality?

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I will argue that NIPD will have significant impact on fetal medicine and will give rise to new ethical questions, which concern the fundamental understanding of pregnancy, natality, and generative relation. With the establishment of NIPD a routine is prepared which normalizes a suspicion against the health status of the next generation unless the test proves negative. For routine the heredity and familial relations are scrutinized and evaluated. The decision is not anymore: Do I want a child? but: Do I want a child with this genetic disposition? Will the attention shift from the care of good family relations to the routine of close examination of body material and its acceptance after careful consideration? If the materiality of the body stands under close scrutiny, then the question must be posed: Can there be ever acceptance of a person, of a child, without hesitation, without constraint but by simply saying “yes” with (unconditioned) love.

Human enhancement - a case against human nature?

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Technological development has enabled humanity to change (or, as it is often said, enhance) its nature. The idea of human enhancement, as a contemporary theoretical example of a human desire to transcend itself biologically, poses the question of human nature. In this paper the idea of human nature will be examined in terms of its continuity and volatility, especially in light of the conception of man/woman as a “defective being (mangelhaftes Wesen), which appears in philosophy under different versions (Anaximander, Plato, Thomas Aquinas, Immanuel Kant, Johann Gottfried von Herder, Arnold Gehlen, Erich Fromm etc.). This understanding of human nature suggests that humanity is biologically imperfect (for example if we compare it with non-human animals, the former is biologically less equipped for the life in nature), but precisely this insufficiency is what enables it to construct a “human world” (culture and institutions). Therefore, this idea reveals a crucial contradiction in an encounter between the human person and technology. On one side, because it derives from his/her biological imperfection, the interpretation of the human person as a “defective being” can exculpate the desire to technologically enhance itself. On the other hand, human accomplishments, especially culture, may also be interpreted as a product or compensation of this same “imperfect” nature. From this perspective technological improvement of biological “imperfection” does not reveal as salutary anymore, but, on the contrary, as a destruction of a possibility of a “human” world.

Ethical issues regarding the services offered by new commercial genetic testing companies

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Commercial genetic testing services are popular in much of the developed world with the results used in determining ancestry, risks for common diseases, and the presence of unusual characteristics. It is estimated that perhaps 500,000 Americans to date are tested with these services, made available through the simple submission of a sample of saliva to genetic testing services based largely in the American South or West where an individual's DNA is tested against a panel of several hundred thousand genetic polymorphisms. For as little as 100-200 US dollars one can learn if (s)he is a carrier for sickle cell disease or cystic fibrosis or the gene which determines rate of HIV progression, whether one shows an unusually high risk for Alzheimer disease, Parkinson disease, or shows a predilection for obesity, diabetes or heart disease. Leading companies include 23andme, Family Tree DNA, and Oxford Ancestors, all private venture enterprises where findings are often used to further research advances and enhance the scientific profile of these companies.

Findings are reported in areas where the science remains developmental such as Alzheimer genetics, where the attributable risk of genetic markers in causing disease is only slowly evolving such as Parkinson disease, and where the polygenic nature of diseases defies easy genetic contributions such as diabetes.

Is it ethical to provide such testing commercial to the public-at-large? Should testing be limited to the clinical examination setting? Why is the medical community restricted in its determinations of body electrolytes or levels of common medications while genetic tests are so widely available? Are there risks when the nature of future polymorphism discoveries is unknown and the banking of commercial samples might be used for determination of undiscovered alleles linked to violence, sexuality, or intelligence? Should the results be provided to the community only within the context of specialized and licensed medical training?

With certain nations (eg, Italy) banning the use of such services, what can be done when results are available to any public client who simply provides via international mail saliva and money? Do such services violate the standard tenets of medical ethics? Is there a violation of privacy or of international scientific agreements? Is the widespread dissemination and access to genetic profiles a violation of basic human rights? Does the likelihood that results will expose the identity of parents giving up children for adoption limit their use? Private decisions made decades ago are being made transparent with current scientific advances. If one advances yet another few decades, is it not possible that the exposure of genetic identity is attendant with a type of disclosure or risk that we today fail to understand? Should national or international guidelines be developed which circumscribe the activities of commercial testing services and how can such restrictions apply to unknown developments in the future?

Moral distance and public health

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It is widely recognised that people tend to care less about people who are distant in time and space from them. In many regards this is understandable; we care more about our families than about strangers, and care more about people alive now than about those who are not yet born. However, there are many cases in which moral distance is more problematic, and can

reveal a lack of empathy or of moral imagination. One example is the case of a person who believes assisted suicide to be totally wrong until he experiences a relative dying in a very slow and undisguised way, and changes his mind. Here, the lessening of the distance from the issue led to a change in moral attitude. Had this person had better moral imagination, he might have changed his view without having to witness an event. Another example is climate change. Even now, when most people recognise that are facing a potentially devastating problem, many nonetheless engage in extremely unenvironmental behaviours, partially because they are removed from the effects of their actions, which will be more obvious elsewhere in the world at a future date.

While this topic has been discussed quite comprehensively, particularly in terms of our obligation to protect future generations, the harm done to public health by moral distance has gone largely unremarked. In this paper, I use three examples to illustrate the damage that moral distance can do, and suggest that much of it could be prevented if various professions placed greater emphasis on developing the moral imaginations of their practitioners. The three examples are overprescription of antibiotics, which harms those who will really need them; doctors' complicity in families vetoing donation of their loved one's relatives, which harms those who could have benefitted from the organs; and misreporting of clinical trials, which harms millions of patients all over the world. It is concluded that teaching people and doctors to use their moral imaginations will help to minimise the problem of moral distance and help to protect public health.

The Ethics of Rarity in Healthcare Resource Allocation

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Do treatments for rare or very rare conditions need special consideration in the allocation of healthcare resources?

I take as my starting point the idea that patients in a healthcare system should be treated equally, fairly and consistently. This means that both outcomes and opportunity matter. On the one hand, a healthcare system is required to use the resources it has in the best way. On this, equality of outcome approach, two treatments that have the same outcome ought to be resourced to the same extent. If treatment A has a better outcome than treatment B then (other things being equal) A should be prioritised over B. On the other hand, a healthcare system should ensure that people are given an equal opportunity at the best health possible for them. On this, equality of opportunity approach, each person, rather than their ability to be made healthy, is to be treated equally alongside other people. This means giving each person an equal opportunity at the best health possible for them.

Both equality of outcome and equality of opportunity are important in the fair allocation of healthcare resources. However, on a single system of resource allocation (be it local, regional or national), those who suffer from conditions that are rare or very rare are systematically disadvantaged because they are deprived of an equal opportunity at a healthy life. This is because such a system cannot deal with the extreme range of cost and evidence related issues that the treatment of rare or very rare conditions raise.

I argue in this presentation that a separate process of resource allocation for the treatment of rare or very rare conditions and which has a settled, ring-fenced budget would be well placed to ensure that equality of opportunity at health is provided for this group in a way that is consistent with the other principles of fair healthcare resource allocation.

Facilitating social innovation: exploring the roots of paternalism in post-Soviet health care

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Social innovation, as a way of introducing new and better practices, is one of the important drivers of ethical progress. Being a country in transition, Latvia is undergoing change in all of its social institutions, including that of health care. As it has been noted, “The rise of western standards in medical and research ethics was simultaneously contradicted by tradition of hierarchical paternalism, inherited from Soviet medicine, and pragmatic selfishness of the newly introduced free market economy.” (Silis, 2010, 58-59)

Soviet health care system was notoriously paternalistic; patients usually were poorly informed and restricted in their choices. As an attempt to evaluate the social innovation and ethical progress in the field of health care, in 2012 we performed a qualitative enquiry into truth-telling practices and attitudes of Latvian physicians and medical students. The results of this study are described in the paper “Truth-telling and the asymmetry of the attitude to truth-telling to dying patients in Latvia” (to be published in a special issue of *Studia Philosophica Estonica*).

One of the most important results of this study was that after more than 20 years the old paternalistic practices are still found in Latvian health care. To shed some light on the origin of these standards and to evaluate the level of achieved innovation as well as to set the goals for the future, we set to perform a literature survey of relevant Soviet-era publications on medical ethics during the first half of 2013. It will be one of the first attempts to address this largely unexplored field which could prove interesting and relevant to a number of Eastern European countries having a similar heritage.

At the conference we intend to present the main findings of a content analysis of Soviet medical ethics, or as it was called back then – deontology. We will summarize ethical principles and give analysis of the arguments that were used train soviet health care specialists. We will also attempt to envisage strategies for social innovation and change.

What Czech Patients and Nurses Think about Nursing Ethics?

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Nursing ethics is a relatively new issue in health care ethics. In the Czech Republic nursing ethics was a real matter of interest only in last few years. Recently School for Nursing and Social Studies at South Bohemian University recognised nursing ethics as an important issue and management of the School decided to fund some research.

In the context of discursive ethics we believe that besides philosophical analysis some information about opinion of agents in the field is needed. Such information will help to fit the theoretical analyses in the real nursing practice in the Czech Republic. Therefore in the first step we decided to provide qualitative research based on non-directive really free interviews to ask for issues relevant to patients and nurses. Nursing ethics was not yet discussed in public, so we can suppose that the Czech nurses as well as patients are not indoctrinated by theoretical assumptions of experts in the field. The dark side of this is our expectation that respondents will lack vocabulary to ascribe own ideas and wishes in the field of ethics. Their responses will not be very rich. Putting together responses of sufficient sample of respondents will enable us to create a list of items concerning nursing ethics

relevant to Czech nurses and patients. The research will be provided in March to June 2013 and we will present results of the research in our paper.

Attitudes toward genomics and knowledge of genetics among Israeli people

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Israelis are heavy consumers of genetic tests; and leaders of research into novel uses of reproductive technology. This study examines the relationship between the attitude of lay Israeli respondents toward genomics and their knowledge about human genetics and reproduction. The study included Jewish and Arab Israeli participants who answered a structured self-report questionnaire.

The attitude of the respondents in this study was positive about using genetic technologies for medical purposes; however, people were less favourable toward using genetic tools for non-medical purposes. The respondents in this sample were not knowledgeable in genetics; however, respondents did well in items related to inherited diseases; which suggest there is some degree of awareness about the inheritance of disease both among the Jewish and Arab populations of Israel.

Nevertheless, there was a significant difference between the attitude of the Jewish and the Arab respondents; which support studies suggesting that the attitudes of a particular group towards prenatal genetic testing may be influenced by cultural beliefs. The study concludes that a better understanding of the social and cultural aspects of the perceptions of lay people toward human genetics is required. Further research is needed in order to understand cultural aspects of particular groups' views.

The neuroscientific research on humor and its possibilities to improve health care using a concept of “ethical humor”

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There are many books applying humor to health care, for example: Karyn Buxman (ed.): *Nursing Perspectives on Humor* (1995), Waleed A. Salameh and William F. Fry, Jr. (Eds.): *Humor and Wellness in Clinical Intervention* (2001), Paul McGhee: *Health, Healing and the Amuse System* (1996), Allen Klein: *The Healing Power of Humor* (1989), Vera Robinson: *Humor and the Health Professions* (1991).

In the book of Begoña Carbelo, *El humor en la relación con el paciente* (2008), the author says that in practice, humor is used to reduce patient anxiety and, in many cases, to control the aggressiveness. Carbelo offers examples of how humor can promote mental health, help manage pain and improve care of terminally ill patients.

The book edited by Angel Rodriguez Idígoras, *The therapeutic value of humor* (2002), reflects also the value of humor to improve the health of patients.

These authors tell us that humor can help sufferers to laugh at themselves and then to accept themselves with their vulnerabilities, and provides new data to find better solutions.

In recent times, there is an emerging literature that investigates the brain basis of humor. Among the most relevant authors we can mention: Bihrlé, Brownell, Powelson, Gardner, Gillikin, Derks, McGhee, Shammi, Stuss, Svebak, Derks, Coulson, Kutas, Goel, Dolan, Mobbs and Fried. They analyze the brain basis of humor by studying brain injuries, EEG-electroencephalogram (brain wave activity) and fMRI (neuroimaging). Rod. A. Martin, in his

extraordinary book *The Psychology of Humor* (2007) reviews the works of these neuroscientific researchers. He concludes that humor research in patients with brain lesions seem to suggest a particularly important role of the right hemisphere, but brain imaging research (and EEG studies) indicate that humor involves coordinated activities of many regions in both hemispheres.

These investigations have reached very diverse conclusions and occasionally contradictory. My position is that this diversity is produced because they do not handle a unified concept of humor. I consider necessary to draw up a concept of “ethical humor”, absent in the background of these studies.

Among the authors who have written about the ethics of humor at present we may include, at least, Ronald de Sousa, Joseph Boskin and John Morreall. I emphasize the book of Morreall entitled *Comic Relief. A Comprehensive Philosophy of Humor* (2009), which contains two chapters on the ethics of humor. In his book, Morreall tells us that there are morally questionable forms of humor, and that these forms have to be rejected, but there are many forms of humor that are valuable. This author argues that valuable forms of humor promote both the intellectual virtues (open-mindedness, creativity, critical thinking) and the moral (honesty, integrity, humility). My position is that we need to identify and clearly define valuable forms of humor, in order to be possible to make research of its neurological basis. If we do not do that, we will not know how to use neuroscientific knowledge on humor to improve ethically healthcare. I conclude my presentation by offering some features that characterize the “ethical humor”.

Action-based theory in WHO’s international classification of functioning, disability and health (ICF)

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WHO’s ICF presents itself as a unified conceptual framework for description of human functioning from the perspective of body, person and society. It defines the central concept of human action without, however, using the concept of intention. We argue that the ICF should be based on action theory and that there are three indispensable concepts for describing human action: person, environment, and intention.

The ICF manual defines, on the one hand, a medical model as a *biomedical disease model (BDM)*. The disabled person is described without considering human intentions. On the other hand, the social model is described in terms of action – intending the “full participation of people with disabilities in all areas of social life”. Claiming to integrate the two models, ICF’s biopsychosocial model nevertheless describes the person in relation to the environment without considering his/her intentions. This engenders a serious contradiction in ICF’s attempt to integrate the two models.

The contradiction can be eliminated by viewing the disabled individual as an *acting* person, based on a view of the person as a biological and humanistic being. Thus, what we call an *action-oriented health model (AHM)* should replace the biomedical model. In this model, biological knowledge of the human being is considered within holistic models of self-organizational and systems biology. Intention as a humanistic concept is recognized as a necessary component of the model which also has a spiritual dimension.

In an empirical project we analyze social insurance certificates written by experts in mental health care. Some certificates describe the patients in general terms by using the BDM. Other certificates describe the patients in particular terms, by presenting a short patient’s biography

and specifying intentions and relevant factors in their present environment. These certificates are written in the perspective of AHM. Others, again, combine these two models.

In our analysis of the patient's work potentialities – as described in the certificates –, we indicate the consequences choice of health care model have for the contents of the assessments. Based on BDM, the assessments of patients' work possibilities are general and made in terms of general facilitators, such as "gradual increase of work".

Assessment of work possibility, based on AHM, is described in particular terms. Specific aspects of the patient's interaction with barriers and/or facilitators in the work environment are sometimes described by this model. Examples are psychological vulnerability related to work, co-workers as facilitator, patient's intention concerning concrete work training and information why specific vocational training failed.

We conclude that in those health/social care contexts, where it is important to promote the person's potential for improved functional ability, an AHM is necessary and fruitful. Hence, ICF's integrated biopsychosocial model should fulfill this condition by having the person's intention as a necessary component in its conceptual model.

Disability and selective reproduction

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Knowledge obtained from the Human Genome Project and applied to medicine, combined with assisted reproduction techniques (IVF, PGD, PND) make the reproductive choices, which were earlier unimaginable, possible. On the other hand, the new genomic medicine gives rise to many intricate ethical problems and challenges, to which one may count the broadly discussed issue of selective procreation (selective abortion and selection of embryos). In my paper I will address the problem of disability in the context of reproductive decisions based on genetic information. I will pose a question of whether knowledge about health risks concerning offspring may, or should affect procreative decisions; and whether selective procreation may and should be considered as a moral obligation of prospective parents, or rather as a moral harm to people with disabilities. I will analyze the concept of harm and discuss who can be harmed by a reproductive decision – whether it could be a future child, people with disabilities, or society. I will also discuss how disability may be understood in our societies (providing medical and social definitions), and whether disability rights could be violated by selective abortion or selection of embryos. To answer these questions I will present four philosophical approaches: (1) utilitarian (the argument from quality of life; the argument from costs and burdens); (2) autonomy-based (the argument from procreative autonomy); (3) equality-based (the argument from social contract; the argument from equality and dignity; the argument from capabilities); (4) recognition- and care-based (the argument from social recognition; the argument from parental relationship; the expressivist argument). The paper will be mainly based on critics of the utilitarian line of argumentation and on defending the recognition- and care based approach. The main thesis of the paper is that public health policy in the domain of reproduction and genetics should be sensitive to the problem of disability and take into account the social consequences of the promotion of selective procreation. The problem will be illustrated by case studies addressing the issues of the limits of reproductive liberty and the challenges of genetic counseling.

Resources of innovation in medical-genetic counseling

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Medical-genetic counseling represents one of main practical leverages for improving health care at global as well as local and community levels, for melioration of general social-psychological climate and increasing social acceptance of the most discussable scientific biotechnological innovations. The potential of medical-genetic counseling is far to be completely harnessed due to several factors as:

1. lack of worldwide accepted common standards and clear norms of medical-genetic counseling;
2. too important influence of cultural, religious, spiritual, value or mentality aspects for performing medical-genetic counseling;
3. wrong preconception on secondary role and dependence of medical-genetic counseling of other procedures as components of contemporary healthcare system: laboratory, biotechnological or genetic engineering methods of diagnostics, prophylaxis or therapy.

The objective of the study consists in identification of innovation resources of increasing of importance of medical-genetic counseling for improving the quality of public health care, using such methods as analysis, comparison, extrapolation, modeling. The perspective of innovative approach for better exploitation of potential of medical-genetic counseling for sustainable and long-term improving of entire healthcare, represents a new mainstream in future development of medicine and public health care. There are several types of resources for increasing the importance in the structure of health care, the macro-social impact and the quality of contemporary medical-genetic counseling:

1. Increasing of professional and humanistic capacity of medical staff involved in delivery of medical-genetic care.
2. Enhancing of ethical-normative background of medical-genetic counseling and the growth of the role of the compliance of moral principles and values during medical-genetic counseling.
3. Reconsideration of the importance of selective applying of biotechnological and laboratory methods during the diagnosis, prophylaxis and treatment of genetic illnesses. This is important to be done in conditions of organic necessity for drastic protection measures against different of types of risks.
4. Territorial ramification and spatial expanding of the system of medical-genetic assistance in isolated and small communities, inclusively using the opportunities of telemedicine, for better preferment and responding to the interests of individual persons. This approach has crucial importance especially for improving the prophylaxis of hereditary dysfunctions and illnesses as well as for enhancing the mobility and efficiency of medical-genetic assistance in the populations with high incidence of the most severe genetic diseases.

In conclusion, it is required a coordinated application of the full spectrum of available resources to streamline medical-genetic counseling as a lever to ensure a high level of health care, based on a new and revised concept of public health in the context of modernizing of society, where the protection and promotion of public health is a prerequisite for the general welfare.

Medical innovation and hope

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Hope is the fuel that drives medical innovation. Hope is an essential element of virtually all activity in medicine. Patients hope for a cure; for relief from pain; to return home. Physicians hope to make the correct diagnosis; that their prescribed treatments will be effective; that research will discover new and more effective treatments. Physicians ultimately hope to offer their patients hope. All hope is future-oriented. In medicine, hope looks for a new path toward healing in cases that challenge the effectiveness of the old ways. Hope is, therefore, fundamentally linked to innovation. This innovation-driving hope is not always accurately understood, however. Sometimes it is even disdained, as when physicians see people putting themselves at risk chasing therapies that are apparently nothing more than false hopes. In general, hope is a desire for something and the expectation of receiving it. Some have reduced the concept of hope to an emotion and disparaged it as the root of the sorts of false hope that drive patients to seek useless and even dangerous therapies. Others, however, have urged physicians to see the positive benefits of hopeful emotions. Hope should indeed be encouraged in medicine, but to see why we must go beyond the understanding of hope as an emotion. Hope requires not only a feeling of optimism but also a rational plan for explaining the expectation that one's desire will be satisfied. Hope may be understood from the vantage points of philosophy, psychology, and theology. Each offers valuable insight and a different sort of rational plan to explain hope in the context of health care. Philosophical hope offers conceptual clarity about the very nature of hope. Psychological hope roots hopeful plans in the empirical world. Theological hope is a virtue; it offers a higher level of meaning in the experience of suffering and the pursuit of health. Understanding the complexity of hope should prove beneficial to our thinking about the best ways to pursue medical innovation. This can help us to challenge the presupposition that hope is a single entity. When we begin to see hope as composed of a number of smaller hopes, we can discern rational frameworks from which to assess which hopes are most valuable and which hopes are really false hopes. We can thus begin to see how hope orients the ways in which we will engage with the future. We can begin to understand what sorts of innovations are worth pursuing and which will ultimately be counterproductive.

Participation rate or informed choice? Rethinking the European performance indicators for mammography screening

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Background: Mammography screening (MS) as a measure for early detection of breast cancer involves potential benefits (reduced mortality) and harms (overtreatment) for the participating women. Despite controversies about the likelihood of these benefits and harms almost all experts conclude that the choice to screen or not to screen needs to be made by the individual patient who is adequately informed. However, the "European guideline for quality assurance in breast cancer screening and diagnosis" specifies a participation rate of 70% as the key performance indicator for mammography screening.

Discussion: The existing evidence on potential benefits and harms speaks against a priori judgments as to whether a certain percentage of women should participate in MS. In preference-sensitive conditions (such as MS) patients value outcomes differently or equipoise exists between closely matched strategies. Such situations require well informed (shared)

decision making that takes the patient's preferences into account. If evidence on potential benefits and harms of MS fails to justify what participation rate is desirable, does survey research on women's attitudes towards MS provide a better justification? Survey data demonstrate that a substantial proportion of women would participate in MS after being adequately informed about benefits and harms. However, to evaluate the performance of MS programs we should evaluate not just how women decided in academic surveys that according to their study protocol applied high standards for shared decision making and informed choices. We need to evaluate whether in real-life physician counselling on MS allows women to make informed choices. Can cost-benefit ratios for MS (e.g. *costs per life year saved*) justify what participation rate is desirable? Cost per life year saved do not discount for the harms that come with overdiagnoses, overtreatments and the potential psychological harm inherent in any MS program. This brings us back to the need to know whether women make informed choices in real-life. Measuring informed choice as primary endpoint in preventive medicine clearly is a new concept. However, this concept is more and more applied in practice.

Conclusion: Those who agree that the complex trade-offs between potential benefits and harms of MS require individual (value) judgments by adequately informed women must conclude that the participation rates defined by the European guideline for quality assurance in breast cancer screening and diagnosis are not reasonable for serving as key performance indicator. Participation rates shed no light on (and partly conceal) the more important question of how women have been informed and counselled before making a decision to participate in MS. A reasonable performance indicator for MS (from a patient oriented point of view) would measure the percentage of informed choices ("informed choice rate"). However, the implementation and evaluation of informed choice rates as a performance indicator for MS pose several methodological, practical, and ethical challenges. For example, determining whether a choice was informed or not requires several methodological and value judgments. Those responsible for national MS programs should work on and implement feasible and valid measures to assess the informed choice rate (or any other reasonable performance indicator).

Towards responsible medical and surgical innovations

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Medical and surgical innovations have unquestionably contributed greatly to providing important treatments for patients. For example, umbilical cord blood transplantation was largely developed under an innovation pathway and is now considered to be an acceptable treatment option for an array of malignant and non-malignant conditions. However, innovations may pose substantial risks to individual patients who are among the first to receive them because of their inherent risks and/or the nature of patients' underlying disease. Further, innovations may pose risk if the motivations of those innovating privilege other interests over the best interests of patients. Non-financial interests may plausibly be related to scientific enthusiasm, which may regrettably prompt the premature or excessive use of innovations without adequate protections. In addition, financial incentives may create harm for those accessing therapies for devastating diseases, such as the use of non-validated cell-based interventions. Beyond these individual level concerns, populations of patients could be harmed if innovations are not promptly and properly evaluated. Here, a paradigmatic example is the use of autologous bone marrow transplantation for breast cancer, which was delivered to thousands of women before data from randomized clinical trials demonstrated that this

burdensome treatment was not beneficial. In order to help minimize such ethical concerns, the International Society for Stem Cell Research has offered guidelines for stem cell-based medical innovation. Under these guidelines, innovation in a few patients is permissible provided that there is: 1) a written plan; 2) peer-review and approval; 3) an institution accountable; 4) qualified personnel and appropriate facilities; 5) informed consent; 6) an action plan for adverse events; 7) resources for complications; and 8) a commitment to contribute to generalizable knowledge. Since it is unclear how well this approach to governance of medical innovation will work in practice, it will be important for those employing it to provide rich descriptions of its successes and failures. Regardless, history suggests that it will be especially important to prepare for the challenges that will be encountered when moving from innovation to research governance given the incentives for innovators to maintain the status quo. That is, mounting positive experiences with innovative approaches, the understandable desires of patients to receive them, and the inherent bureaucratic and economic burdens of conducting research may pose barriers to conducting research that is needed to ensure that innovations are actually safe and effective. Being familiar with how such transitions have been negotiated in high-profile cases, such as the use of maternal-fetal surgery for spina bifida, may prove to be useful in this regard. Nevertheless, while it is possible to adumbrate conceptual models for medical innovation, a robust model is wanting. Further experience with the governance of innovations should contribute to developing and refining such a model.

Ethics and the Electronic Medical Record: Google Glass, Filter, Mirror, or Screen?

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The electronic medical record has the potential to improve patient care by enhancing communication, decreasing errors, facilitating prevention, serving as a tool for research, and controlling health care costs. Less appreciated in the general enthusiasm for this innovation are a number of potential ethical pitfalls, including the potentiation of breaches in confidentiality, changes in the way physicians spend their clinical time, deleterious changes in patient-physician interactions, information overload, corruption of the validity of population-based research data, and paradoxical increases in cost. Whether the electronic medical record can be re-designed in a way that overcomes these problems is an open question.

The relevance of Heidegger's philosophy of technology for biomedical ethics

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Heidegger's thoughts on modern technology have received much attention, but, with a few exceptions, the influence has been sparse in biomedical ethics. The reason for this might be that Heidegger's position has been misinterpreted to equal a general hostility towards modern science and technology, and that Heidegger himself never subjected medical technologies to scrutiny but was concerned rather with industrial technology and information technology. In the presentation, Heidegger's philosophy of modern technology is introduced and then brought to bear on medical technology. The main relevance of it for biomedical ethics is found to be that the field needs to focus upon epistemological and ontological questions in the philosophy of medicine related to the structure and goal of medical practice. Heidegger's philosophy can help us to see how the scientific attitude in medicine must always be balanced

by and integrated into a phenomenological way of understanding the life-world concerns of patients. A critical development of Heidegger's position can also provide us with a criterion to distinguish the uses of medical technologies that are compatible with such an endeavor from the technological projects that are not.

Is evolution a serious biosafety risk factor in synthetic biology?

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Synthetic biology is an emerging research field that combines engineering approach with biological systems. It uses engineering strategies of standardization, decoupling, and abstraction to achieve predictability and reliability of a behaviour of designed biology systems. The goal is to achieve by these strategies a production of universal interchangeable biological parts, a kind of LEGO assembly pieces (cf. BioBricks), which can be aggregated into entirely new artificial combinations for useful purposes. These completely new artificial life forms which never occurred in nature with ability to reproduce themselves represent a serious biosafety risk problem connected with intended or unintended release of them in the environment. They are by definition "alien" species to our biosphere, so the question is, how serious is the risk of their uncontrolled invasion the natural environment . Several types of control mechanisms for synthetic biology organisms have been suggested, like self-destruction triggering by suicide genes for example. But the question is how these mechanisms would be evolutionary stable under a strong selective pressure? On an example of rabbits spread in Australia and failed attempts to bring their population growth under control by deadly viruses we are going to demonstrate how difficult is to predict the behavior of invading organisms in real world environments, and how important is to take evolutionary processes into consideration about risk assessment of synthetic biology organisms.

Should "informed consent" apply to information disclosure based on biological samples and data?

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Otlowski has sought to explore "the essence of the concept of consent itself" (Otlowski MFA, Tackling legal challenges posed by population biobanks: reconceptualising consent requirements, *Med Law Rev*, 2012; 20(2): p.204) in her analysis of consent in the context of biobank research. However, I would go further, and suggest that the ethical justifications for requiring consent for interventional research may not be the same as for consent that is sought for disclosing subject information or data already held. For example, privacy is a major consideration in biobank research, and not in interventional research; and "informational flow" is in the opposite direction in the two situations. In addition, it will be shown that the processes in these situations are different. This paper argues that these process and theoretical differences are sufficient to view "consent" in the two situations as different concepts, and suggests the phrase "permission to disclose" would be more appropriate in the information disclosure situations, such as biobank research.

Stochastic Epistemology: Uncertainty & Clinical Health Care

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Uncertainty has commonly been regarded as a sign of failure in Western healthcare practice. For the last 100 years or so, the aim of medical science has been to reduce or eliminate uncertainty from diagnosis and treatment prescription. The assumption has been that all illness has a rational and 'knowable' scientific explanation that 'good' practitioners can identify and which, if applied, can lead to effective treatment. Much of the focus in medical schools has been on diagnosing through algorithmic decision-trees, with treatment based on protocols and guidelines. While appropriate for well understood and can leave students without a strategy for dealing with situations where no physical explanation can be found – so called medically unexplained symptoms (MUS).

In the last few years this situation has been challenged by a number of academics and practitioners and uncertainty has received considerable airing in the medical literature. In this presentation I will argue that uncertainty is not the same as doubt and doesn't stem from ignorance. Rather than being viewed as an undesirable component of clinical life, uncertainty should be regarded as the beating heart of clinical epistemology. This is based on the idea that clinical decision-making – knowing how to act for good in the face of a specific patient's illness and suffering (phronesis) – is different from knowing about mechanisms and processes (episteme). In particular I will explore the concept of 'aporia' (the pathless path) as a way of dealing with uncertainty in practice. This argues that clinical decision-making in achieving a desired goal is more like navigating across an unmarked terrain, where several options are possible, than following a well-marked map.

Innovation in rheumatoid arthritis

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Rheumatoid Arthritis (RA) used to be considered to be part of the normal ageing process. Little or nothing was known about the cause of the swollen, painful and gnarled joints. Then, in the middle of the twentieth century, the picture arose of rheumatism as a basically immunological illness, so that it was redefined in pathogenic and etiological terms. The research and diagnosis of RA were no longer based only on a clinical picture (the state of the joints), but also on new blood-related parameters, known as the rheumatoid-factor. It soon appeared that Juvenile Rheumatoid Arthritis (JRA) was not the same disease as adult rheumatoid arthritis. More recently, research has centred on biomarkers. This innovation led to a change in a) research practice, b) clinical practice and c) the relation between these two. The purpose of this lecture is to describe on the basis of empirical research, how these changes present themselves in a specific case. It so happens that the department of child immunology of the UMC of Utrecht (Netherlands) combines scientific laboratory research with patient care.

This paper will address the following aspects.

a) Scientific research focuses on a feverish search for new biomarkers by means of proteomics (protein research). This research generates gigantic data bases allowing bio-computer scientists to perform cluster analyses, which hopefully will reveal the pathophysiological mechanisms that may influence the development of JRA, so that eventually the appropriate medication may be developed for each patient, and the illness may be slowed down, or stopped, or even cured at an early stage.

b) In clinical practice, new insights lead to new diagnostics, treatments and new questions, which in turn inspire new research. At which point, does one consider someone to be ill? It used to be that JRA was diagnosed when joints were tender and swollen. Now it may very well happen that a person feels quite healthy, while a blood analysis may indicate the presence of JRA. Clinical professionals must therefore make choices. When does one tell a patient that he or she has JRA, when must treatment set in, when can one say that an illness is in remission, so that treatment can be stopped? What medication should be given to what patient?

c) In a way, the redefinition of JRA (in a nutshell, from joint related symptoms to blood analysis) disconnects scientific research from the physician who is confronted by his or her patient. The patient does not suffer from an increase of IL1, he or she suffers from stiff joints, from pain and fatigue. This increased distance between the laboratory and the physician's office involves the risk that new scientific discoveries are no longer optimally translated into better patient care. What do we do in order to bridge this gap?

Public health ethics and health planning under resources constraints

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Countries under severe resources constraints (“developing countries”) where for example only 10-20 US\$ per capita and year are available for provision of curative, preventive and rehabilitative health services and health promotion, face formidable challenges in health planning and particularly in priority setting. It is the aim of the presentation to (i) place health planning within a context of public health ethics and the related equity principles, (ii) describe the approaches used in priority setting and informed decision-making in health planning in developing countries, (iii) discuss the relevance of the approaches applied in developing countries for the health sector in developed countries and (3) suggest how and to what extent the concept of minimizing burden of ill-health could be applied in health planning respecting the ethical principles to reach equitable health service provision in any health care delivery setting.

The evolution of public health ethics and health planning approaches will be reviewed with a particularly reference to the interesting fact that key principles of health planning and public health ethics were already developed by Daniel Bernoulli (1700-1782) in Basel in the 18th century, but only now find their way into the discussion of in public and global health issues. Case studies of health planning under resources constraints from Africa (Tanzania, Ghana) and Europe (France, Switzerland) are presented and comparatively analyzed with regards to the structures, functions and performance of health systems as well as the qualitative and quantitative methodology applied to reduce inequalities in the planning and priority setting process. Particular reference is made to the paradigm change of planning from maximizing good health to reducing burden and how this paradigm change has helped to address effectively key issues of rationalisation and rationing in health system when complemented by public health ethical considerations and an informed socio-political discourse. Learning from the experience from resource constraint health systems also lead to innovative approaches for “well-off” health systems and shows how limited resources can be spent effectively for better health outcomes and by respecting equity principles.

Abortion on demand, as a midcourse for ethical responsibility of governments

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The beginning of life issues cover, paradoxically, the ethical deliberation regarding the values about ending life. The discussions focus on decision-making concerned with the termination of prenatal life. The debates question the status, the identity of the embryo and fetus, *vis-à-vis* woman's right to self-determination and fulfill her free will on her own body as an autonomous individual. It is undeniable that the fetus has potential to be born as a human being, if not intervened. The conflict between the woman's right to decide on her own body and the status of the embryo as a potentiality to evolve into a human being, has not been solved. The legal limit for abortion on demand seems to be a midcourse of action to support both the autonomy of the woman by enabling her to make decision on her own future and also to protect the fetus on the basis of the value of life after a certain period of time in the womb. Abortion on demand is ethically indispensable to prevent the maternal mortality due to the unlawful abortion and to assure the life of fetus. The Abortion Act (Nufus Planlamasi Hakkinda Kanun) in Turkey has provided the legal basis of this ethical conflict by guiding both the couples and the health professionals since it was enacted in 1979. The scientific data confirm that not only the maternal mortality has gone down, but also education on the family planning and contraception have improved considerably since the Law was ratified. The recent traditional debates in Turkey on equalizing abortion as an act of murder seem to arouse a public reaction and, protest on part of the health professionals to disrupt this ethical balance. This paper attempts to take up the matter in the perspective of value of life and the idea human right by taking into consideration of recent arguments and legal amendments carried out in Turkey, by giving emphasis to right to health, women's health, right to reproduction, right to privacy and right to self-determination.

Ethics of premature babies: In defence of the grey zone

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In cases of extremely premature birth, the choice between intensive and palliative care can be very difficult. Major prognostic uncertainty for babies born in week 23 to 24 of gestation complicates the medical assessment, and leads to guidelines advising resuscitation to be offered on an individual basis. The ethics of such a grey zone is complicated and controversial. What does such a grey zone mean: That the uniqueness of each case is decisive, that the uncertainty of prognosis renders ethical decision making impossible, or that there simply is no right or wrong decision in these cases? What is special about the babies of the grey zone? Indeed, is there any morally significant difference between these babies and other persons, or do we illegitimately discriminate against premature babies in saying that there are? Can we live with any such grey a zone at all: Is it not the task of ethics to offer clear guidance here? In this paper I will defend the ethical legitimacy of a grey zone in making life-and-death decisions for extremely premature newborn babies.

Public health and the principle of fairness: ethical re-considerations in a globalizing context

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Recently, the European Commission signaled the problem of ageing and the expected shortage of care provisions, and plans to facilitate intercontinental labour migration from 2020 onwards. In such a globalizing context of health care two groups are in danger of getting underprivileged. As the founding mother of care theory, Joan Tronto, pointed out, the social hierarchy of a particular society is revealed in the way in which care labour, both paid and unpaid, is distributed. The underprivileged are care givers, professionals who are at the bottom of the labour market. The ranking works in terms of gender, ethnicity and migration. But, as care-givers use to say: 'The lowest in the hierarchy are patients (or clients or residents). So, there is an urge to rethink our care-arrangements in a globalizing context. Some feel this will offer opportunity for cultural exchange, others have their reservations.

Two questions can be raised. How will care-depending people feel if nobody of their own social circle is willing to look after them? And what will immigrant care workers experience when they become part of the care-drain from the west to the south?

In West-European countries, the evaporation of family-based care arrangements within the course of two generations is a mere fact. A new moral basis for care-arrangements is needed. Therefore:

a) we should acknowledge that the health care sector is in a profound crisis which goes beyond a shortage of means and money: professionals, patients and their relatives are crying out loud for a type of caring which combines professional skills with human warmth and empathy.

b) we should base our future care-arrangements on the principle of **fairness** (integrating the vision of global justice and neighbourly love).

When Fair Trade was introduced, it seemed to contradict the dynamics of the market economy. Nevertheless people were actually willing to pay more for a smaller banana because they felt that the banana is a contribution to a righteous economic order in which small farmers receive their fair share.

Parallel to that, the idea of FAIR TRADE can be introduced. It is not a fixed moral program but an invitation for an ongoing ethical dialogue and ethical practice.

Five keys to FAIR CARE are:

- 1. Let us respect care-givers and facilitate care organizations*
- 2. Let us re-value the activities of care-giving and care-receiving as a mode of living*
- 3. Let us re-distribute care-giving so that no citizen is excluded, break through the boundaries of gender, class, and ethnicity*
- 4. Let us find the courage to limit health care demands*
- 5. Appeal to care-dependent people's capacity to give and share*

FAIR CARE protects and cherishes the well-being of the most vulnerable and the underprivileged on a global scale. It is a non-exploitative care, which is fairly valued and fairly shared. FAIR CARE costs more and brings more. There is added value in it - as it enhances global justice and human flourishing.

Which ethical principles should guide us in the prioritisation debate?

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Prioritisation in healthcare is an issue of growing importance, especially in the Western world. Prioritisation has always existed –it has always been an extremely important issue in developing countries - and will always be necessary in the healthcare sector on various levels and in a variety of ways. However, in a democracy people want, and should have the right, to know and to have a chance to influence the grounds on which health priorities are decided. One way of achieving this is to reveal the decision makers' views concerning prioritisation. Both politicians and physicians are important decision makers with regard to prioritisation and resource allocation and their views concerning how increasing healthcare costs should be financed are highly relevant and should be taken into account. But the debate about prioritisation should also be held on a more basic level. Not the politicians and physicians but the general public should be made aware and eventually choose which principles should be used by the policy makers to make decisions concerning prioritisation. The reason for this is very simple. Various European systems are financed through taxation and are governed by political decisions made in democratically chosen bodies. In this paper I want to propose three basic ethical principles which should guide and guide the public in the prioritisation process and have to be known and accepted by the public.

These ethical principles seem to be very reasonable and fair. The first principle is *the principle of human dignity*—meaning that human dignity should not be dependent on people's personal qualities or functions within the community, such as their ability, social status, income, etc., but is a part of their very existence. The second principle is *the principle of need and solidarity*—meaning that most of the care resources should be given to those who are most in need, with special consideration being given, for example, to children, patients who have dementia or are not conscious, and others who have difficulty in communicating with those around them. The third principle is *the cost-efficiency principle*—meaning that the aim should be a reasonable costs/effect relationship, measured in terms of improved health and enhanced quality of life.

Some would like to add a fourth principle which is much more controversial. It is *the principle of personal responsibility* for one's own health. The implication is that one is personally responsible for both the prevention of ill-health and for choosing a healthy lifestyle. Along with that there is also suggested to that individuals should take a certain amount of financial responsibility for public healthcare. In this paper all these principles will be discussed with special reference to the more controversial principle of personal responsibility.

Ethical principles guiding innovation in occupational medicine

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Occupational medicine as a part of Public health brings a lot of ethical questions about human rights. This medical branch complicates the standard relationship between doctor and patient by adding an additional side – the employer. Occupational medicine specialists work to secure the safety, working capacity and good health of the employees. They also have to cope with the employers' expectations and provide their companies with the highest standards required by law. Satisfying these two groups may lead to conflicts of interest that could be avoided only by relying on ethical principles.

In recent years, laws have been introduced to regulate the quality of occupational health in Bulgaria with that of developed European countries. An example of this is the implementation of mandatory electronic patient health records held by occupational health services. This research explores the positive and negative aspects of this innovation examined on the basis of fundamental ethical principles. Basic ethical points in this study are: Benefits and harms; Respect for human vulnerability and integrity; Respect for privacy and confidentiality; & Justice.

Managing oneself in telecare environments

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Innovations in home health care technology are largely directed towards promoting self-management. In this paper I argue that a patient can only manage her own health problems insofar she can trust her clinician and her telecare environment to make certain decisions for her. Furthermore, I argue that her interests are partly opaque to her “managing self”, which means that her clinician shares a responsibility with her to interpret and act upon those interests, rather than this being fully her own responsibility. A telecare environment promotes self-management in a meaningful way when it allows patient and doctor to jointly and interactively tailor that environment to the patient’s needs.

I start out by discussing which telecare technologies are usually taken to enhance self-management. Patients perform measurements at home and are responsible for uploading data. E-coaching provides new tools for patients to plan, monitor, and control a healthier lifestyle. Online portals allow patients to systematically and more precisely register and report their symptoms and problems to their clinicians. Staying at home or at work also allows patients to stay in charge of their lives in a more general sense, making health care less disruptive and more comfortable. I will discuss results from an interdisciplinary research project on attitudes of trust among COPD patients that use telecoaching, and hypertension patients that use telemonitoring systems.

Next, I develop an analogy between the concept of self-management and that of informed consent. Both are understood as contributing to patient autonomy, and both may actually undermine that autonomy if operationalized in the wrong way. In the case of informed consent, the problem is that patients face increasingly unworkable consent forms in order for institutions to establish that the patient has signed off on all relevant information about their treatment. In the case of self-management, the problem could become that caretakers and telecare developers will increasingly view themselves as service providers that the autonomous patient decides to make use of in order to manage their health.

A more promising way to think about autonomy is in terms of trust (e.g. O’Neil 2000, *Autonomy and Trust in Bioethics*, Cambridge UP) and tailoring. You respect the autonomy of a patient by giving her good reasons to trust that you provide her with information and care tailored to her individual needs and values. In the case of consent, that means providing information which enables the patient to decide between treatment alternatives from her own perspective. In the case of self-management, it means that health care providers are responsible for their patients in a way that service-providers are not responsible for their customers. The patient needs good reasons to trust that her self-caring activities address her medical needs in ways that she herself may not be in the best position to understand, which means that she trusts her clinical environment - both her medical doctor and the relevant home health technology - to “manage her self-management.”

Does clinical equipoise withhold innovation? Arguments against an obligation to participate in biomedical research

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In 2008 S. Joffe and F.G. Miller published, one of the series of articles criticizing the idea of a clinical equipoise - *Bench to Bedside: Mapping the Moral Terrain of Clinical Research*. They present there a few promising randomized clinical trials which were withheld because of “ethical constraints”. Joffe and Miller believe that this “ethical overkill” withholds innovation in biomedical research and advocated for the change from “therapeutic orientation” in clinical research into “scientific orientation”. They also ask to resign from the doctrine of clinical equipoise.

A few years earlier, in 2005 John Harris advocated the obligation of participation in biomedical research. If “we all benefit from the existence of the social practice of medical research” because of medical innovation, then we also have a duty to participate in it. Harris also stressed that he is not going to legitimate any methods of compulsion in research and that he is not advocating mandatory participation in research.

I would like to examine those views. I would also reflect of their impact for the quality of the protection of human subjects in the countries with lower ethical standards (eg. M. Waligora, Failures in clinical trials in the European Union. Lessons from the Polish Experience, *SciEngEth*).

Health Resource Allocation and the Global Burden of Disease

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The Global Burden of Disease (GBD) project, which has been supported by the World Bank, the World Health Organization, and (most recently) by the Bill and Melinda Gates Foundation, is largest-ever systematic effort to describe the global distribution and causes of a wide array of major diseases, injuries, and health risk factors. Reports from its most recent iteration, which filled the entire 13 December 2013 issue of *The Lancet*, involved nearly 500 researchers in over 300 institutions in 50 countries. Health resource allocation should be responsive to the needs of the population, and this global map of health needs will influence decisions on what is spent for health, particularly in the developing countries. The GBD leadership has emphasized that mapping the burden of disease is a value-laden enterprise that requires a series of key ethical choices at every stage, including the conceptualization of the project and of its key “Disability-Adjusted Life Year” measure. This talk will identify some of these choices and will provide a brief account of decisions made in the latest GBD iteration.

Rethinking health technology assessment from ethical and legal perspectives

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Health technology assessment (HTA) is a utilitarian assessment of health technologies (such as drugs, techniques, modes of delivery) for efficiency, cost-effectiveness, and social and ethical acceptability. Recently HTA programs are being set up all over the world and HTA is applied

as a problem oriented endeavour dealing with tragic choices in healthcare distribution policy. However, even though the assessment of ethical and social aspects of a health technology is listed as one of the objectives of HTA, studies show that HTA reports are often poorly informed by ethical and social theories and rarely incorporate community views. It is because ethical and social aspects are regarded as consequences of health technology in HTA approach and only “effects” of technology or “impacts” of technological change are assessed. HTA fails to consider and to respond what has caused technological changes and which questions are justified in framing assessments from ethical and social perspectives. The ignorance is also caused by HTA’s negligent attitude toward the fact that technology and society are “co-constructions” and fast-paced health technology might cause the society to re-examine and reclassify the conceptual tool through which healthcare rationing decisions or criteria are established. Therefore, after reviewing several cases in UK (such as *Otley, R v. Barking & Dagenham NHS Primary Care Trust, Eisai Ltd. v. NICE, Servier Laboratories Ltd. v. NICE, and Fraser & Short v. NICE*), this paper proposes that HTA should be conceptualized as two-phase process in which the first phase involves assessing health technology for efficacy and the second evaluating the wider ethical and social impact of the technology. Furthermore, in the second phase a diverse disciplinary and methodology base should be applied and at least four strands should be included. *First*, sociological accounts of health technology should be considered essential rather derivative in HTA. This involves questions of how health technology transforms health/disease concepts and what “the good ends of life” are. *Second*, theoretical critiques of utilitarianism, consequentialism, welfarism, and sum-ranking should be taken into consideration in HTA and non-utilitarian criteria should be set out. This involves questions of how to identifying commensurable values, to explore contradictions between empirical claims and normative frameworks, and to balance conflicts between scientific and societal understandings and needs. *Third*, as applicable mechanism for addressing priorities of different health technologies, HTA should bring into it the search for a political conception of distributive justice, which attempts to resolve competing claims to healthcare and too ther social goods. This involves questions of what a fair healthcare distribution is and on the basis of which criteria resource allocation should be effectuated. *Fourth*, the contextual exercise of informed choice and democratic deliberation is of particular importance in HTA decision-making process. An environment for democratic deliberation then should be established to engage not only experts but also broader community in discussion of new health technologies. This involves questions of what information the content of the consent information should contain and which members of the public should be involved in which processes.

Pre-implantation genetic diagnosis and rational choice under uncertainty

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In my talk I would like to present an original argument in favour of a parental duty to use pre-implantation genetic diagnosis (PGD). I will argue that PGD would be chosen as a selection method by any rational agent in a hypothetical situation in which: 1) not every embryo could be implanted; 2) there is a risk for birthing a child with a serious genetic disorder. To demonstrate this I will present a hypothetical case that proves that my argument could be accepted by the supporters of every moral doctrine, because it is not based on strong moral presumptions, but on commonly shared criteria of rational decision under uncertainty. I will assume that the decision about the method of selection is done in a society in which in vitro fertilization (IVF) procedure and the creation of supernumerary embryos is permissible and it is performed. This assumption is rather uncontroversial, since IVF is permitted by the law in every European country, even in those countries where other issues related to the protection

of human embryos are regulated in more restrictive way (e.g. Ireland, Poland). Therefore my argument shows that PGD is a parental duty and should be at least legally permitted (if not required), because of the principle similar to the principle of respect for patient autonomy. In this case the principle consists in a respect for the hypothetical choices of embryos: I argue that if they could decide, they would choose PGD as a method of selection. My argumentation is polemical with at least two dominant views on PGD. Firstly, I will not argue that PGD benefits supernumerary embryos, as it is sometimes thought (see: Malek & Daar, 2012, Walker, forthcoming). This difference (between what embryos would choose and what would benefit them) has an important consequences for the scope of morally required genetic tests: my argument shows that any rational agent would want to avoid serious genetic disorder that significantly shortens her or his life, but it does not mean that she or he would choose the life that could be expected to go best (Savulescu & Kahane, 2009). Therefore my argument does not weigh in favour of (or against) so called “positive selection” (for example, because of expected well-being). Secondly, it is commonly assumed that pre-implantation genetic diagnosis (PGD) cannot be accepted as a morally permissible method of selection by those who maintain that human embryos have full right to life from the very beginning (Bioethical Committee of the Polish Academy of Sciences, 2012). My argument demonstrates that this assumption is false, because the choice of PGD as a selection method is based only on some uncontroversial criteria of rational decision under uncertainty. I sum up my presentation demonstrating the important implications of my argument for recent debates about the legal regulations of IVF and PDG which are commonly performed in Poland, but as yet has not been regulated by law. 2

References:

- Bioethical Committee of the Polish Academy of Sciences (2012), “The Statement about Pre-implantation Genetic Diagnosis”, available online (in Polish): <http://www.bioetyka.pan.pl/images/stories/Pliki/stanowisk%20kb%20nr%202-2012.pdf>
- J. Malek, J. Daar (2012), “The Case for a Parental Duty to Use Preimplantation Genetic Diagnosis for Medical Benefit” *The American Journal of Bioethics* 12(4): 3-11
- J. Savulescu, G. Kahane (2009), “The moral obligation to create children with the best chance of the best life” *Bioethics* 23(5): 274-90
- M. Walker (forthcoming), “Eugenic Selection Benefits Embryos”, *Bioethics* Early View: doi:10.1111/j.1467-8519.2012.02000

The implicit metaphysics of synthetic biology: How the idea of a synthetic cell is challenging our understanding of life and embodiment

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The living cell is the most astonishing laboratory on earth, in which thousands of biochemical reactions take place in concert. Building on Nobel laureate Richard Feynman famous quote “What I cannot create I do not understand”, the ultimate grail or challenge in contemporary life sciences is the synthesis (bottom-up, from its chemical components) of an artificial living cell. Various research consortia around the globe are currently working on this ambitious idea. It would symbolise the completion of two centuries of intense research exploring the boundary between the living and the non-living. It would signify an impressive leap forward, not only for science, but for society as well. According to experts in this field, it would allow us to mimic nature, i.e. to use nature’s own technologies in order to develop bio-compatible materials and artificial tissues that merge into living bodies. The nature-technology or nature-artefact divide would blur. It would emphasise to what extent our basic understanding of nature and embodiment is changing, not only on biological, chemical and physical levels, but

on a 'metaphysical' level as well. Nature emerges as an enormously sophisticated and complex laboratory which we are beginning to understand and from which much can still be learned by mimicking the processes and materials of nature on a molecular level (biomimesis). Yet, this new vision of nature in general and the human body in particular raises issues of concern as well. How will we use this new sway over nature? Who will be able to use the new power to reconstruct the living? Would a synthetic cell – or Franken-cell as it is sometimes called – be 'unnatural'? And what about dual use, brain doping and enhancement? Building on Hegel's claim that there is more metaphysics in science that scientists are usually inclined to acknowledge, I will argue that, before moving into the plethora of bioethical issues involved, the ontological shift (the implicit metaphysics of synbio) *as such* must be addressed. Notably, I will focus on the paradoxical tension between admiration for nature (as a highly sophisticated lab) on the one hand, and the will to control, modify and improve nature (primarily in the context of medical applications) on the other.

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